

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 485 and 489

[CMS-3419-P]

RIN 0938-AU92

Medicare and Medicaid Programs; Conditions of Participation (CoPs) for Rural Emergency Hospitals (REH) and Critical Access Hospital CoP Updates

AGENCY: Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services (HHS).

ACTION: Proposed rule.

SUMMARY: This proposed rule would establish conditions of participation that Rural Emergency Hospitals (REH) must meet to participate in the Medicare and Medicaid programs. These requirements are intended to ensure that a high quality of care is furnished by REHs. This proposed rule also includes changes to the requirements Critical Access Hospital would have to meet to participate in the Medicare and Medicaid programs. Proposed payment policies and enrollment policies for REHs will be developed under separate rulemaking.

DATES: To be assured consideration, comments must be received at one of the addresses provided below by August 29, 2022.

ADDRESSES: In commenting, please refer to file code CMS-3419-P.

Comments, including mass comment submissions, must be submitted in one of the following three ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to <https://www.regulations.gov>. Follow the "Submit a comment" instructions.

2. By regular mail. You may mail written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3419-P, P.O. Box 8016, Baltimore, MD 21244-8010.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-3419-P, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following website as soon as possible after they have been received: <https://www.regulations.gov>. Follow the search instructions on that website to view public comments. CMS will not post on *Regulations.gov* public comments that make threats to individuals or institutions or suggest that the individual will take actions to harm the individual. CMS continues to encourage individuals not to submit duplicative comments. We will post acceptable comments from multiple unique commenters even if the content is identical or nearly identical to other comments.

I. Background

A. Introduction

Americans who live in rural areas of the nation make up about 20 percent of the United States (U.S.) population, and they often experience shorter life expectancy, higher all-cause mortality, higher rates of poverty, fewer local doctors, and greater distances to travel to see health care providers, compared to their urban and suburban counterparts.¹ In addition, one in five rural residents identifies as Black, Hispanic, American Indian/Alaska Native (AI/AN), Asian American/Pacific Islander (AA/PI), or a combination of ethnic backgrounds. Compared to the non-Hispanic White rural population, these rural minority groups often and regularly experience several disadvantageous social determinants of health.²

The health care inequities that many rural Americans face raise serious

concerns that the trend for poor health care access and worse outcomes overall in rural areas will continue unless the potential causes of such health care inequities are addressed.

There have been growing concerns over the closures of rural hospitals and critical access hospitals (CAHs). Between 2010 and February 2022, 138 rural hospitals stopped providing inpatient services, 44 of which were Critical Access Hospitals. There were 75 complete hospital closures where all services ended and 63 hospital conversions where inpatient services ended but some type of health care service continued.³ Rural hospitals report they continue to face the threat of closure because they lack sufficient patient volume to offer traditional hospital inpatient acute care services required for Medicare payment; however, the demand still exists for emergency and outpatient services in areas served by these hospitals. Rural hospitals are essential to providing health care to their communities and the closure of these hospitals limits access to care for the communities they once served and reduces employment opportunities, further impacting local economies. Barriers such as workforce shortages, can impact health care access in rural communities and can lead to unmet health needs, delays in receiving appropriate care, inability to get preventive services, financial burdens, and preventable hospitalizations.⁴

The Consolidated Appropriations Act (CAA) of 2021 (Pub. L. 116-260), was signed into law on December 27, 2020. In this legislation, Congress established a new rural Medicare provider type: Rural Emergency Hospitals (REHs). These providers will furnish emergency department and observation care, and other specified outpatient medical and health services, if elected by the REH, that do not exceed an annual per patient average of 24 hours. Hospitals that were CAHs or rural hospitals with not more than 50 beds, participating in Medicare, as of the date of enactment of the CAA, may submit an application to convert to and enroll in Medicare as an REH. An REH will receive Medicare payment for REH services furnished on or after January 1, 2023.

REHs are expected to help address the barriers in access to health care, particularly emergency services and other outpatient services that result

¹ Rural Health Research Gateway. (2018). Rural Communities: Age, Income, and Health Status. <https://www.ruralhealthresearch.org/assets/2200-8536/rural-communities-age-income-health-status-recap.pdf>.

² Health Resources & Services Administration (2021). Rural Hospital Programs. <https://www.hrsa.gov/rural-health/rural-hospitals/>.

³ UNC: Cecil G. Sheps Center for Health Services Research. (2022). Rural Hospital Closures. <https://www.shepscenter.unc.edu/programs/projects/rural-health/rural-hospital-closures/>.

⁴ Healthy People 2020 (n.d.) Access to Health Services. <https://www.healthypeople.gov/2020/topics-objectives/topic/Access-to-Health-Services>.

from rural hospital closures, and by doing so, may help address observed inequities in health care in rural areas.

On January 20 and 21, 2021, President Biden issued three Executive orders related to issues of health equity: Executive Order 13985 “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government;”⁵ Executive Order 13988, “Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation;”⁶ and Executive Order 13995 “Ensuring an Equitable Pandemic Response and Recovery.”⁷

Executive Order 13985, “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government,” requires the Federal Government to pursue a comprehensive approach to advancing equity for all, including people of color and others who have been historically underserved, marginalized, and adversely affected by persistent poverty and inequality by recognizing and working to redress inequities in its policies and programs that serve as barriers to equal opportunity. In accordance with this Executive order, persons who live in rural areas are identified as belonging to underserved communities that have been adversely affected by inequality.

Executive Order 13988, “Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation,” requires the Federal Government to prevent and combat discrimination, including when accessing health care, on the basis of gender identity or sexual orientation, and to fully enforce Title VII of the Civil Rights Act. This Executive order also requires the Federal Government to fully enforce other laws that prohibit discrimination on the basis of gender

identity or sexual orientation, all of which impact all persons, including those in rural communities.

In accordance with Executive Order 13995, “Ensuring an Equitable Pandemic Response and Recovery,” the Federal Government must identify and eliminate health and social inequities resulting in disproportionately higher rates of exposure, illness, and death related to COVID-19 and take swift action to prevent and remedy differences in COVID-19 care and outcomes within communities of color and other underserved populations. The Executive order highlights the observed inequities in rural and Tribal communities, territories, and other geographically isolated communities. We believe the services furnished by REHs, could be one means of addressing some of the issues raised in these orders, particularly, barriers to access health care in rural communities.

Consistent with these Executive orders, in implementing the new REH provider type, we are committed to advancing equity for all, including racial and ethnic minorities, members of the lesbian, gay, bisexual, transgender, and queer/questioning (LGBTQ) community, people with limited English proficiency, people with disabilities, rural populations, and people otherwise adversely affected by persistent poverty or inequality.

We are proposing at this time to establish conditions of participation (CoPs) for REHs as a new Medicare provider type, consistent with the provisions of section 125 of the CAA. In developing the proposed CoPs for REHs, we have considered the role that we believe REHs can play in helping to advance equity and ensure access to available services and quality health care in rural communities. Proposed payment and enrollment policies for REHs will be developed in separate rulemaking.

B. Statutory Authority and Establishment of Rural Emergency Hospitals as a Medicare Provider Type

Section 125 of Division CC of the CAA was signed into law on December 27, 2020 and establishes REHs as a new Medicare provider type that will receive Medicare payment for services furnished on or after January 1, 2023. Section 125 of the CAA added section 1861(kkk) to the Social Security Act (the Act), which sets forth the requirements for REHs. Section 1861(kkk)(2) of the Act defines an REH as a facility that is enrolled in the Medicare program as an REH; does not provide any acute care inpatient services (other than post-REH, that is after discharge from an REH, or

post-hospital extended care services furnished in a distinct part unit licensed as a skilled nursing facility (SNF)); has a transfer agreement in effect with a level I or level II trauma center; meets certain licensure requirements; meets requirements of a staffed emergency department; meets staff training and certification requirements established by the Secretary of the Department of Health and Human Services (the Secretary); and meets certain CoPs applicable to hospital emergency departments and CAHs with respect to emergency services.

Additionally, section 125(a)(1) of the CAA added section 1861(kkk)(1) of the Act, which requires that REHs provide emergency department services and observation care, and, at the election of the REH, other medical and health services furnished on an outpatient basis, as specified by the Secretary through rulemaking. The REH must also have a staffed emergency department 24 hours a day, 7 days a week, have a physician, nurse practitioner, clinical nurse specialist, or physician assistant available to furnish rural emergency hospital services in the facility 24 hours a day, and meet applicable staffing requirements similar to those for CAHs.⁸

In order to become an REH, section 1861(kkk)(3) of the Act requires that the facility, on the date of enactment of the CAA, 2021 (December 27, 2020), was a CAH or a rural hospital with not more than 50 beds. For the purpose of REH designation, the statute defines rural as a county (or equivalent unit of local government) considered rural (as defined in section 1886(d)(2)(D) of the Act), or treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act. To be treated as being located in a rural area for the purpose of REH eligibility, we are proposing as part of this proposed rule that a hospital located in a metropolitan county must have had an active reclassification from urban to rural status as specified in 42 CFR 412.103 as of December 27, 2020. In addition, the REH must meet certain other requirements under section 1861(kkk) of the Act, including, but not limited to the following:

- An annual per patient average of 24 hours or less in the REH;
- Staff training and certification requirements established by the Secretary;
- Emergency services CoPs applicable to CAHs;

⁸ Congress.gov. (2020). H.R.133—Consolidated Appropriations Act, 2021. <https://www.congress.gov/116/bills/hr133/BILLS-116hr133enr.pdf>.

⁵ 86 FR 7009 (Jan. 25, 2021). The White House. (2021). Briefing Room: Executive Order on Advancing Racial Equity and Support for Underserved Communities Through the Federal Government. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-advancing-racial-equity-and-support-for-underserved-communities-through-the-federal-government/>.

⁶ 86 FR 7023 (Jan. 25, 2021). The White House. (2021). Briefing Room: Executive Order on Preventing and Combating Discrimination on the Basis of Gender Identity or Sexual Orientation. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/20/executive-order-preventing-and-combating-discrimination-on-basis-of-gender-identity-or-sexual-orientation/>.

⁷ 86 FR 7193 (Jan. 26, 2021). The White House. (2021). Briefing Room: Executive Order on Ensuring an Equitable Pandemic Response and Recovery. <https://www.whitehouse.gov/briefing-room/presidential-actions/2021/01/21/executive-order-ensuring-an-equitable-pandemic-response-and-recovery/>.

- Hospital emergency department CoPs determined applicable by the Secretary;
- The applicable SNF requirements (if the REH includes a distinct part SNF);
- A transfer agreement with a level I or level II trauma center; and
- Any other requirements the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in an REH.

Starting on January 1, 2023, an REH that provides rural emergency hospital services (as defined in section 1861(kkk)(1) of the Act) will receive a Medicare payment for those services pursuant to section 1834(x)(1) of the Act, as added by section 125 of the CAA, that is equal to the amount of payment that would otherwise apply under the Medicare Hospital Outpatient Prospective Payment System (OPPS) for covered outpatient department services increased by 5 percent. The beneficiary co-payments for these services will be calculated the same way as under the OPPS for the service, excluding the 5 percent payment increase. In addition, section 1834(x)(2) of the Act provides an additional monthly facility payment to an REH. The details of the payment policies for REHs will be developed in separate notice and comment rulemaking.

To participate in the Medicare program and receive payment for services furnished to Medicare beneficiaries, providers of services such as hospitals, home-health agencies, hospices, SNFs, and now REHs must enter into a provider agreement with Centers for Medicare & Medicaid Services (CMS), in accordance with section 1866 of the Act. Medicaid providers (every person or institution providing services under the state plan), likewise, must enter into agreements with state Medicaid agencies to be eligible for participation in that program as described in section 1902(a)(27) of the Act. By entering into a provider agreement, a facility agrees that it will comply with the applicable requirements of the Medicare and Medicaid statutes and the regulations that the Secretary issues under the respective statute.

Section 1861(kkk)(7) of the Act requires the Secretary to establish quality measurement reporting requirements for REHs, which may include claims-based outcome measures and/or patient experience surveys. An REH is required to submit quality measure data to the Secretary with respect to each year beginning in 2023 (or each year beginning on or after the date that is one year after one or more

measures are first specified), and the Secretary is required to establish procedures to make the data available to the public on the CMS website. Quality measure specifications and quality reporting requirements for REHs will be developed in future rulemaking.

The Quality Improvement Organization requirements of the Act shall apply to REHs in the same manner that they apply to hospitals and CAHs, in accordance with section 1866(a) of the Act (as amended by section 125(b)(1) of the CAA). In addition, the requirements established at section 1864 of the Act for hospitals and CAHs to be surveyed for compliance with the CoPs shall apply to REHs in the same manner as other hospitals and CAHs, in accordance with section 125(d)(2) of the CAA.

Under section 1864 of the Act, CMS uses state surveyors to determine whether a provider or supplier subject to certification qualifies for an agreement to participate in Medicare. Additionally, under section 1865 of the Act, some providers or suppliers subject to certification have the option to instead elect to be accredited by private accrediting organizations (AOs) whose Medicare accreditation programs have been approved by CMS as having standards and survey procedures that meet or exceed all applicable Medicare requirements and be deemed to meet Federal requirements. The survey process for Medicare- and Medicaid-participating providers and suppliers provides an opportunity for these providers and suppliers to demonstrate compliance with all of the applicable CoPs, conditions for coverage (CfCs), conditions for certification, or requirements. The methods used by CMS to determine compliance with the regulations include surveys conducted by a state survey agency, surveys conducted by AOs that have deeming authority for Medicare providers and suppliers, and self-attestation. CMS would require REHs participating in Medicare to demonstrate and maintain compliance with the provisions included in the final rule.

