RURAL EMERGENCY HOSPITALS: CMS FINALIZES KEY POLICIES FOR NEW MEDICARE PROVIDER TYPE (PART 2 OF 2)

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By: Darlene S. Davis, Gabriel T. Scott, Steven G. Pine, Ashley E. Davis

On 1 November 2022, the Centers for Medicare & Medicaid Services (CMS) published the 2023 Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System final rule (the OPPS Final Rule or the Rule).[1] In addition to finalizing policies related to the OPPS and ASC payment system for calendar year 2023, the Rule also finalized a number of provisions related to the new rural emergency hospital (REH) provider type, including policies addressing REH enrollment, payment, Conditions of Participation (CoPs), quality reporting, and the federal physician self-referral law (Stark Law).

As discussed in our recent client alerts on REHs—available here and here—that described the proposed CoPs for REHs[2] and the proposed enrollment and payment policies for REHs in the 2023 OPPS and ASC Payment System proposed rule,[3] the REH provider category was established by Section 125 of the Consolidated Appropriations Act, 2021.[4] Rural hospitals with not more than 50 beds and critical access hospitals (CAHs) that were enrolled in Medicare as of 27 December 2020 may apply to convert to and enroll in Medicare as an REH, and Medicare-enrolled REHs will receive payment for REH services provided on or after 1 January 2023.

For ease of reference, this client alert is divided into two parts. This is Part 2, which focuses on the finalized REH policies for enrollment and CoPs. Part 1, which focuses on the REH policies finalized in the Rule for payment and quality reporting, is available here.[5] In particular, we highlight below areas where the policies related to REH enrollment and CoPs that were finalized in the OPPS Final Rule contain modifications or clarifications to the proposed policies in those areas, as described in our prior alerts.

KEY FINALIZED POLICIES FOR REHS: ENROLLMENT AND COPS

Summary

The finalized enrollment policies and CoPs for REHs largely followed the proposed policies. As discussed below, CMS finalized as proposed the enrollment policies for REHs to allow CAHs and rural hospitals to convert to REHs by permitting them to bypass the traditional Medicare provider enrollment processes. This flexibility, however, goes only one direction, and the Rule offers an important distinction for REHs that seek to return to their prior enrollment status as CAHs or rural hospitals.

With respect to the CoPs, a majority of the proposed CoPs were finalized as proposed. One particularly noteworthy modification was CMS's decision to reverse course on its proposed staffing requirements and instead require REHs to be staffed at all times by an individual competent in the skills needed to address emergency medical care.

The finalized policies for REHs should cause CAHs and rural hospitals considering whether to convert to REHs to assess the areas in which they are located, and analyze the potential regulatory and financial implications resulting from such conversion. In addition to weighing the potential economic benefits with the necessary organizational changes, a hospital considering REH conversion also should address whether the loss of the hospital's current designation as a CAH or rural hospital as a result of an REH conversion could preclude the ability to return to the hospital's prior enrollment status.

FINALIZED REH ENROLLMENT AND OUTPATIENT OBSERVATION NOTICE PROVISIONS

REH Enrollment

The REH enrollment policies were largely finalized as proposed, including the following:

- CAHs and rural hospitals eligible to enroll as REHs may do so by submitting a Form CMS-855A change of information (CHOI) instead of an initial enrollment.[6]
- Application fees will not apply.

CMS clarified an important distinction applicable to hospitals that convert to REHs and then later seek to return to their previous enrollment status as CAHs or rural hospitals.[7] As we noted in a prior client alert, even though Section 1861(kkk)(4)(B)(i) of the Social Security Act references a "conversion" from an REH back to a CAH or rural hospital, as opposed to a termination and an initial enrollment, an REH's ability to convert back to its prior provider category may be limited by a variety of factors, including state certificate of need laws or licensure requirements. On this issue, CMS clarified in the OPPS Final Rule that while a CAH or rural hospital meeting the applicable requirements can convert to an REH by filing a Form CMS-855A CHOI application, conversion from an REH back to a CAH or rural hospital does not follow the same process.[8]

Specifically, CMS noted that a CAH or rural hospital that converts to an REH terminates its enrollment as a CAH or rural hospital.[9] Once the CAH or rural hospital has converted to an REH, any subsequent change to a different provider or supplier type, including enrollment as a CAH or rural hospital, would require an initial enrollment application, compliance with the applicable requirements, and payment of an application fee.[10] This distinction is particularly important with respect to the location requirements for designation as a CAH, which in relevant part, require the CAH to (a) be located either more than a 35-mile drive (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or CAH; or (b) have been certified as a CAH before 1 January 2006 on the basis of being a necessary provider of health care services to residents in the area.[11]