C. Summary of Comments by Interested Parties in Response to REH Request for Information

In preparation for developing these proposed standards and to gain a clear understanding of the challenges faced by facilities providing health care services in rural communities, we published a Request for Information (RFI) on REHs in the proposed rule, “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 FR 42018) on August 4, 2021. CMS sought public input on a broad range of issues to inform our policymaking in establishing this new provider type. The RFI solicited public input on the concerns of rural providers, including in the areas of health and safety standards, health equity, payment policies, quality measures and quality reporting, and additional considerations and unintended consequences that should be considered during the development of standards for REHs. As previously noted in section I.B of this proposed rule, the details of the payment policy and quality measures and quality reporting requirements for REHs will be developed via future rulemaking.

Commenters on the RFI generally noted that CMS should remain flexible in the development of standards for REHs and take into consideration the challenges associated with the provision of health care services in rural communities. Specific themes from the comments received centered on suggested CoPs including requirements for staffing, transfers, and supervision, services that should be offered by REHs, and the health equity implications for REHs. Several commenters stated that the CoPs currently in place for CAHs would be sufficient for REHs and that the CoPs for REHs should not be more rigorous than those for CAHs. Commenters also recommended that REHs should provide maternal health, behavioral/mental health services, and telehealth services to further support the communities that they will serve. With regard to health equity, several interested parties commented that REHs could have significant value for underserved, rural populations by maintaining local access to care, reducing travel times for care, and serving as leaders for community health improvement efforts including efforts to address the social determinants of health. We note that CMS is committed to reducing inequities in rural communities and we are considering the best approach to address health equity in the standards for all Medicare- and Medicaid-participating providers and suppliers, including REHs.

The REH RFI public comments are available for review at <https://www.regulations.gov/document/CMS-2021-0124-0002/comment>. We have reviewed all comments from interested parties and have taken them into consideration while drafting this

proposed rule. We appreciate the interested parties' input and responses to our outreach efforts thus far.

During the development of the policies to implement this new provider type, we reviewed the public comments received on the REH RFI, and held public listening sessions with national organizations representing interested parties as well as tribal communities. We also gave presentations at CMS' hospital, rural health, and SNF open door forums and sought public feedback. We carefully reviewed the hospital and CAH requirements to determine which requirements would be appropriate (as is or based on modification) for REHs.

II. Provisions of the Proposed Regulation

A. Rural Emergency Hospital Conditions for Participation (Proposed Part 485, Subpart E)

We propose to add a new subpart E in 42 CFR part 485, to incorporate the REH CoPs. Proposed subpart E which would include all the health and safety standards for REHs. Overall, the proposed requirements are modeled closely after the CoPs for CAHs. In some instances, we have also proposed requirements that are similar to the CoPs for hospitals and CfCs for Ambulatory Surgical Centers (ASCs). In each of the sections below, we specify the existing requirements for CAHs, hospitals, or ASCs that we used to guide the proposed requirements.

1. Basis and Scope (Proposed § 485.500)

We propose to set forth the basis and scope of part 485, subpart E, at § 485.500. As previously noted, proposed part 485, subpart E, would implement section 1861(kkk) of the Act, which establishes the requirements that an REH must meet in order to participate in the Medicare program. Section 1833(a) of the Act serves as the basis for the establishment of payment of benefits covered under Medicare for REHs.

2. Definitions (Proposed § 485.502)

At § 485.502, we propose to define certain terms that would be used throughout the REH CoPs. We propose to define the term "Rural Emergency Hospital or REH" in accordance with the definition set forth in section 1861(kkk) of the Act. In accordance with the Act, we propose to define Rural Emergency Hospital or 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 REH 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.

We received several comments on the REH RFI indicating that the average length of stay should be increased in certain instances, such as when the REH is providing services to a patient who is in need of inpatient psychiatric or inpatient rehabilitation services. The commenters stated that placement of these patients in an inpatient facility could be difficult with some patients potentially remaining in the REH for observation services for weeks. Commenters noted further that these patients may produce an average length of stay that exceeds the proposed 24-hour annual per patient average length of stay. Other commenters requested that CMS be flexible in recognizing bed capacity issues for those patients awaiting placement in an inpatient facility and practice enforcement discretion related to the proposed length of stay requirement.

However, in accordance with section 1861(kkk)(1)(A) of the Act, services furnished by the REH must not exceed an annual per patient average of 24 hours in the REH. We would expect an REH to transfer patients whom the REH determines require a higher level of care as soon as possible. We do understand that there may be occasional circumstances in which a facility is not immediately available to provide a higher level of care, resulting in patients receiving services at the REH for more than 24 hours. However, we believe that this will occur at a frequency that will not seriously affect the REH's average length of stay. As a result, we do not anticipate that the REH would be at risk for exceeding the statutory annual per patient average length of stay of 24 hours or less.

3. Basic Requirements (Proposed § 485.504)

At § 485.504 we propose to set forth the basic requirements for REHs in accordance with section 1861(kkk) of the Act. Participating REHs would be limited to those facilities that meet the definition in proposed § 485.502 and have in effect a provider agreement as defined at 42 CFR 489.3. We would add REHs to the list of providers required to obtain a provider agreement at § 489.2(b) in the "Conforming Amendments" section of this proposed rule.

4. Designation and Certification of REHs (Proposed § 485.506)

At § 485.506 we propose to set forth the criteria for CMS certification of an REH in accordance with section 1861(kkk) of the Act. We propose to establish that CMS would certify a facility as an REH if the facility was, as of the date of enactment of the CAA, a CAH, or a hospital as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds located in a county (or equivalent unit of local government) considered rural (as defined in section 1886(d)(2)(D) of the Act), or treated as being located in a rural area pursuant to section 1886(d)(8)(E) of the Act. In addition, to be treated as being located in a rural area for the purpose of REH eligibility, we are proposing as part of this proposed rule that a hospital located in a metropolitan county must have had an active reclassification from urban to rural status as specified in section 42 CFR 412.103 as of December 27, 2020.

5. Compliance With Federal, State, and Local Laws and Regulations (Proposed § 485.508)

Consistent with the requirements for all Medicare- and Medicaid-participating providers and suppliers, we propose to require REHs to comply with Federal, state, and local laws and regulations.

At § 485.508(a) we propose to require the REH to be in compliance with applicable Federal laws, state, and local laws and regulations. In accordance with section 1861(kkk)(5) of the Act, we also propose to require at § 485.508(b) that the REH is located in a state that provides for the licensing of such hospitals under state or applicable local law. In addition, under § 485.508(b)(1) and (2), we propose that the REH be licensed in the state as an REH or be approved as meeting standards for licensing by the agency in the state or locality responsible for licensing hospitals. We note that in many instances, states and localities, have more stringent laws and regulations than the Federal requirements. In cases in which state law or regulations are more stringent, the REH would need to comply with the more stringent state or local requirements to meet the proposed requirements at § 485.508(a).

At § 485.508(c), we propose to require that the REH ensure that personnel are licensed or meet other applicable standards required by state or local laws to provide services within the applicable scope of practice. Some commenters on the REH RFI recommended that CMS encourage

licensure portability among health care practitioners. Commenters indicated that allowing practitioners to practice in multiple states would greatly support both in-person and virtual care models in rural areas where the closest health care provider may be across the state line. This proposed standard does not prohibit a practitioner that is licensed in a different state than where the REH is located from providing care at the REH; state laws govern whether this is permissible.

6. Condition of Participation: Governing Body and Organizational Structure of the REH (Proposed § 485.510)

To ensure appropriate oversight of the REH, we propose at § 485.510 to require the REH to have an effective governing body, or responsible individual or individuals, that is legally responsible for the conduct of the REH. This aligns with the CAH CoP for organizational structure at § 485.627(a). In addition to oversight, we expect the responsibilities of the governing body or responsible individual to include ensuring that the REH is effectively executing its policies and decision-making about the REH's vision, mission, and strategies. If an REH does not have an organized governing body, we propose to require that the person or persons legally responsible for the conduct of the REH carry out the functions specified in this part that pertain to the governing body.

Consistent with the hospital governing body CoPs at § 482.12, we propose at § 485.510(a)(1) to require the governing body, in accordance with state law, to determine which categories of practitioners are eligible candidates for appointment to the medical staff. Additionally, consistent with the interpretive guidelines for CAHs in Appendix W of the State Operations Manual for the standard for *Governing Body or Responsible Individual* at § 485.627(a), we propose to require that the governing body of the REH appoint members of the medical staff after considering the recommendations of the existing members of the medical staff. The role of the medical staff is the promotion of patient safety and the quality of care. This proposal would give maximum flexibility to an REH in determining and granting staff privileges and organizing its medical staff, and it would allow the REH to grant specific privileges related to patient care to various other types of licensed practitioners as it needed, in addition to the privileges it would choose to grant to doctors of medicine or osteopathy. For example, an REH could choose to grant medical staff privileges to nurse practitioners and physician assistants if

this is allowable under state law. We also propose to require that the REH's governing body must ensure that its medical staff is accountable to the governing body for the quality of patient care provided by the REH; organizes itself under bylaws; and ensures that the criteria for selection to the medical staff are individual character, competence, training, experience, and judgment.

Many rural populations suffer from limited access to care due to a shortage of health care professionals, especially physicians. Often times, clinicians other than physicians provide important care services to rural communities with physicians providing oversight. This may occur in many different ways, including via the use of mobile health, video and audio technologies, digital photography and remote patient monitoring. With the development of technology that facilitates "telemedicine," a physician could utilize a variety of methods to provide health care services, including being on-site at a facility or at a distant site furnishing services remotely to a patient located at an originating site.

Commenters on the REH RFI noted that REHs should be able to be an originating site (that is, the location where a Medicare patient receives medical services from a physician or other clinician through a telecommunications system) for the provision of telehealth services. As noted in the CY 2022 Medicare Physician Fee Schedule final rule (86 FR 65057), section 125(c) of the CAA amended section 1834(m)(4)(C)(ii) of the Act to add REHs to the list of permissible telehealth originating sites. In accordance with section 1834(m)(4)(C)(ii)(XI) of the Act, as added by section 125(c) of the CAA, we finalized a revision to § 410.78(b)(3) of our regulations to add REH, as defined in section 1861(kk)(2) of the Act, as a permissible originating site for telehealth services furnished on or after January 1, 2023.

For the purposes of this rule, similar to our interpretation in the policy set out in our final rule, "Medicare and Medicaid Programs; Changes Affecting Hospital and Critical Access Hospital Conditions of Participation: Telemedicine Credentialing and Privileging" (76 FR 25550 through 25556), we see telemedicine as encompassing the overall delivery of health care to the patient through the practice of patient assessment, diagnosis, treatment, consultation, transfer and interpretation of medical data, and patient education all via a telemedicine link (for example, audio, video, and data telecommunications as

may be utilized by distant-site physicians and practitioners). Therefore, in order to make clear that the credentialing and privileging provisions proposed for REHs are not limited to the narrower subset of services and sites eligible for Medicare telehealth payment, we chose to use the term, "telemedicine," throughout this rule instead of "telehealth." As noted previously, payment policies for REHs, including for services furnished via telehealth/telemedicine, will be addressed in separate notice and comment rulemaking.

In recognition of the important role that telemedicine can play in the provision of care in rural communities, we believe it is necessary to establish a more efficient process for REHs to credential and privilege clinicians who provide telemedicine services for the REH's patients. We are proposing 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. We believe that like small hospitals and CAHs seeking to provide enhanced access to care through the use of telemedicine services for their patients, REHs might lack the resources to fully carry out the traditional credentialing and privileging process for all of the physicians and practitioners that may be available to provide telemedicine services. In addition to the costs and administrative staff needed for this process, REHs would also most likely not have in-house medical staff with the clinical expertise to adequately evaluate and privilege the wide range of specialty physicians that larger hospitals can provide their patients through the use of telemedicine services. Therefore, at § 485.510(a)(8) we are proposing that REH's governing body ensure that when telemedicine services are furnished to the REH's patients through an agreement with a Medicare-participating hospital (the "distant-site"—the site at which the physician or practitioner is located at the time the service is provided via a communications system, as defined at section 1834(m)(4)(A) of the Act), the agreement must specify that it is the responsibility of the governing body of the distant-site hospital providing the telemedicine services to meet the requirements in § 485.510(a)(1) through (7) with regard to its physicians and practitioners who are providing telemedicine services. These provisions

cover the distant-site hospital's governing body responsibilities for its medical staff that all Medicare-participating hospitals must currently meet and that REHs would be required to meet when this rule is finalized. The proposed requirements at § 485.510(a)(8) would allow the governing body of the REH whose patients are receiving the telemedicine services to grant privileges based on the recommendations of its medical staff, who would rely on information provided by the distant-site hospital, as a more efficient means of privileging the individual distant-site physicians and practitioners. This provision would be accompanied by the proposed requirement in the "Medical staff" CoP at § 485.510(a), which would provide the basis on which the REH's governing body, through its agreement as noted above, can choose to have its medical staff rely upon information furnished by the distant-site hospital when making recommendations on privileges for the individual physicians and practitioners providing such services. This option would not prohibit an REH's medical staff from continuing to perform its own periodic appraisals of telemedicine members of its staff, nor would it bar them from continuing to use the proposed traditional credentialing and privileging process proposed at § 485.512(a)(2). The intent of this proposed requirement is to relieve burden for REHs by providing for a less duplicative and more efficient privileging scheme with regard to physicians and practitioners providing telemedicine services. However, in an effort to ensure accountability to the process, we are proposing within this same provision (§ 485.512(a)(3)) that the REH, in order to choose this less burdensome option for privileging, must ensure that (1) the distant-site hospital providing the telemedicine services is a Medicare-participating hospital; (2) the individual distant-site physician or practitioner is privileged at the distant-site hospital providing telemedicine services, and that this distant-site hospital provides a current list of the physician's or practitioner's privileges; (3) the individual distant-site physician or practitioner holds a license issued or recognized by the state in which the REH, whose patients are receiving the telemedicine services, is located; and (4) with respect to a distant-site physician or practitioner granted privileges by the REH, the REH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital this

information for use in its periodic appraisal of the individual distant-site physician or practitioner. We are also proposing, at a minimum, the information sent for use in the periodic appraisal would have to include all adverse events that may result from telemedicine services provided by the distant-site physician or practitioner to the REH's patients and all complaints the REH has received about the distant-site physician or practitioner. We are also proposing at § 485.512(c)(5) to require that REH's medical staff bylaws include criteria for determining privileges and a procedure for applying the criteria to individuals requesting privileges. We are proposing to add language to stipulate that in cases where distant-site physicians and practitioners are requesting privileges to furnish telemedicine services through an agreement with an REH, the criteria for determining those privileges and the procedure for applying the criteria would be subject to the proposed requirements at §§ 485.510(a)(8) and (9) and 485.512(a)(3) and (4).

Similar to the revisions we made in the "Changes Affecting Hospital and Critical Access Hospital Conditions of Participation" final rule (76 FR 25556), we have also concluded that it is important that the medical staff of a distant-site telemedicine entity, which may not be a Medicare-participating hospital, be included in an optional and streamlined credentialing and privileging process for those REHs electing to enter into agreements for telemedicine services with such entities. However, similar to the situation we faced for hospitals and CAHs in the May 2011 final rule (that is, the inclusion of distant-site telemedicine entities into this streamlined process without CMS having any regulatory or oversight authority over these entities), we realized that the proposed requirements for REHs would need to hold distant-site telemedicine entities accountable to the originating-site REH for meeting CMS practitioner credentialing and privileging standards. And like the current requirements for hospitals and CAHs using telemedicine services, REHs would need to provide, upon request when surveyed, the most current telemedicine services agreement showing that the distant-site entities providing the services are required to comply with the CMS standards (even though CMS has no direct authority over those entities) in order for the REH to make use of the more streamlined process when credentialing and privileging practitioners from these distant-site telemedicine entities.

Similar to our regulations proposed for REHs using the telemedicine services of distant-site Medicare-participating hospitals, the written agreement between the REH and the distant-site telemedicine entity would be the foundation for ensuring accountability on both sides. However, due to the differences already discussed between Medicare-participating distant-site hospitals providing telemedicine services and distant-site practitioners under section 1834(m) of the Act providing similar services, there must also be differences in the way the regulations are written.

Therefore, we are also proposing requirements that would apply to the credentialing and privileging process and the agreements between REHs and distant-site telemedicine entities (§§ 485.510(a)(9) and 485.512(a)(4)). These provisions would require the governing body of the REH (or responsible individual), through its written agreement with the distant-site telemedicine entity, to ensure that the distant-site telemedicine entity, acting as a contractor of services, furnishes its services in a manner that enables the REH to comply with all applicable CoPs and standards. For the contracted services, the applicable CoPs and standards would include, but are not limited to, the credentialing and privileging requirements for distant-site physicians and practitioners furnishing telemedicine services.

7. Condition of Participation: Provision of Services (Proposed § 485.514)

Several commenters on the REH RFI indicated that CMS should remain flexible in the development of the standards for REHs and that the standards should closely mirror the CAH requirements, where appropriate. Consistent with the CAH CoPs at § 485.635(a)(1), we propose at § 485.514(a) to require that the REH's health care services must be furnished in accordance with appropriate written policies that are consistent with applicable state law and at § 485.514(b) that the REH must have policies that are developed with the advice of members of the REH's professional health care staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff. This requirement aligns with the CAH CoPs at § 485.635(a)(2).

At § 485.514(c) we propose requirements for the written policies to include a description of the services the REH furnishes (including those furnished through agreement or arrangement), policies and procedures

for emergency medical services, guidelines for the medical management of health problems, and policies and procedures that address the post-acute care needs of all patients receiving services furnished by an REH. Because the statute prohibits REHs from the provision of inpatient services (with the exception of patients receiving SNF services in a distinct part SNF), post-acute care for an REH patient is any care the REH patient receives once they are discharged from the REH. Lastly, at § 485.514(d), we propose to require the policies to be reviewed at least biennially by the group of professional personnel required at § 485.514(b) and updated as necessary by the REH. These requirements align with the CAH CoPs at § 485.635(a)(3).

8. Condition of Participation: Emergency Services (Proposed § 485.516)

In accordance with section 1861(kkk)(2)(D)(iv) of the Act, as added by section 125(a)(1)(B) of the CAA, REHs must comply with the CAH emergency services requirements at § 485.618 as well as the hospital emergency services requirements, which are located at § 482.55, as determined to be applicable. We note that at § 482.12(f) if emergency services are not provided at the hospital, the governing body must assure that the medical staff has written policies and procedures for appraisal of emergencies, initial treatment, and referral when appropriate. Conversely, CAHs are required by the CoPs to provide emergency services, resulting in different emergency services requirements for each of these provider types. However, one similarity in the hospital and CAH emergency services requirements is that CAHs and hospitals (should they choose to provide emergency services) are required to have emergency services that meet the needs of their respective patients presenting at the individual facility. We believe that it is important that the REH emergency services also meet the needs of its patients. As such, at § 485.516 we propose to require that the REH must provide the emergency care necessary to meet the needs of its patients in accordance with acceptable standards of practice.

Additionally, because the primary function of an REH is to provide emergency services, similar to the requirements for hospitals, we propose at § 485.516(a) 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. We anticipate that there will be

instances in which a patient is receiving outpatient services other than emergency services and may unexpectedly require care in the emergency department. In this instance, having emergency services that are integrated with the other departments of the REH will facilitate care coordination and promote patient-centered care.

At § 485.516(b), we propose that there be adequate medical and nursing personnel qualified in emergency care to meet the needs of the facility. To comply with this requirement, we would expect the REH to conduct an analysis based on the anticipated staffing needs and once the REH begins to provide services, the analysis would include actual staffing needs. Lastly, at § 485.516(c), we propose to require the REH to provide emergency services that meet the CAH requirements specified at § 485.618(a) through (e), as required by section 1861(kkk)(2)(D)(iv)(I) of the Act. We are seeking 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.

9. Condition of Participation: Laboratory Services (Proposed § 485.518)

We believe that like hospitals, REHs should provide laboratory services that are determined to be appropriate and necessary based on the level of services provided at the REH. This portion of the provision aligns with the hospital CoP at § 482.27. Efficient laboratory support is a crucial to providing quality emergency services, especially given the continued rise in emergency department visits. Efficient laboratory support positively impacts emergency services by contributing to the assessments used to determine diagnosis and treatment and whether a patient should be discharged home or transferred to a higher level of care. Emergency departments generally provide laboratory services by utilizing point of care testing, a laboratory technician based in the emergency department, or an emergency department stat (“Statim”, Latin for “immediately”) laboratory either directly or through a contractual agreement with a laboratory. Overall, the ability to provide quality laboratory services in the emergency department decreases the overall length of stay for patients, therefore we are proposing at § 485.518 that REHs, similar to CAHs (§ 485.635(b)(2)), must provide basic laboratory services that are essential to the immediate diagnosis and treatment of the patient. The CAH requirements cite specific laboratory

services that should be provided by the CAH, such as 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. However, we believe that given the REH’s nature of primarily providing emergency services, it is appropriate that REHs provide laboratory services that are consistent with nationally recognized standards of care for emergency services. In addition to the laboratory services identified in the CAH CoPs, we encourage the REH to provide laboratory services that include a complete blood count, basic metabolic panel (also known as a “chem 7”), 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. In accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA), at § 485.518(a), we are proposing to require that the REH must ensure that all laboratory services provided to its patients are performed in a facility certified in accordance with the CLIA requirements at 42 CFR part 493. Furthermore, at § 485.518(b) we are also proposing that REHs must have emergency laboratory services available that would be essential to the immediate diagnosis of the patient, 24 hours a day. This proposal is appropriate given the provision that REHs must provide emergency services 24 hours a day. In addition, this proposal is consistent with comments received on the REH RFI noting that laboratory services should be required for REHs.

10. Condition of Participation: Radiologic Services (Proposed § 485.520)

Radiologic services play an integral role in the provision of emergency services. Commenters on the REH RFI noted that radiologic services, also referred to as imaging services, should be provided at REHs. A study in the *American Journal of Roentgenology* noted that, “The use of imaging in the emergency department (ED) has increased over time, and by 2010 nearly half of all ED visits in the U.S. included at least one imaging test.”⁹ These

⁹ Ali S. Raja, Ivan K. Ip, Aaron D. Sodickson, Ron M. Walls, Steven E. Seltzer, Joshua M. Kosowsky, and Ramin Khorasani (2014). *American Journal of*

imaging tests include computed tomography (CT), also known as a computerized axial tomography (CAT) scan, magnetic resonance imaging (MRI), and ultrasound. These tests can be used to diagnose bone fractures, infections, arthritis, injuries from trauma, tumors and cancers. They can also be used to monitor and evaluate the growth and development of a fetus, and offer a way to examine many of the body's internal organs such as the liver, gallbladder, kidneys, and bladder.

We expect that REHs will need to provide radiologic services given their focus on emergency services and given the number of emergency department patients who receive imaging services. Therefore, we propose that the REH radiologic requirements mirror the hospital radiologic requirements found at § 482.26, which is consistent with the current CAH standard at § 485.635(b)(3) and interpretative guidelines for CAHs in Appendix W of the State Operations Manual (SOM).

The CAH standard for radiology services found at § 485.635(b)(3) requires and that these services are furnished by personnel qualified under state law and do not expose patients or staff to radiation hazards. In addition, we note that the interpretative guidelines for § 485.635(b)(3) in Appendix W of the SOM provides guidance for designating qualified radiologic personnel, developing policies and procedures that ensure safety from radiation hazards, inspecting and maintaining radiologic equipment, and maintaining CAH radiology records.

We are proposing to align the REH requirements with the hospital requirements for radiologic services and propose additional standards related to safety, personnel responsibilities, and record keeping. We believe that facilities that may transition to an REH would presently be performing these activities to support the delivery of radiology services. We also believe that these proposed requirements are in accordance with the interpretative guidelines that CAHs currently follow for the provision radiological services. We do not expect these proposed requirements to create additional burden for REHs over those applicable to CAHs.

As such, at § 485.520, we propose to require that the REH must provide diagnostic radiologic services. We propose to require that all radiologic services furnished by the REH must be provided by qualified personnel in

accordance with state law and do not expose REH patients or personnel to radiation hazards at § 485.520(a). Like hospitals, we are also proposing to require that the REH must have radiologic services that meet the needs of their patients. For example, we expect an REH that is located in a mining community to offer x-ray services due to the effects of mining on one's lungs or an REH being able to furnish ultrasounds to evaluate the growth and health of a fetus.

At § 485.520(b), we are proposing basic factors relating to safety hazard standards for patients and personnel by specifying that the REH must institute proper safety precautions, perform periodic inspections of equipment, periodically check radiation workers for exposure, and only provide radiologic services based on the order of practitioners with clinical privileges or authorization by the medical staff and governing body. We propose the personnel standard at § 485.520(c) to require that a qualified radiologist, or other personnel qualified under state law either full-time, part-time, or on a consulting basis interpret radiologic tests that require specialized knowledge. This requirement can be fulfilled through arrangements with off-site providers via telehealth. Like hospitals, we propose that the radiologist in an REH must sign reports only of their interpretations. We propose to allow the medical staff and the individual responsible for radiological services to designate who is qualified to use radiological equipment. Lastly, at § 485.520(d), we also propose to require that records of departmental activities be maintained and that radiological reports and films be preserved for 5 years, consistent with the proposed requirements for the maintenance and retention of the REH medical records.

11. Condition of Participation: Pharmaceutical Services (Proposed § 485.522)

Pharmaceutical services are another integral part of the provision of health care services in an emergency department. The Journal of Medical Toxicology cited in a 2018 article that, "Clinical pharmacists are integral to the care and safety of patients in the hospital, particularly in specialty and high-risk settings. Emergency departments (EDs) represent care environments that carry unique risks."¹⁰ The article continues to note,

"Adult and pediatric patients present with undifferentiated medical, neurological, traumatic, psychiatric, and surgical complaints 24 [hours] a day, 7 days a week. Patients are generally unfamiliar to the emergency care providers, may be unable to communicate relevant medical information, and may require time-sensitive interventions. When present, ED crowding is associated with increased risk for medication errors."¹⁰ Given these identified risks, we believe that the REH should have standards for pharmaceutical services.

While the current CAH requirements do not have a separate CoP for pharmaceutical services, there are standards throughout the CAH CoPs for the oversight, storage, and administration of drugs and biologicals. Regulations at § 485.623(b)(3) requires the CAH to store drugs and biologicals properly, and § 485.635(a)(3)(iv) requires the CAH to develop rules for the storage, handling, dispensation, and administration of drugs and biologicals including a drug storage area administered in accordance with accepted principles. In addition, there are standards throughout the CAH CoPs regarding provisions for infection prevention and control and antibiotic stewardship programs that reference pharmacy leadership and pharmacy services. Therefore, we believe that providers that may transition to an REH would currently be performing the proposed REH requirements to support the delivery of pharmaceutical services; we do not expect these proposed requirements to create additional burden for REHs.

We are proposing to require that the REH's pharmaceutical services meet the needs of the patients at proposed § 485.522. According to the American Society of Health-System Pharmacists Guidelines on Emergency Medicine Pharmacy Services, some factors that an ED is expected to consider when determining how the pharmaceutical services can best meet the needs of the patients include the type and setting of the ED (for example, academic, community, urban, or rural), the size of the ED, the number of annual visits, the patient population served, and any specialty services available.¹¹ At § 485.522(a), we propose to require the REH to have a pharmacy or drug storage

American College of Medical Toxicology, 14(1), 114–116. <https://doi.org/10.1007/s13181-017-0634-4>.