FINALIZED POLICY ON USE OF THE MEDICARE OUTPATIENT OBSERVATION NOTICE (MOON) BY REHS

CMS finalized its proposed policy not to require REHs to use the MOON, which in part requires hospitals and CAHs to provide written notification and an oral explanation of such notification to individuals receiving observation services as outpatients for more than 24 hours.[12] Although CMS acknowledged that there may be "occasional circumstances" in which patients receive observation services at an REH for a period exceeding 24

hours because a facility is not immediately available to provide a higher level of care, REHs are nonetheless not required to provide the MOON because the applicable statutory requirements apply only to hospitals and CAHs.[13]

Finalized REH CoPs

REH CoPs Finalized as Proposed

CMS finalized the following REH CoPs as proposed:

- Basis and Scope (§ 485.500);[14] Basic Requirements (§ 485.504);[15] Designation and Certification of REHs (§ 485.506);[16] Compliance With Federal, State, and Local Laws and Regulations (§ 485.508);[17] Governing Body and Organizational Structure of the REH (§ 485.510);[18] Provision of Services (§ 485.514);[19] Emergency Services (§ 485.516);[20] Radiologic Services (§ 485.520);[21] Pharmaceutical Services (§ 485.522);[22] Additional Outpatient Medical and Health Services (§ 485.524);[23] Infection Prevention and Control and Antibiotic Stewardship Programs (§ 485.526);[24] Nursing Services (§ 485.530);[25] Discharge Planning (§ 485.532);[26] Patient's Rights (§ 485.534);[27] Agreements (§ 485.538);[28] Medical Records (§ 485.540);[29] Emergency Preparedness (§ 485.542);[30] Physical Environment (§ 485.544)[31] ;and Skilled Nursing Facility Distinct Part Unit (§ 485.546).[32]

Clarifications to Certain Policies Finalized as Proposed

While the policies for Designation and Certificate of REHs at § 485.506 were finalized as proposed, CMS clarified the following in the final rule in response to comments:

- Facilities that were CAHs or rural hospitals with not more than 50 beds as of 27 December 2020 and then subsequently closed after that date are eligible to seek REH designation, provided the facility meets all the CoPs for REHs in order to re-open as an REH.[33]
- CMS will determine whether a rural hospital has no more than 50 beds by calculating the number of available bed days during the most recent cost reporting period divided by the number of days in the most recent cost reporting period.[34]

In regard to the policies for Compliance With Federal, State, and Local Laws and Regulations at § 485.508, which were finalized as proposed, commenters inquired whether licensed practitioners could practice at REHs in multiple states, either in-person or virtually. CMS clarified that the finalized policy does not prohibit a practitioner that is licensed in one state from providing care at an REH in another state, where permissible under state law.[35]

REH CoPs Finalized With Modifications

CMS finalized modified versions of the proposed policies for the following REH CoPs:

- Definitions (§ 485.502);[36] Laboratory Services (§ 485.518);[37] Staffing and Staff Responsibilities (§ 485.528);[38] and Quality Assessment and Performance Improvement Program (QAPI Program) (§ 485.536).[39]

Definitions (§ 485.502)

CMS finalized its proposed definitions under § 485.502 with minor modifications.[40] In regard to the REH policy on average length of stay (LOS), commenters recommended that the average LOS be increased and requested exemptions to the LOS requirement, specifically for low risk labor and delivery.[41] CMS explained that the LOS

policy for REHs is set by statute and could not be altered.[42] CMS also clarified the methodology used to determine the annual per patient average LOS for REHs.[43]

Laboratory Services (§ 485.518)

In § 485.518, CMS finalized its proposal requiring REHs to furnish laboratory services, either directly or under contract, and that emergency laboratory services must be available 24 hours a day.[44] In regard to the scope of laboratory services, CMS states in the Rule that it strongly encourages, but does not require, REHs to provide laboratory services that include the following: a complete blood count, basic metabolic panel, magnesium, phosphorus, liver function tests, amylase, lipase, cardiopulmonary tests, lactate, coagulation studies, arterial blood gas, venous blood gas, quantitative human chorionic gonadotropin, and urine toxicology.[45] CMS finalized this provision with a modification to the language in § 485.518 specifically noting that the laboratory services offered by REHs—including the services recommended by CMS—be consistent with the patient population served by REHs.[46]

Staffing and Staff Responsibilities (§ 485.528)