¹¹ American Society of Health-System Pharmacists (2021). ASHP guidelines on emergency medicine pharmacist services. *Am J Health-Syst Pharm*, 78(3):261–275. <https://doi.org/10.1093/ajhp/zxaa378>.

Roentgenology, (203)2, 355–360. <https://doi.org/10.2214/AJR.13.11892>.

¹⁰ Farmer, B.M., Hayes, B.D., Rao, R., Farrell, N., & Nelson, L. (2018). The Role of Clinical Pharmacists in the Emergency Department. *Journal of medical toxicology: official journal of the*

area that is administered in accordance with accepted professional principles and in accordance with state and Federal laws. Additionally, we propose to require at § 485.522(a)(1) that a registered pharmacist or other qualified individual in accordance with state scope of practice laws direct the pharmaceutical services or, when appropriate, have a drug storage area that is supervised by an individual who is competent to do so. Rural communities are often challenged by the lack of pharmacists willing to move to rural areas and for this reason, we recognize that there may be REHs that can provide pharmaceutical services only by having a drug storage area that is under the supervision of a qualified individual. In these instances, the facility must establish qualifications for the individual with oversight of the drug storage area for competency purposes and ensure that someone is fulfilling the role who meets those requirements. This is consistent with the interpretive guidelines for the CAH CoPs contained in Appendix W of the SOM for § 485.635(a)(3). We are proposing that this individual be available for a sufficient time to provide such oversight based on the scope and complexity of the services offered at the REH. This individual would not be required to be a full-time pharmacist. We believe sufficient time provides the REH with the flexibility to determine how frequently the pharmacist or other qualified individual is available.

Furthermore, the CAH interpretive guidelines for § 485.635(a)(3) states that the compounding, packaging, and dispensing of drugs be consistent with accepted professional principles. In accordance with the Food and Drug Administration, accepted professional principles for compounding, packaging, and dispensing of drugs include having a licensed pharmacist, or in some cases a physician, perform these activities (or having them performed under the supervision of a licensed pharmacist, when appropriate). As such, we propose at § 485.522(b) that all compounding, packaging, and dispensing of drugs must be done by a licensed pharmacist or a licensed physician, or under the supervision of a pharmacist or other qualified individual in accordance with state scope of practice laws and be performed consistent with state and Federal laws. In addition, we propose that all drugs and biologicals must be kept in secure areas, and locked when appropriate. All drugs listed in Schedules II, III, IV, and V as outlined in the Comprehensive Drug Abuse Prevention and Control Act of 1970

(Pub. L. 91–513, as amended), must be locked within a secure area and only authorized personnel may have access to locked areas. We propose that outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use and drugs and biologicals can only be removed from the pharmacy or storage area by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and state law. These proposed requirements are also consistent with the CAH interpretive guidelines for § 485.635(a)(3).

Lastly, at § 485.522(c) we propose to set forth the standards for the administration of drugs. We note that the existing CAH CoP at § 485.635(a)(3)(iv) requires that the CAH have written policies that include the rules for the storage, handling, dispensation, and administration of drugs and biologicals. The CAH CoPs continue to require that these rules provide that there is a drug storage area that is administrated in accordance with accepted professional principles. Similarly, we propose to require that drugs be prepared and administered in an REH according to established policies and acceptable standards of practice and consistent with the CAH requirement at § 485.635(a)(3)(v), we propose to require that any adverse reactions be reported to the physician responsible for the patient and documented in the record. While the CAH CoPs require that the CAH have procedures for reporting adverse drug reactions and errors in the administration of drugs, we recognize that a nationally recognized standard of practice is to report adverse drug reactions to the physician responsible for the care of the patient. We propose at § 485.522(c)(2) and (3) respectively, that the REH must administer blood transfusions, blood products and intravenous medications in accordance with state law and approved medical staff policies and procedures, and that orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician or other authorized prescriber. We also propose at § 485.522(c)(4) to require that the REH have a procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

12. Condition of Participation: Additional Outpatient Medical and Health Services (Proposed § 485.524)

In addition to the provision of emergency services and observation

care, section 1861(kkk)(1)(A)(ii) of the Act allows REHs to provide additional outpatient medical and health services as specified by the Secretary through rulemaking. We received comments on the REH RFI recommending that CMS allow REHs to provide additional outpatient services that include radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services. We are proposing at § 485.524 that REHs be allowed to provide additional medical and health outpatient services that include, but are not limited, to those identified by commenters. We note that the REH may provide additional outpatient medical and health care services beyond those specified; however, we expect that the REH would be able to demonstrate that the service is needed based on an assessment of its community as required by proposed § 485.524(a). The decision should be based on a health needs assessment that is achieved by taking a systematic approach to ensuring that the services furnished by an REH are appropriate and meet the needs of the community.

Commenters on the REH RFI highlighted that providing rehabilitation services to rural communities requires overcoming the challenges of the landscape, limited referral options, and a shortage of therapists.

In addition, one of the health care needs in many rural communities is improving access to maternal health care services. As noted in CMS' Issue Brief *Improving Access to Maternal Health Care in Rural Communities*:¹²

A lack of access to high quality maternal health services in rural communities is the result of many factors including hospital and obstetric department closures, workforce shortages, and access to care challenges arising from the social determinants of health which have contributed to disparities in maternal health care for rural women and their babies. These access challenges can result in a number of negative maternal health outcomes including premature birth, low-birth weight, maternal mortality, severe maternal morbidity, and increased risk of postpartum depression. These health disparities affect American Indian and Alaska Native and women of color disproportionately. Since one in five Americans live in a rural community, including approximately 18 million women of reproductive age, it is critical that federal, regional, state, local agencies and communities work together to improve access to high quality maternal health services in rural communities.

¹² Centers for Medicare and Medicaid Services (2019). *Improving Access to Maternal Health Care in Rural Communities—Issue Brief*. <https://www.cms.gov/About-CMS/Agency-Information/OMH/equity-initiatives/rural-health/09032019-Maternal-Health-Care-in-Rural-Communities.pdf>.

The issue brief, which was published in 2019, highlights the role hospitals closures have played in the access issues to maternal health services in rural communities, noting that between 2004 and 2014, 179 rural counties lost or closed their hospitals obstetric services, contributing to the fact that fewer than 50 percent of rural women have access to perinatal services within a 30-mile radius.¹²

Additionally, the Biden-Harris Administration has made it their highest priority to improve access to maternal health care services. The Administration published a fact sheet on April 13, 2022, announcing actions to be taken to address the maternal health crisis in the United States (*Fact Sheet: Biden-Harris Administration Announces Additional Actions in Response to Vice President Harris's Call to Action on Maternal Health*, <https://www.whitehouse.gov/briefing-room/statements-releases/2022/04/13/fact-sheet-biden-harris-administration-announces-additional-actions-in-response-to-vice-president-harris-call-to-action-on-maternal-health/>). These actions include:

- Calling on states to expand their postpartum Medicaid and Children's Health Insurance Program coverage;
- Proposing the "Birthing-Friendly" hospital designation to drive improvements in maternal health outcomes and maternal health equity;
- Engaging the health care industry to improve health outcomes;
- Strengthening Maternal, Infant, and Early Childhood Home Visiting (MIECHV) Programs;
- New funding for the State Maternal Health Innovation and Implementation (State MHI) Program;
- Publication of a new Maternal Health Best Practice Guide for providers to incorporate telehealth for prenatal and postpartum care, and monitoring within high-risk pregnancy;
- Investing in doulas;
- Restoring access to Title X family planning services nationwide to fill service gaps caused by the withdrawal of Title X providers from the program; and
- Including in the proposed FY 2023 budget a proposed \$470 million to be used to reduce maternal mortality and morbidity rates; expand maternal health initiatives in rural communities; implement implicit bias training for healthcare providers; create pregnancy medical home demonstration projects; and address the highest rates of perinatal health disparities, including by supporting the perinatal health workforce.

Given the highlighted challenges faced by those living in rural

communities of accessing maternal health services and consistent with the Administration's priorities in improving access to these services, we believe it would be beneficial that REHs provide maternal health services that include prenatal care, low-risk labor and delivery and postnatal care. We are seeking input on the issue of whether REHs should be permitted to provide low-risk labor and delivery, and whether or not we should require that the REH also provide outpatient surgical services in the event surgical labor and delivery intervention is necessary. REHs should base their determination on what is considered a "low-risk" delivery on nationally recognized standards and guidelines. If a laboring patient presents to the REH for labor and delivery services and subsequently requires emergency surgical intervention, the REH would be responsible for providing the emergency and stabilizing treatment prior to transfer, including any emergency surgical procedures including but not limited to c-sections. Once the patient is stabilized, they may be transferred to an appropriate level of care for mother and baby given that the average length of inpatient stay for an uncomplicated c-section is 2.7 days.¹³ In such cases, we would encourage the REH to provide the patient's follow-up and postpartum care so long as the patient's needs are within the scope of practice of the practitioners providing services at the REH. We would expect that the REH would leverage clinicians other than only physicians so that a variety of trained professionals or support persons could help to address barriers to access to care and the maternal health workforce shortage in rural areas by utilizing nurse practitioners, nurse midwives, and doulas as allowed by state law.

The provision of behavioral health services is also a challenge in rural communities. According to the Rural Health Information Hub, ". . . approximately 7.7 million nonmetropolitan adults reported having any mental illness (AMI) in 2020, accounting for 20.5% of nonmetropolitan adults. In addition, 1.8 million, or 4.8%, of adults in nonmetropolitan areas reported having serious thoughts of suicide during the year."¹⁴ The Rural Health Information

Hub also presents specific challenges in this area, including the following:¹⁵

- *Accessibility*—Rural residents often travel long distances to receive services, are less likely to be insured for mental health services, and providers are less likely to recognize a mental illness.

- *Availability*—Chronic shortages of mental health professionals exist and mental health providers are more likely to practice in urban centers.

- *Affordability*—Some rural residents may not be able to afford the cost of health insurance or the cost of out-of-pocket care if they lack health insurance.

- *Acceptability*—Rural residents may be more susceptible to the stigma of needing or receiving mental health care in small communities where everyone knows each other and fewer choices of trained professionals can lead to a lack of faith in confidentiality, as well as a reliance on the informal care of family members, close friends, and religious leaders.

Several commenters on the REH RFI indicated that REHs should provide behavioral health services that include substance use disorder treatment. According to the Centers for Disease Control and Prevention, "Rates of drug overdose deaths are rising in rural areas, surpassing rates in urban areas."¹⁵ Additionally, treatment for alcohol and illicit drug use was generally the same or higher in nonmetropolitan counties compared to metropolitan counties, according to data from the 2018 National Survey on Drug Use and Health (Substance Abuse and Mental Health Services Administration, <https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHDetailedTabs2018R2/NSDUHDetTabsSect5pe2018.htm#tab5-9a>). The survey highlighted substance use disorders related to alcohol, methamphetamines, and opioids, particularly noting that rural counties exhibited a higher rate of opioid overdoses than urban counties and that opioid misuse is high in states with large rural populations. There are several factors that contribute to substance use disorder in rural communities, including high rates of poverty and unemployment, increased availability of prescription opioids, and barriers to treatment. These barriers include the level of complexity related to treatment of substance use disorders, which includes individual and group counseling, inpatient and outpatient treatment, case management, and

¹³ Federspiel, J.J., Suresh, S.C., Darwin, K.C., & Szymanski, L.M. (2020). Hospitalization Duration Following Uncomplicated Cesarean Delivery: Predictors, Facility Variation, and Outcomes. *AJP reports*, 10(2), e187–e197. <https://doi.org/10.1055/s-0040-1709681>.

¹⁴ Rural Health Information Hub (2021). *Rural Mental Health*. <https://www.ruralhealthinfo.org/topics/mental-health>.

¹⁵ Center for Disease Control and Prevention (2017). *Rural Health—Drug Overdose*. <https://www.cdc.gov/ruralhealth/drug-overdose/>.

medication, as well as additional services and programs. Difficulties associated with navigating these treatment modalities may, and often does lead to delays in treatment. This adds to existing access to care issues in rural communities where there are shortages of providers, ultimately resulting in delays in treatment. This further illustrates the need for behavioral health services in rural areas, given the access to care issues which are more prevalent in rural areas when compared to non-rural areas. Additionally, given the data provided related to substance use in rural communities, we would expect that some REHs may be interested in being opioid treatment providers. We note that providing these services is not prohibited by the statute at 1866(kkk) so long as the treatment remains an outpatient service, given that the statute does prohibit REHs from providing inpatient services (except those services provided in a distinct part SNF of the REH).

If the REH chooses to provide additional outpatient medical and health services, we propose at § 485.524(a)(1) to require that the provision of the additional service be based on nationally recognized guidelines and standards of practice, aligning the proposed requirement with the hospital CoPs for outpatient services at § 482.54. Given that the REH does not provide inpatient services, patients requiring a higher level of care would be required to be transferred to an acute care hospital or CAH. As a result of this, and based on comments received on the REH RFI, we further propose to require that the REH have a system in place for referral from the REH to different levels of care, including follow-up care, as appropriate. Some of the REH RFI comments also indicated that REHs should be required to have 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. Hospital admissions and transfers account for roughly 20 percent of all patient dispositions from the emergency department across the U.S.¹⁶ As a result, we can expect that REHs will transfer at least 20 percent of their patients so we agree with commenters and are therefore proposing to require that REHs have 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.

Ensuring effective communication between providers of health care services and patients and their family is a critical element in the provision of care and the discharge or transfer of patients. We are proposing to require that the REH have effective communication systems in place between the REH and patients (or responsible individuals) and their family, ensuring that the REH is responsive to their needs and preferences. We believe this would assist with effective care coordination as well as improved patient outcomes.

At § 485.524(b), we propose personnel requirements for REHs who choose to provide additional outpatient medical and health services. These requirements ensure that the additional services provided by the REH are overseen by at least one responsible individual, have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, and are provided by a physician or other clinician with experience and training in the specialty service area.

At § 485.524(c) we propose to specify standards that REHs must have for ordering outpatient medical and health services that are consistent with the hospital requirements at 42 CFR 482.54(c). Specifically, we propose to require outpatient medical and health services to only be ordered by a practitioner who: (1) is responsible for the care of the patient; (2) is licensed in the state where they provide care to the patient; (3) is acting within their scope of practice under state law; and (4) is authorized in accordance with state law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. We also propose that these requirements would apply to those practitioners who are appointed to the REH's medical staff and who have been granted privileges to order the applicable outpatient services; and those practitioners not appointed to the medical staff, but who satisfy the above criteria for authorization by the REH for ordering the applicable outpatient services and for referring patients for such services.

Lastly, the importance of allowing REHs to provide outpatient surgical services was especially noted by commenters in response to the REH RFI. A 2011 rural policy brief by the Rural Policy Research Institute (RUPRI) Center for Rural Health Policy Analysis states that, "Like residents of any community,

rural residents have surgical needs that range from the predictable (e.g., cataract procedures) to the emergent (e.g., appendectomy). Innovations in surgery over the past several decades have made possible the provision of many surgical procedures on an outpatient basis, reducing inpatient admissions."¹⁷ The policy brief found that across four states (Colorado, North Carolina, Vermont, and Wisconsin) in 2011, surgeries were performed across 107 CAHs with an average of 522 outpatient procedures performed per year. This is 75 to 80 percent of the total surgical procedure volume in the state for that year and demonstrates that there will be a need for outpatient surgical services in communities in which CAHs convert to an REH. Therefore, we propose at § 485.524(d) to set forth standards for an REH performing outpatient surgical services that are consistent with the CAH requirements for surgical services at § 485.639. These include proposed standards for ensuring that the services are conducted in a safe manner by qualified practitioners with specific protocols for administering anesthesia.

Given that in accordance with the statutory provision at section 1861(kkk)(1)(A) of the Act services furnished by the REH must not exceed an annual per patient average of 24 hours in the REH, we expect REHs, like ASCs, to provide surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission.

13. Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Programs (Proposed § 485.526)

The Department of Health and Human Services (HHS) is particularly concerned about health care associated infections (HAIs), as they are a significant cause of morbidity and mortality in the U.S. In 2015, there were an estimated 687,000 cases of HAIs in U.S. hospitals with 72,000 inpatients with HAIs that died during that same time period.¹⁸ Additionally, HHS is concerned about the growing threat to patient safety posed by organisms that are resistant to antibiotics, referred to as "multi-drug resistant organisms (MDROs)." Options for treating patients

¹⁶ American College of Emergency Physicians—ACEP Now (2019). Latest Data Reveal the ED's Role as Hospital Admission Gatekeeper. <https://www.acepnow.com/article/latest-data-reveal-the-eds-role-as-hospital-admission-gatekeeper/>.

¹⁷ Rural Policy Research Initiative Rural Health Center for Rural Health Policy Analysis—Rural Policy Brief (2011). Surgical Services in Critical Access Hospitals, 2011. <https://rupri.public-health.uiowa.edu/publications/policybriefs/2015/Surgical%20Services%20in%20CAHs.pdf>.

¹⁸ Centers for Disease Control and Prevention (2020). Data Portal. <https://www.cdc.gov/hai/data/portal/index.html>.

with MDRO infections are very limited, resulting in increased mortality, as well as increased hospital lengths of stay and costs. In response, HHS launched an Action Plan in April 2009 with updates in 2013 and 2018 toward the prevention and elimination of HAIs. (HHS. “HHS Action Plan to Prevent Healthcare-Associated Infections.” Accessed 5 March 2014 <https://www.hhs.gov/ash/initiatives/hai/actionplan/index.html>.) The HHS Action Plan identifies policy changes, some addressed here in this proposed rule, in an effort to provide better, more efficient care.

We are proposing a CoP for infection prevention and control and antibiotic stewardship programs for REHs at § 482.526 in an effort to mirror similar infection prevention and control requirements for hospitals and CAHs (at §§ 482.42 and 485.640, respectively) that reflect state-of-the-art practices and terminology. We are also proposing a standard that would require an REH to develop and maintain an antibiotic stewardship program as an effective means to improve REH antibiotic-prescribing practices and curb patient risk for possibly deadly *Clostridium difficile* infections (CDIs), as well as other future, and potentially life-threatening, antibiotic-resistant infections. We would promote better alignment of an REH’s infection control and antibiotic stewardship efforts with nationally recognized guidelines and emphasize the role and accountability of an REH’s governing body in program implementation and oversight. We believe that these requirements, together, would promote a more patient-centered culture of safety focused on infection prevention and control as well as appropriate antibiotic use (consistent with the requirements for hospitals and CAHs), while allowing REHs the flexibility to align their programs with the guidelines best suited to them.

Therefore, similar to the requirements that we finalized with regard to infection prevention and control and antibiotic stewardship programs for hospitals and CAHs in the September 30, 2019 final rule “Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction; Fire Safety Requirements for Certain Dialysis Facilities; Hospital and Critical Access Hospital (CAH) Changes To Promote Innovation, Flexibility, and Improvement in Patient Care” (84 FR 51732), we are proposing in this rule that each REH has facility-wide infection prevention and control and antibiotic stewardship programs that are coordinated with the REH quality assessment and performance

improvement (QAPI) program, for the surveillance, prevention, and control of HAIs and other infectious diseases and for the optimization of antibiotic use through stewardship. Further, we are proposing in this rule at § 485.526(a)(1) that the REH ensure that an individual (or individuals), who are qualified through education, training, experience, or certified in infection, prevention and control, are appointed by the governing body, or responsible individual, as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program at the REH and that the appointment is based on the recommendations of medical staff and nursing leadership.

At § 485.526(a)(2) we propose that the infection prevention and control program, as documented in its policies and procedures, employ methods for preventing and controlling the transmission of infections within the REH and between the REH and other health care settings. The program, as documented in its policies and procedures, would have to employ methods for preventing and controlling the transmission of infection within the REH setting (for example, among patients, personnel, and visitors) as well as between the REH (including outpatient services) and other institutions and health care settings. At § 485.526(a)(3) we are proposing that the infection prevention and control program include surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and that the program also address any infection control issues identified by public health authorities. We are proposing at § 485.526(a)(4) that the infection prevention and control program reflect the scope and complexity of the services provided by the REH.

At § 485.526(b)(1) we propose to set standards for the organization and policies of the antibiotic stewardship program. Specifically, we propose to require that the REH’s governing body ensure that an individual, who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship is appointed as the leader of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff and pharmacy leadership. The proposed requirements at § 485.526(b)(2)(i) through (iii) would ensure that certain goals for an antibiotic stewardship program are met. These include demonstrating coordination among all components of

the REH responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, and nursing and pharmacy services; documenting the evidence-based use of antibiotics in all departments and services of the REH; and documenting improvements, including sustained improvements, in proper antibiotic use. We believe that these three components are essential for an effective program.

The provisions at § 485.526(b)(3) and (4) would require the REH to ensure that the antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use, and that the REH’s stewardship program reflects the scope and complexity of services offered. We believe these proposed requirements are necessary to promote a facility-wide culture of quality improvement.

We would require that the governing body or responsible individual ensure that the infection prevention and control issues identified by the infection prevention and control professionals be addressed in collaboration with REH leadership. Therefore, at § 485.526(c)(1)(i) and (ii), we propose certain requirements that the governing body or responsible individual must adhere to including—

- Ensuring systems are in place and operational for the tracking of all infection surveillance, prevention, and control, and antibiotic use activities to demonstrate the implementation, success, and sustainability of such activities; and

- Ensuring all HAIs and other infectious diseases identified by the infection prevention and control program and antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with REH QAPI leadership.

At § 485.526(c)(2)(i) through (vi), we propose that the responsibilities of the infection prevention and control professionals would include the development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines. The infection preventionist(s)/infection control professional(s) would be responsible for all documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

Additionally, the infection preventionist(s)/infection control professional(s) would be responsible for the following—

- Communication and collaboration with the REH's QAPI program on infection prevention and control issues;
- Competency-based training and education of REH personnel and staff including professional health care staff and, as applicable, personnel providing services in the REH under agreement or arrangement, on the practical applications of infection prevention and control guidelines, policies and procedures;
- Prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by REH personnel; and
- Communication and collaboration with the antibiotic stewardship program.

At § 485.526(c)(3), we propose requirements for the leader(s) of the antibiotic stewardship program that are similar, but not identical, to the proposed responsibilities for the REH's designated infection preventionist(s)/infection control professional(s) at proposed § 485.526(c)(2). We believe that an REH's antibiotic stewardship program is the most effective means for ensuring appropriate antibiotic use. We also believe that such a program would require a leader who is responsible and accountable for its success. Therefore, we propose that the leader of the antibiotic stewardship program would be responsible for the development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics. We do not expect that each new leader would develop a new antibiotic stewardship program, unless it is determined that a new program is necessary. We also propose that the leader of the antibiotic stewardship program would be responsible for all documentation, written or electronic, of antibiotic stewardship program activities. The leader would also be responsible for communicating and collaborating with medical and nursing staff, pharmacy leadership, and the REH's infection prevention and control and QAPI programs, on antibiotic use issues.

We also propose that the leader would be responsible for the competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the practical applications of

antibiotic stewardship guidelines, policies, and procedures.

Similar to a standard in the hospital CoPs, we propose a standard at § 485.526(d) for REHs that would allow for the governing body of an REH that is part of a system consisting of multiple, separately certified hospitals, CAHs, and/or REHs using a single system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, to elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities, including any REHs, after determining that such a decision is in accordance with all applicable state and local laws. We are proposing a similar standard for CAHs at § 485.640(g), which is discussed in section B.3 of this proposed rule. The system's single governing body would be responsible for ensuring that each of its separately certified REHs met the requirements of this section. We note that each separately certified REH subject to the system's single governing body would need to demonstrate that the unified and integrated infection prevention and control and antibiotic stewardship programs:

- Were established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each REH;
- Established and implemented policies and procedures to ensure that the needs and concerns of each of its separately certified REHs, regardless of practice or location, are given due consideration; and
- Had mechanisms in place to ensure that issues localized to particular REHs were duly considered and addressed.

The REH would also need to demonstrate that it had designated a qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship at the REH to be responsible for:

- Communicating with the system's unified infection prevention and control and antibiotic stewardship programs;
- Implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs; and
- Providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to REH staff.

Finally, in response to the COVID-19 pandemic, on September 2, 2020, CMS published an interim final rule with comment period to track the incidence and impact of COVID-19 to assist public health officials in detecting outbreaks and saving lives (85 FR 54820). CMS then published a final rule with comment containing reporting requirements for hospitals and CAHs to report acute respiratory illness during the public health emergency (PHE) for COVID-19 (85 FR 86304) on December 4, 2020. Lastly, on November 5, 2021, CMS published an interim final rule with comment establishing COVID-19 vaccination requirements for most Medicare- and Medicaid-certified providers and suppliers (86 FR 61623). Consistent with the recent changes we made to the hospital and CAH infection control CoPs related to COVID-19 (87 FR 28108) and the declared PHE, we are proposing the following three standards in this proposed rule for REHs:

- Reporting of data related to viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential, which would require an REH to electronically report information on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection), SARS-CoV-2/COVID-19, and other viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential only when the Secretary has declared a Public Health Emergency, directly related to such specific pathogens and infectious diseases.
- COVID-19 reporting, which would require an REH to electronically report information about COVID-19 and seasonal influenza in a standardized format specified by the Secretary, including the REH's current inventory supplies of any COVID-19-related therapeutics that have been distributed and delivered to the REH and the current usage rate for those therapeutics beginning at the conclusion of the COVID-19 PHE, and continuing until April 30, 2024, unless the Secretary specifies an earlier end date.
- COVID-19 Vaccination of REH staff, which would require the REH to develop and implement policies and procedures to ensure that all staff, with the exception of those with valid exemptions, are fully vaccinated for COVID-19 until November 4, 2024, unless the Secretary specifies an earlier end date for the requirements of this paragraph. Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 establishes a general 3-year timeline for publishing a Medicare final regulation after a

proposed regulation or an interim final regulation has been published. The referenced November 4, 2024 date aligns with the statutory 3-year “Section 902” deadline for the IFC that implemented the COVID–19 staff vaccination requirements for the provider and supplier types covered under that rule.

14. Condition of Participation: Staffing and Staff Responsibilities (Proposed § 485.528)

Sections 1861(kkk)(1)(B)(i) and (ii) of the Act require that the emergency department of the REH be staffed 24 hours a day, 7 days a week. We propose to implement this requirement at § 485.528(a). The statute does not speak to the type of staff at the REH that is required to fulfill this role. As such, we believe that REHs should have the flexibility to determine how to staff the emergency department at the REH 24 hours, 7 days a week. We expect that the individual(s) staffing the emergency department is competent to receive patients and activate the appropriate medical resources for the treatment of the patient. This includes, but is not limited to notifying a practitioner of the patient’s arrival in the emergency department. Such staff may include a nurse, nursing assistant, clinical technician, or an emergency medical technician, (EMT).

Furthermore, in accordance with section 1861(kkk)(1)(B)(iii) of the Act, we propose for REHs to meet the applicable CAH requirements at § 485.631 for staffing and staff responsibilities. We believe that many of the CAH staffing requirements are appropriate for application to REHs and as a result, at § 485.528(b) through (e), we set for the proposed standards for staffing, responsibilities of the doctor of medicine or osteopathy, physician assistant, nurse practitioner, and clinical nurse specialist responsibilities similar to CAHs. For instance, the CAH CoPs require at § 485.631(a)(5) that a registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the CAH has one or more inpatients. Since REHs are required to furnish emergency services and observation care, we are proposing a similar requirement as CAHs to require that a registered nurse, clinical nurse specialist, or licensed practical nurse be on duty whenever the REH has one or more patients receiving emergency services or observation care.