In what is likely the most significant change to the proposed CoPs for REHs, CMS finalized § 485.528 with a modification that requires REHs to be staffed at all times by an individual who is competent in the skills needed to address emergency medical care.[47] Notably, CMS did not specify the licensure, qualifications or credentials this individual must have; REHs are permitted to determine the appropriate qualifications and credentials of this individual based on their unique needs and circumstances. In response to comments recommending REHs be required to have a clinician on-site at all times, CMS revised the proposed staffing requirements, which would have required REHs to have a physician or practitioner on call and available on-site during specified time frames.[48]

QAPI Program (§ 485.536)

CMS revised the final provisions under § 485.536(a)(2) to require REHs to specifically measure, analyze, and track staffing as an indicator related to health outcomes and reductions in medical errors.[49] This modification was in part the result of the policy change for staffing requirements at § 485.528, and CMS noted that incorporating staffing into the REH's QAPI Program would address the concerns raised by commenters.[50]

WHAT'S NEXT

The finalized policies for REHs will take effect on 1 January 2023. When determining whether to convert to an REH, eligible CAHs and rural hospitals should carefully assess the implications of this change in provider type, including from financial and regulatory perspectives. Among other considerations, such an assessment should review the enrollment policies and CoPs for REHs, as well as relevant state-level authorities, such as requirements related to facility licensure and certificates of need, where applicable. Given that the conversion to an REH will result in significant changes to Medicare reimbursement and the services offered, hospitals should consider whether REH conversion is a viable option.

When determining whether to convert to an REH, eligible CAHs and rural hospitals should carefully assess the implications of this change in provider type, including from a financial and regulatory perspective. Among other considerations, such an assessment should give attention to the enrollment policies and CoPs for REHs, as well

as relevant state-level authorities such as facility licensure requirements and certificates of need, where applicable.

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 rule-makings. Contact the authors of this article or another K&L Gates lawyer for assistance with the OPPS Final Rule or the new REH provider category.

FOOTNOTES

[1] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating; COVID-19, CMS-1772-FC, (Nov. 1, 2022), https://public-inspection.federalregister.gov/2022-23918.pdf.

[2] 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) (to be codified in a new subpart E of 42 C.F.R. pt. 485).

[3] Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating, 87 Fed. Reg. 44,502 (proposed July 26, 2022).

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

[5] A separate client alert on the Rule's finalized Stark Law policies for REHs is forthcoming.

[6] OPPS Final Rule, CMS-1772-FC at 1257-58 (codified at 42 C.F.R. § 424.575(b)).

[7] *Id*. at 1258-61

[8] *Id*. at 1259–60.

[9] *Id*. at 1258–60.

[10] *Id*. at 1259–60.

[11] 42 C.F.R. § 485.610(c).

[12] OPPS Final Rule, CMS-1772-FC at 1262.

[13] Id. at 1262.

[14] *Id*. at 1164.

[15] *Id*. at 1167.

[16] *Id*. at 1169.

[17] *Id*. at 1170.

[18] *Id*. at 1176.

[19] *Id*. at 1177.

[20] *Id*. at 1180.

[21] *Id*. at 1184.

[22] *Id*. at 1187.

[23] *Id*. at 1192.

[24] *Id*. at 1200.

[25] *Id*. at 1204.

[26] *Id*. at 1211.

[27] *Id*. at 1218.

[28] *Id*. at 1225.

[29] *Id*. at 1227.

[30] *Id*. at 1238.

[31] *Id*. at 1237.

[32] *Id*. at 1238.

[33] *Id*. at 1168 (codified at 42 C.F.R. § 485.506(c)).

[34] *Id*.

[35] *Id*. at 1170.

[36] *Id*. at 1167.

[37] *Id*. at 1180.

[38]*Id*. at 1202.

[39] *Id*. at 1222.

[40] *Id*. at 1167.

[41] *Id*.

[42] *Id*. at 1165–66.

[43] *Id*. at 1166-67.

[44] *Id*. at 1180 (codified at 42 C.F.R. § 485.518).

[45] *Id*.

[46] *Id*. at 1181.

[47] *Id*. at 1202 (codified at 42 C.F.R. § 485.528(a)).

[48] *Id*. at 1202-03.

[49] *Id*. at 1222.

[50] *Id*.

KEY CONTACTS

DARLENE S. DAVIS
PARTNER

RESEARCH TRIANGLE PARK
+1.919.466.1119
DARLENE.DAVIS@KLGATES.COM

GABRIEL T. SCOTT
PARTNER

RESEARCH TRIANGLE PARK
+1.919.466.1263
GABRIEL.SCOTT@KLGATES.COM