We also propose to require standards for the periodic review of clinical privileges and performance that are also identical to the CAH standards at § 485.631, with the exception of the CAH standard at § 485.631(b)(1)(iv),

which requires that the CAH periodically review and sign the records of all inpatients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants. We are not proposing this standard for REHs given that the REH would provide outpatient services exclusively.

We do not believe that it is necessary to apply the CAH requirement that a doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant is available to furnish patient care services at all times the CAH operates (§ 485.631(a)(4)) to REHs. Instead, we are proposing to require that the REH standards align with the CAH emergency services requirements at § 485.618. The CAH provision at § 485.618(d) requires that there be a doctor of medicine or osteopathy, a physician assistant, a nurse practitioner, or a clinical nurse specialist, with training or experience in emergency care, on call and immediately available by telephone or radio contact, and available on site within specified timeframes. This allows for the alignment of the REH proposed provisions with the CAH emergency services standards, as required by the statute.

In response to the REH RFI, commenters indicated that CMS should require board-certified emergency physicians to serve as medical directors of the REH. While we agree that having a board-certified emergency physician serving as the medical director of the REH would benefit patients by ensuring that the REH is overseen by a highly qualified physician with a high level of expertise in emergency medicine, we believe that requiring this of REHs would be unduly burdensome due to the challenges faced by rural communities in obtaining and retaining medical professionals to provide health care services. While we are not proposing to require that REHs have a board-certified emergency physician serve as the medical director, we would encourage REHs to have such a physician serve in the capacity of medical director if possible.

15. Condition of Participation: Nursing Services (Proposed § 485.530)

The CoPs for hospitals and CAHs include a provision for nursing services. However, given that each of these providers offers acute care inpatient services, we do not believe that all of the nursing services requirements for hospitals and CAHs would be appropriate for REHs, which is an outpatient-only provider. In evaluating the appropriateness of nursing services

requirements for REHs, we also took into consideration the CfCs for ambulatory surgery centers at 42 CFR part 416 since they only offer outpatient services.

Consistent with the hospital requirements, we propose to require that REHs have an organized nursing service that is available to provide 24-hour nursing services at § 485.530 for the provision of patient care. We believe that the REH should have a sufficient number of nurses available to provide services, based on the number of patients receiving services in the REH and the level of care required to be provided to those patients.

Similar to the standard hospitals at § 482.23(a), we propose at § 485.530(a) to require that patient care responsibilities must be delineated for all nursing service personnel and that nursing services must be provided in accordance with recognized standards of practice. Also consistent with the hospital standards for nursing services, we propose to require at § 485.530(b) that the REH have a director of nursing who is a licensed registered nurse and who is responsible for the operation of the nursing services.

16. Condition of Participation: Discharge Planning (Proposed § 485.532)

Hospitals and CAHs have very similar discharge planning requirements at §§ 482.43 and 485.642, respectively. These requirements were revised in the final rule entitled “Medicare and Medicaid Programs; Revisions to Requirements for Discharge Planning for Hospitals, Critical Access Hospitals, and Home Health Agencies, and Hospital and Critical Access Hospital Changes to Promote Innovation, Flexibility, and Improvement in Patient Care” (84 FR 51836). Many commenters on the REH RFI noted the importance of having in-depth discharge planning requirements for REHs, highlighting the need for REH patients to have safe, well-coordinated discharge processes due to the availability of fewer health care resources in rural environments. As a result, we propose to closely align the proposed discharge planning requirements for REHs with the requirements for hospitals and CAHs. Specifically, we are proposing at § 485.532 to require that the patient’s discharge plan address the patient’s goals of care and treatment preferences. During the discharge planning process, we would expect that the appropriate medical staff would discuss the patient’s post-acute care goals and treatment preferences with the patient, the patient’s family or their caregiver/

support persons (or both) and subsequently document these goals and preferences in the medical record. We would expect these documented goals and treatment preferences to be taken into account throughout the entire discharge planning process. We note that as a provider of emergency services, the REH may receive patients from nursing homes who require emergency care. Having a robust discharge planning process in place is imperative for this patient population. There may be instances in which a patient comes to the REH from a nursing home and the nursing home expresses an intent not to accept the patient or delays the patient's return back to the nursing home after the completion of emergency care by the REH. Under these circumstances, we would encourage the REH to contact their State's long-term care ombudsman or State Survey Agency. We also encourage the REH to inform patients who arrive from or are discharged to a long-term care facility about how to contact the Ombudsman and State Survey Agency, as there may be quality of care or quality of life concerns to be reported. The Administration of Community Living's Long-Term Care Ombudsman Programs, ". . . work to resolve problems related to the health, safety, welfare, and rights of individuals who live in LTC facilities, such as nursing homes, board and care and assisted living facilities, and other residential care communities. Ombudsman programs promote policies and consumer protections to improve long-term services and supports at the facility, local, state, and national levels."¹⁹

At § 485.532(a) introductory text and (a)(1), we propose to require that REHs implement a discharge planning process to begin identifying, early in the provision of services, the anticipated post-discharge goals, preferences, and needs of the patient and begin to develop an appropriate discharge plan for patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning. Timely identification of the patient's goals, preferences, and needs and development of the discharge plan would reduce delays in the overall discharge process. Patient referrals to or consultation with community care organizations will be a key step, for some, in assuring successful patient outcomes. Therefore, we believe that

discharge planning for patients is a process that involves the consideration of the patient's unique circumstances, treatment preferences, and goals of care, and is not solely a documentation process.

In addition, in order to encourage patient engagement and understanding of their discharge plan or instructions, we recommend that providers follow the National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health and Health Care (<https://www.thinkculturalhealth.hhs.gov/clas/standards>), which provide guidance on providing instructions in a culturally and linguistically appropriate manner. We remind providers of their obligations to take reasonable steps to provide meaningful access to individuals with limited English proficiency in accordance with Title VI of the Civil Rights Act of 1964 and section 1557 of the Patient Protection and Affordable Care Act (the Affordable Care Act). In addition, providers are reminded to take appropriate steps to ensure effective communication with individuals with disabilities, including the provision of auxiliary aids and services, in accordance with section 504 of the Rehabilitation Act, the Americans with Disabilities Act, and section 1557 of the Affordable Care Act (see, <https://www.hhs.gov/civil-rights> and <https://www.ada.gov> for more information on these requirements). Discharge planning would be of little value to patients who cannot understand or appropriately follow the discharge plans discussed in this proposed rule. Without appropriate language assistance or auxiliary aids and services, discharge planners would not be able to fully involve the patient and caregiver/support person in the development of the discharge plan. Furthermore, the discharge planner would not be fully aware of the patient's goals for discharge.

Additionally, effective discharge planning would assist REHs in complying with the U.S. Supreme Court's holding in *Olmstead v. L.C.* (527 U.S. 581 (1999)), which found that the unjustified segregation of people with disabilities is a form of unlawful discrimination under the ADA. We note that effective discharge planning may assist REHs in ensuring that individuals being discharged who would otherwise be entitled to institutional services, have access to community-based services when—(1) such placement is appropriate; (2) the affected person does not oppose such treatment; and (3) the placement can be reasonably accommodated. As noted by comments received in response to the REH RFI, discharge planning should focus on

returning the patient to a home or community-based setting to the fullest extent possible with necessary supports and service. These proposed discharge planning standards are aimed at achieving this goal.

At § 485.532(a)(2), we propose to require an REH to perform a discharge planning evaluation that must include an evaluation of a patient's likely need for appropriate services following care that has been furnished by an REH, including, but not limited to, hospice care services, post-REH extended care services, home health services, and non-health care services and community-based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.

At § 485.532(a)(3) we propose to require that the patient's discharge needs evaluation and discharge plan must be documented and completed on a timely basis, based on the patient's goals, preferences, strengths, and needs, so that appropriate arrangements for post-REH care are made before discharge. This requirement would prevent the patient's discharge or transfer from being unduly delayed. We expect that in response to this requirement, REHs would establish more specific time frames for completing the evaluation and discharge plans based on the needs of their patients and their own operations. All relevant patient information would be incorporated into the discharge plan to facilitate its implementation and the discharge plan must be included in the patient's medical record. The results of the evaluation must also be discussed with the patient or patient's representative. Furthermore, we believe that REHs will use their evaluation of the discharge planning process, with solicitation of feedback from other providers and suppliers in the community, as well as from patients and caregivers, to revise their timeframes, as needed. We encourage REHs to make use of available health information technology, such as electronic health records, as well as entities that can facilitate exchange, such as health information exchanges, to enhance the efficiency and effectiveness of their discharge process.

At § 485.532(a)(4), we propose to require the REH to arrange for the development and initial implementation of a discharge plan for those patients so identified as well as for other patients upon the request of the patient's physician. We propose at § 485.532(a)(5) to require that a registered nurse, social worker, or other personnel qualified in

¹⁹ Administration of Community Living (2021). Long-Term Care Ombudsman Program. <https://acl.gov/programs/Protecting-Rights-and-Preventing-Abuse/Long-term-Care-Ombudsman-Program>.

accordance with the REH's discharge planning policy coordinate the discharge needs evaluation and the development of the discharge plan.

At § 485.532(a)(6) we propose to require that the REH's discharge planning process must ensure an ongoing patient evaluation throughout the patient's REH stay or visit to identify any changes in the patient's condition that would require modifications to the discharge plan. The evaluation to determine a patient's continued stays at the REH (or in other words, their readiness for discharge or transfer), is a current standard of medical practice.

We propose to require at § 485.532(a)(7) that the hospital assess its discharge planning process on a regular basis and include, as part of the assessment, an ongoing review of a representative sample of discharge plans. We expect that this would include patients who were emergency department revisits, or presented to the emergency department within 30 days of a previous visit, to ensure that the REH is responsive to the discharge needs of patients.

In addition to standards for evaluating the discharge needs of patients and the development of discharge plans, the hospital and CAH discharge planning provisions also require that the hospital and CAH assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, home health agency (HHA), SNF, inpatient rehabilitation facility (IRF), or long-term care hospital (LTCH) data on quality measures and data on resource use measures. Furthermore, the CoPs require the hospital and CAH to ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences. We believe these requirements are applicable to REHs given that we expect some patients of the REH to be discharged to a post-acute care provider. As result, we propose at § 485.532(a)(8) to require REHs to share data on quality measures and resource use measures of local post-acute care providers with patients to assist them in selecting a post-acute care provider.

We propose at § 485.532(b) to require that the REH must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service

providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

The Agency for Healthcare Research and Quality released an environmental scan report on Improving the Emergency Department Discharge Process, that evaluated the state of the emergency department discharge process and ways in which it can be improved.²⁰ The report found that a high-quality emergency department discharge incorporates the following:

- Informs and educates patients on their diagnosis, prognosis, treatment plan, and expected course of illness. This includes informing patients of the details of their visit (treatments, tests, procedures).
- Supports patients in receiving post-emergency department discharge care. This might include medications, home care of injuries, use of medical devices/equipment, further diagnostic testing, and further health care provider evaluation.
- Coordinates emergency department care within the context of the health care system (other health care providers, social services, etc.).

We believe discharge planning requirements proposed for REHs address the goals identified in the report.

17. Condition of Participation: Patient's Rights (Proposed § 485.534)

It is imperative for patients to have the ability to exercise certain rights and protections while seeking and receiving necessary care and services at an REH. As previously mentioned, the appropriate provision of behavioral health is very important in the treatment and safety of patients and staff. Behavioral health is a challenge in rural areas, due to the accessibility, affordability, acceptability and availability of these services. We anticipate beneficiaries may rely on REH's to access behavioral health care services, therefore we believe it is important to have policies and procedures in place for REHs and CAHs (discussed later in this rule) in the event of a mental health crisis and the need for the use of restraints and seclusions. We propose to establish a CoP for

patient's rights at § 485.534 that would set forth the rights of all patients to receive care in a safe setting and provide protection for a patient's emotional health and safety as well as their physical safety. Furthermore, we propose to establish the patient's rights CoP for REHs closely to the patient's rights CoP for hospitals at § 482.13. This would include proposed requirements for the REH to inform patients of and exercise their rights, address privacy and safety, adhere to the confidentiality of patient records, responsibilities for the use of restraint and seclusion, and adherence to patient visitation rights. We propose to add these same patient's rights CoPs for CAHs, as well. Some of these requirements are currently in the SOM for CAHs while some are not explicitly required. We believe that these patient rights provisions are important for hospitals, CAHs, and REHs. However, we note that some of the provisions proposed in this section for REHs and, also for CAHs as discussed later, are less prescriptive than those for hospitals because we are proposing to allow for these providers to develop policies and procedures based on the scope of services they provide and patient populations that they serve. For example, we believe that REHs, like CAHs, will have a lower volume of patients than hospitals and the use of restraints and seclusion would not be as frequent as other providers. REHs would not be providing inpatient services and if a patient presents at the REH in crisis or needing a level of care so acute that restraints or seclusions may become necessary, we would expect the REH to arrange for the transfer of the patient to a higher level of care. We are specifically soliciting comments on the appropriateness of the patient's rights requirements proposed for restraint and seclusion, the potential need to require standards that are more stringent to address patient protections, and the feasibility of implementing such requirements in rural communities.

Notice of Rights

At § 485.534(a), we propose that an REH must inform each patient, or when appropriate, the patient's representative (as allowed under state law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible. This includes a proposal to require the REH to establish a process for the oversight and prompt resolution of patient grievances and for informing each patient whom to contact to file a grievance.

²⁰ Johns Hopkins University, Armstrong Institute for Patient Safety and Quality (2014). Improving the emergency department discharge process: environmental scan report. (Prepared by Johns Hopkins University, Baltimore, MD, under Contract No. HHS 2902010000271.). Agency for Healthcare Research and Quality; Publication No. 14(15)-0067-E. <https://www.ahrq.gov/sites/default/files/wysiwyg/professionals/systems/hospital/edenvironmentalscan/edenvironmentalscan.pdf>.

Exercise of Rights

At § 485.534(b), we propose to specify those rights a patient has regarding their medical care, which includes the right to make informed decisions regarding their care, to be fully informed about such care, and the right to request or refuse treatment. We note that this right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. In addition, we propose to specify that the patient also has the right to formulate advance directives and to have REH staff and practitioners who provide care in the REH comply with these directives.

Privacy, Safety, and Confidentiality of Patient Records

At § 485.534(c), we propose to specify that the patient has the right to personal privacy, receive care in a safe setting, and be free from all forms of abuse or harassment. At § 485.534(d), we propose to specify that the patient has the right to the confidentiality of their medical records and the right to access their medical records. When requested, we propose that the REH must provide the patient with their records in a form and format requested by the requestor and within a reasonable timeframe, as not to frustrate the legitimate efforts of individuals to gain access to their own medical records.

Use of Restraints and Seclusion

At § 485.534(e), we propose those patient's rights relating to the use of restraints and seclusion. We are proposing requirements that are less burdensome than those existing restraint and seclusion requirements for hospitals because given the level of services provided by REHs and the anticipated patient volume, we expect the likelihood of their need to utilize restraints and seclusion to be relatively low. In addition, in the event that there are patients requiring restraint and seclusion we would expect them to be transferred to a higher level of care. We note that we have similar expectations for CAHs and are proposing similar requirements for CAHs in this rule. Specifically, we propose to specify that all patients have the right to be free from physical or mental abuse, from corporal punishment, and from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. We propose that restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible

time. We propose to define restraint as any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move their arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, off of a stretcher, or out of a chair, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). We propose to define seclusion as the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

At § 485.534(e)(2), we propose to require that the restraint or 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 at § 485.534(e)(3) that the type or technique of restraint or seclusion used must be the least restrictive intervention that will be effective to protect the patient, staff member, or others from harm. At § 485.534(e)(4), we propose that the REH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice. These requirements allow for the REH to use restraints and seclusion in the event that it is necessary and as a last resort to respond to immediate safety concerns, but lessens the burden and allows for more flexibility than the existing hospital CoPs. We believe that allowing the REH the flexibility to develop their own policies and procedures for restraints and seclusion based on the scope of services they provide is necessary given their patient volumes, populations, and access to resources. We propose to require that the policies and procedures that are developed be consistent with current standards of practice. As noted, we are soliciting comments on the appropriateness of the patient's rights requirements proposed for restraint and seclusion, the potential need to require

standards that are more stringent to address patient protections, and the feasibility of implementing such requirements in rural communities.

Staff Training Requirements for the Use of Restraints or Seclusion

The following staff training requirements are not as prescriptive as the existing hospital requirements, and we are proposing these same requirements for CAHs in this rule. At § 485.534(f) we propose to establish staff training requirements for the use of restraints and seclusion. Specifically, we propose that the patient has the right to safe implementation of restraint or seclusion by trained staff. We propose at § 485.534(f)(1) that the REH must provide competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the use of restraint and seclusion. To ensure that the use of restraint and seclusion for patients receiving services in an REH is respectful of, and responsive to, individual patient preferences, needs and values, we propose to require that the training be patient-centered. Additionally, to ensure that staff are educated and trained on using the least restrictive intervention necessary for the safety of the patients and REH staff, we propose at § 485.534(f)(2) to require that the REH staff train their staff in alternatives to the use of restraint and seclusion. For example, staff should have trauma-informed knowledge competencies and be aware of effective de-escalation techniques that can be used to avoid the use of restraint and seclusion and the trauma that may be associated with their use. Trained peer workers (people who share similar experiences of being diagnosed with mental health conditions, substance use disorders, or both) and community health workers (CHWs) may also serve a useful role in assisting patients and other staff. This could include helping to monitor use of restraint and seclusion, deescalating interactions with patients and contributing to a positive and supportive environment for patients, family members, and REH staff. REHs are encouraged to consider the use of peer workers and CHWs in their staffing plans. For further information, please see the 2007 guidance on use of peers in the Medicaid program (<https://www.medicaid.gov/federal-policy-guidance/downloads/SMD081507A.pdf>) and resources from the Substance Abuse and Mental Health Services Administration (

support-tools/peers). In addition, facilities are encouraged to consider any nutritional needs while a patient is restrained, such as a need to provide food and water.

Death Reporting Requirements

The following requirements are similar to the hospital requirements at § 482.13. At § 485.534(g), we propose to establish requirements that REHs must follow when reporting deaths associated with the use of seclusion or restraint. Specifically, we propose to require that the REH must report to CMS, by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day the following information—(1) Each death that occurs while a patient is in restraint or seclusion; (2) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion; (3) Each death known to the REH that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. We note that “reasonable to assume” in this context would include, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

For instances when no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the REH staff must record in an internal log or other system, the following information—(1) Any death that occurs while a patient is in such restraints; (2) Any death that occurs within 24 hours after a patient has been removed from such restraints. Furthermore, we propose that staff must also document in the patient's medical record the date and time the death was reported to CMS or recorded in the internal log or other system. Also, for instances when no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), we propose to require that entries into the internal log or other system must be documented no later than seven days after the date of death of the patient, include the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es), and to be made

available in either written or electronic form to CMS immediately upon request.

Patient Visitation Rights

At § 485.534(h), we propose to establish requirements related to a patient's visitation rights. These requirements are consistent with the current hospital and CAH regulations. Specifically, we propose to require that an REH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the REH may need to place on such rights and the reasons for the clinical restriction or limitation. An REH must inform patients (or support persons, where appropriate) of their visitation rights, including any clinical restriction or limitation on such rights, when they are informed of their other rights. Each patient should be informed (or support persons, where appropriate) of the right, subject to their consent, to receive the visitors whom they designate, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend. The patient also has the right to withdraw or deny such consent at any time, not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability, and ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

18. Condition of Participation: Quality Assessment and Performance Improvement Program (QAPI program) (Proposed § 485.536)

Patient safety and quality improvement remains a challenge in our nation's hospitals. In 2001, the Institute of Medicine (IOM) released a pivotal report, “Crossing the Quality Chasm” in which it stated that “the American healthcare delivery system is in need of fundamental change” and recognized that “quality problems are everywhere affecting many patients.”²¹ In a 2004 educational publication co-sponsored by the Office of Inspector General (OIG) of the U.S. Department of Health and Human Services and the American Health Lawyers Association (AHLA), *Corporate Responsibility and Health Care Quality: A Resource for Health*

²¹ Institute of Medicine (US) Committee on Quality of Health Care in America. *Crossing the Quality Chasm: A New Health System for the 21st Century*. Washington (DC): National Academies Press (US); 2001. Available from: <https://www.ncbi.nlm.nih.gov/books/NBK222274/> doi: 10.17226/10027.

Care Boards of Directors, the authors discuss the IOM report and state that the oversight of quality and patient safety is becoming clearly recognized as a core fiduciary responsibility of health care organizations.²² They further note that promoting quality of care and preserving patient safety are at the core of the health care industry and the reputation of each health care organization and suggest that “contemporary health care quality, patient safety and cost efficiency initiatives provide an opportunity for health care organizations to make a positive difference to society while promoting their missions and enhancing their financial success.” In their 2013 expert panel report, the Association of American Medical Colleges describes the work of the competent health professional as not only delivering health care, but also working to improve it, including identifying problems in care delivery and working with others to enhance performance.²³

While progress has been made towards the goal of increased patient safety since the publication of the 2001 IOM report, including a reduction in hospital-acquired conditions (HACs) and hospital fall-related injuries and improvements in patient handoffs, the mitigation of medical errors and adverse events and protection of patient safety remain serious concerns.^{24 25 26} According to 2018 data from the Centers for Disease Control (CDC), approximately 1 in 31 hospital patients develops an HAI, such as a surgical site infections or catheter-related bloodstream infections (CRBIs) and the effects can be painful, costly, and even deadly.²⁷

²² United States Department of Health and Human Services, Office of Inspector General & American Health Lawyers Association. (2004). *Corporate Responsibility and Health Care Quality: A Resource for Health Care Boards of Directors*. https://oig.hhs.gov/documents/compliance-guidance/813/CorporateResponsibilityFinal_9-4-07.pdf.

²³ Association of American Medical Colleges. (2014). *Teaching for Quality: Integrating Quality Improvement and Patient Safety across the Continuum of Medical Education*. <https://www.aamc.org/media/26316/download?attachment>.

²⁴ Agency for Healthcare and Research Quality. (2020, July) *AHRQ National Scorecard on Hospital-Acquired Conditions: Final Results for 2014 through 2017*. <https://www.ahrq.gov/hai/pfp/index.html>.

²⁵ Dupree, E., Fritz-Campiz, A., Musheno, D. (2014). A New Approach to Preventing Falls with Injuries. *Journal of Nursing Care Quality*, 29(2), p. 99–102.

²⁶ Starmer, A.J. et al. (2014). Changes in Medical Errors after Implementation of a Handoff Program. *New England Journal of Medicine*, 371, p. 1803–1812. DOI: 10.1056/NEJMs1405556.

²⁷ Centers for Disease Control and Prevention. (2018, October 5). *Healthcare-Associated Infections*

An effective QAPI program that is engaged in continuous improvement efforts is essential to a provider's ability to deliver high quality and safe care to its patients, while reducing the incidence of medical errors and adverse events. Therefore, we believe the QAPI programs for REHs should conform to the current health care industry standards that require providers to proactively design quality improvement into each program at the outset, monitor data (indicators, measures and reports of staff/residents/families), determine root causes of problems, develop and implement plans that affect system improvement, and monitor the success of this systematic approach to improving quality.

At § 485.536, we propose to require that every REH develop, implement, and maintain an effective, ongoing, REH-wide, data-driven QAPI program. This requirement would ensure that the REH systematically reviews its operating systems and processes of care to identify and implement opportunities to deliver effective care to its patients focusing on improving health outcomes and preventing and reducing medical errors.

In the development of the proposed requirements for the REH QAPI program, we reviewed the CAH QAPI requirements at § 485.641, which we note are also closely aligned with the hospital QAPI requirements at § 482.21. We also took into account the comments on the REH RFI and input from other interested parties who requested that CMS consider the clinical and administrative limitations that rural providers experience and, where appropriate, we have proposed requirements that minimize burden while maintaining the ability of the REH to proactively maximize quality improvement activities and programs.

The proposed QAPI program contains the following five parts: (a) Program and scope; (b) Program data collection and analysis; (c) Program activities; (d) Executive responsibilities; and (e) Unified and integrated QAPI program for an REH in a multi-hospital system.

Similar to the program scope standard for hospitals at § 482.21(a)(1) and (2), at § 485.536(a)(1), we propose to require the REH to have an ongoing QAPI program that reflects improvement in quality indicators related to health outcomes and reductions in medical errors. In proposed paragraph § 485.536(a)(2) we would require REHs to measure, analyze, and track these quality indicators. At § 485.536(b), we propose to mirror the program data

collection and analysis standard for CAHs at § 485.641(b) and require that the REH's QAPI program incorporate quality indicator data including patient care data, quality measures data, and other relevant data in order to attain quality improvement.

Similar to the program activities standard for hospitals at § 482.21(c), at § 485.536(c)(1), we propose to require the REH to set priorities for its performance improvement activities and that these activities are focused on high-risk, high-volume, or problem-prone areas. We also propose to require the REH to consider the incidence, prevalence, and severity of problems in those identified areas and that the set priority areas affect health outcomes, patient safety, and quality of care. At § 485.536(c)(2) and (3), we propose to require the REH's performance improvement activities to track medical errors and adverse events, analyze their cause, and implement preventive actions. We would expect the REH to conduct analyses at regular intervals to track performance and ensure that improvements are sustained.

We propose at § 485.536(d), similar to the standard for executive responsibilities for hospitals at § 482.21(e) that the responsibilities for the REH's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the REH), medical staff, and administrative officials include ensuring that the QAPI program is implemented and maintained, properly evaluated, and appropriately resourced.

Lastly, consistent with the standard included at § 482.21(f) in the hospital CoPs for QAPI programs, we are proposing at § 485.536(e) to allow REHs that are part of a multi-facility system consisting of multiple separately certified hospitals, CAHs, and/or REHs to elect to have a unified and integrated QAPI program if in accordance with all applicable state and local laws. Specifically, we propose to specify that the system's governing body would be responsible and accountable for ensuring that each of its separately certified REHs met the proposed QAPI program requirements. We expect this allowance, if finalized, would be beneficial to REHs that may lack time, resources or staff to implement an REH-specific QAPI program. The REH would be able to benefit from the resources and expertise of a multi-hospital system in implementing their QAPI program, as well as potentially reducing the time and labor investments required to enact and maintain the program.

We are interested in input from the public regarding possible unintended

consequences that could occur as a result of allowing REHs to participate in a unified and integrated QAPI program. We are interested in feedback regarding how the integrated health system's governing body will ensure that they consider the REH's unique circumstances and any significant differences in patient populations and services offered at the REH. We also seek comments regarding how the integrated health system's governing body would ensure that an REH participating in a unified and integrated QAPI program provided the appropriate level of care to patients being treated in the REH, including being appropriately transferred to another facility when necessary.

19. Condition of Participation: Agreements (Proposed § 485.538)

Section 1861(kkk)(2)(C) of the Act, as added by the CAA, requires an REH to have in effect a transfer agreement with a level I or level II trauma center. In accordance with section 1861(kkk)(2)(C) of the Act, at § 485.538 we propose to require that REHs must have in effect an agreement with at least one Medicare-certified hospital that is a level I or level II trauma center for the referral and transfer of patients requiring emergency medical care beyond the capabilities of the REH. We would require that the level I or level II trauma center meets certain licensure requirements including being licensed as a hospital in a state that provides for the licensing of hospitals under state or applicable local law or approved by the agency of such state or locality responsible for licensing hospitals, as meeting standards established for licensing established by the agency of the state. It is also acceptable for the level I or II trauma center to be located in a state other than the state where the REH is located. In addition, we propose to require that the level I or level II trauma center must also be licensed or designated by the state or local government authority as level I or level II trauma center or is verified by the American College of Surgeons as a level I or level II trauma center.

We received several comments to the REH RFI regarding transfer agreements between REHs and hospitals that are not designated as a level I or II trauma center. Specifically, commenters stated that due to distance, or the possibility that level I or level II trauma centers may not have available beds, many rural CAHs currently transfer patients to level III or level IV trauma centers based on the patient's specific needs. Commenters requested that CMS allow these facilities to retain these

agreements, should they convert to REHs. We would expect REHs to comply with the CoP detailed at § 485.538 and to have a transfer agreement in place with a level I or II trauma center. However, we do not believe that the statute precludes an REH from also having a transfer agreement with a hospital that is not designated as a level I or II trauma center. An REH may have pre-existing relationships with hospitals that are not designated as level I or level II trauma centers. In these instances, the proposed requirement would not preclude them from maintaining those relationships and leveraging resources and capacity that may be available to deliver care that is beyond the scope of care delivered at the REH.

We note that section 125(b)(2) of the CAA also amended subparagraphs (I) and (N) of section 1866(a)(1) of the Act, to apply the Emergency Medical Treatment and Labor Act (EMTALA) requirements under section 1867 of the Act, to REHs. One commenter on the REH RFI recommended EMTALA waivers for REHs to divert patients to other hospitals if they require a higher level of care than the REH is able to provide. However, the statutory requirements for REHs do not allow an EMTALA waiver.

20. Condition of Participation: Medical Records (Proposed § 485.540)

The maintenance of a medical records system is a longstanding requirement in both the hospital and CAH CoPs. In the development of proposed requirements for medical records for REHs, we reviewed the CoPs for medical records for CAHs established at § 485.638, including the requirements finalized in the May 2020 final rule, “Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access” (85 FR 25510 through 25585), focused on electronic patient event notifications of a patient’s admission, discharge, and/or transfer to another health care facility or to another community provider. We also considered the comments from the REH RFI that encouraged CMS to closely align the CoPs for REHs with currently established requirements for CAHs. After reviewing the CoPs for medical records for CAHs at § 485.638, we believe that the requirements established for medical records for CAHs are also appropriate for REHs. We also would expect that many facilities that may elect to convert to an REH would presently have these systems in place, which may minimize administrative burden. Therefore, at § 485.540(a), we propose to require that

the REH must maintain a medical records system in accordance with written policies and procedures, that the records must be legible, complete, accurately documented, readily accessible, and systematically organized and that a designated member of the professional staff is responsible for maintaining the records. We also propose to require that for each patient receiving health care services, the REH maintains a record that includes, as applicable, identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient. We propose that the record requirements include reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings and all orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient’s progress, such as temperature graphics or progress notes describing the patient’s response to treatment. Lastly, we propose that the record include dated signatures of the doctor of medicine or osteopathy or other health care professional.

At § 485.540(b) and (c), we propose to require the REH to maintain the confidentiality of record information and to ensure records are retained for at least 5 years from date of last entry, and longer if required by state statute, or if the records may be needed in any pending proceeding.

Lastly, at § 485.540(d), we propose a standard for electronic notifications if the REH utilizes an electronic medical records system or other electronic administrative system that conforms with the content exchange standard at 45 CFR 170.205(d)(2). This requirement is intended to limit the applicability of this CoP to those REHs which currently possess an EHR or other electronic administrative system with the technical capacity to generate information for electronic patient event notifications. As discussed in the CMS Interoperability and Patient Access final rule (85 FR 25585), electronic patient event notifications can be an effective tool for improving care coordination across settings, especially for patients at discharge. We propose to require the REH to demonstrate that the system’s notification capacity is fully operational and sends notifications with at least specified patient information, as

appropriate, and facilitates the exchange of health information when the patient is registered, discharged, or transferred from the REH’s emergency department. Finally, we propose to require that the REH make a reasonable effort to ensure that the system sends the notifications to certain recipients including, the patient’s applicable post-acute care and primary care services providers.

21. Condition of Participation: Emergency Preparedness (Proposed § 485.542)

Over the past several years, the U.S. has been challenged by several natural and man-made disasters. As a result of the September 11, 2001 terrorist attacks, the subsequent anthrax attacks, the catastrophic hurricanes in the Gulf Coast states in 2005, flooding in the Midwestern states in 2008, tornadoes and floods in the spring of 2011, the 2009 H1N1 influenza pandemic, and Hurricane Sandy in 2012 and most recently, the COVID-19 pandemic, readiness for public health emergencies has been put on the national agenda. On September 16, 2016, we published a final rule, “Medicare and Medicaid Programs; Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers” (81 FR 63860), to establish emergency preparedness requirements for Medicare and Medicaid participating providers and suppliers to plan adequately for both natural and man-made disasters, and coordinate with Federal, state, tribal, regional, and local emergency preparedness systems. Disasters can disrupt the health care environment and change the demand for health care services. This makes it essential that health care providers and suppliers ensure that emergency management is integrated into their daily functions and values.

Thus, we are proposing emergency preparedness requirements to establish a comprehensive, consistent, flexible, and dynamic regulatory approach to emergency preparedness for REHs that aligns with the existing emergency preparedness standards for Medicare and Medicaid participating providers and suppliers. These proposed requirements mirror the existing CAH emergency preparedness requirements. The emergency preparedness requirements for all Medicare-participating providers and suppliers are consistent, with some differences based on the provider type (such as inpatient versus outpatient).

Consistent with the standards for all Medicare and Medicaid participating providers and suppliers, we propose to require REHs to comply with all

applicable Federal, state, and local emergency preparedness requirements. In addition, we propose to require that the REH establish and maintain an emergency preparedness program that addresses four core elements that we believe are central to an effective emergency preparedness system. The four elements are: (1) risk assessment and planning; (2) policies and procedures; (3) communication; and (4) training and testing.

At § 485.542(a), we propose to require that REHs develop and maintain an emergency preparedness plan that must be reviewed and updated at least every 2 years. Specifically, we propose to require that the REHs emergency plan must—(1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach, (2) Include strategies for addressing emergency events identified by the risk assessment, (3) Address the patient population, including, but not limited to, the type of services the REH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans, and (4) Include a process for cooperation and collaboration with local, tribal, regional, state, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

At § 485.542(b), we propose to require REHs to develop and implement policies and procedures, that are based on the emergency plan, risk assessment, and communication plan, and must be reviewed and updated at least every 2 years. Specifically, we propose to require that the policies and procedures must address the following:

- Provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, including, but not limited to food, water, medical and pharmaceutical supplies, other sources of energy to maintain temperatures, emergency lighting, fire detection and sewage and waste disposal;
- A system to track the location of on-duty staff and sheltered patients in the REH's care during an emergency, and if staff are being relocated the REH must document the specific name and location of the receiving facility or other location;
- Safe evacuation from the REH, to include consideration of care and treatment needs of the evacuees, staff responsibilities and transportation and identification of the evacuation location(s);

- A means to shelter in place for any patients, staff and volunteers that remain at the REH;

- A system of medical documentation that preserves patient information, protects confidentiality of all patient information and secures and maintains the availability of the records;

- The use of volunteers in an emergency and other staffing strategies, including the process and role for integration of state and federally designated health care professionals to address surge needs during an emergency; and

- The role of the REH under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

We believe that small and rural REHs would be able to develop an appropriate emergency preparedness plan and develop policies and procedures in accordance with our proposed requirements with the assistance of resources in their state and local community guidance.

At § 485.542(c), we propose to require REHs to develop and maintain an emergency preparedness communication plan that complies with both Federal and state law and must be reviewed and updated at least every 2 years. The communication plan must include the following:

- Names and contact information for staff, entities providing services under agreement, patients' physicians and volunteers;
- Contact information for Federal, state, tribal, regional, and local emergency preparedness staff and other sources of assistance;
- Primary and alternate means for communicating with the REH's staff and Federal, state, tribal, regional, and local emergency management agencies;
- A method for sharing information and medical documentation for patients under the REH's care, as necessary, with other health care providers to maintain the continuity of care;
- A means, in the event of an evacuation, to release patient information;
- A means of providing information about the general condition and location of patients under the facility's care; and
- A means of providing information about the REH's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

We would expect patient care to be well-coordinated within the REH, across healthcare providers, and with state and local public health departments and

emergency management agencies and systems to protect patient health and safety in the event of a disaster. The following link is to FEMA's comprehensive preparedness guide to develop and maintain emergency operations plans: https://www.fema.gov/sites/default/files/2020-05/CPG_101_V2_30NOV2010_FINAL_508.pdf. During an emergency, it is critical that REHs, have a system to contact appropriate staff, patients' treating physicians, and other necessary persons in a timely manner to ensure continuation of patient care functions throughout the facilities and to ensure that these functions are carried out in a safe and effective manner.

At § 485.542(d), we propose to require the REH to develop and maintain an emergency preparedness training and testing program that is based on the emergency plan, policies and procedures and communication plan, and reviewed and updated at least every 2 years. We propose to require at § 485.542(d)(1) that the training program include initial training in the emergency preparedness policies and procedures for new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles. We also propose to require the facility to provide emergency preparedness training at least every 2 years, maintain documentation of all emergency preparedness training, demonstrate staff knowledge of emergency procedures, and if the emergency preparedness policies and procedures are significantly updated, conduct training on the updated policies and procedures. The Homeland Security Exercise and Evaluation Program (HSEEP), developed by FEMA, includes a section on the establishment of a Training and Exercise Planning Workshop (TEPW). The TEPW section provides guidance to organizations in conducting an annual TEPW and developing a Multi-year Training and Exercise Plan (TEP) in line with the HSEEP (<https://www.fema.gov/sites/default/files/2020-04/Homeland-Security-Exercise-and-Evaluation-Program-Doctrine-2020-Revision-2-2-25.pdf>).

We propose at § 485.542(d)(2) to require that the REH conduct exercises to test the emergency plan at least annually. Specifically, we propose to require that the REH conduct two testing exercises, a full-scale or functional exercise and an additional exercise of its choice, every 2 years. First, the REH must participate in a full-scale exercise that is community-based. When a community-based exercise is not accessible, we propose that the REH

must conduct a facility-based functional exercise or if the REH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the REH is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event. Second, the REH must conduct an additional exercise, opposite the year the full-scale or functional exercise is conducted, that may include, but is not limited to a second full-scale exercise that is community-based, or an individual, facility-based functional exercise, a mock disaster drill, or a tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan. Lastly, we propose to require that the REH must analyze its response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the REH's emergency plan, as needed.

We propose at § 485.625(e)(1)(i) that REHs must store emergency fuel and associated equipment and systems as required by the 2000 edition of the Life Safety Code (LSC) of the NFPA®. In addition to the emergency power system inspection and testing requirements found in NFPA® 99 and NFPA® 110 and NFPA® 101, we proposed that REHs test their emergency and stand-by-power systems for a minimum of 4 continuous hours every 12 months at 100 percent of the power load the REH anticipates it will require during an emergency.

Finally, at § 485.542(f), we propose to specify that if an REH is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the REH may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, we propose that the unified and integrated emergency preparedness program must demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program and be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

In addition, we propose that each separately certified REH in the system must be capable of actively using the unified and integrated emergency

preparedness program and is in compliance. We also propose that the unified and integrated emergency preparedness program must include a unified and integrated emergency plan that is based on a documented community-based risk assessment, utilizing an all-hazards approach and a documented individual facility-based risk assessment for each separately certified REH within the health system, utilizing an all-hazards approach. Lastly, we propose that the unified and integrated emergency preparedness program must have integrated policies and procedures, a coordinated communication plan, and training and testing programs.

22. Condition of Participation: Physical Environment (Proposed § 485.544)

The LSC is a compilation of fire safety requirements for new and existing buildings, and is updated and published every 3 years by the National Fire Protection Association (NFPA), a private, nonprofit organization dedicated to reducing loss of life due to fire. The Medicare and Medicaid regulations have historically incorporated these requirements by reference, along with Secretarial waiver authority. The statutory basis for incorporating NFPA's LSC into the regulations we apply to Medicare and, as applicable, Medicaid providers and suppliers is the Secretary's facility-specific authority to stipulate health and safety regulations for each type of Medicare and (if applicable) Medicaid-participating facility. For REHs, that statutory authority is set out in new section 1861(kkk)(2)(D)(v) of the Act. The following provisions we have proposed are similar to the Hospital, CAH, and ASC LSC and Health Care Facilities Code requirements.

The 2012 Edition of the Life Safety Code

As stated previously, the LSC is a compilation of fire safety requirements for new and existing buildings, and is updated and published every 3 years by the NFPA. The NFPA 101®2012 edition of the LSC (including the technical interim amendments (TIAs)) provides minimum requirements, with due regard to function, for the design, operation and maintenance of buildings and structures for safety to life from fire. Its provisions also aid life safety in similar emergencies. The NFPA 99® 2012 edition of the Health Care Facilities Code (including the TIAs) provides minimum requirements for health care facilities for the installation, inspection, testing, maintenance, performance, and safe practices for facilities, material, equipment, and

appliances, including other hazards associated with the primary hazards.

We review each new edition of the NFPA 101 and NFPA 99 every 3 years to see if there are any significant provisions that we need to adopt, but there is no requirement to use the most recent version. We will continue to review these documents every 3 years to see if there are relevant or updated provisions that we need to adopt. The 2012 edition of the LSC includes provisions that we believe are vital to the health and safety of all patients and staff. Our intention is to ensure that patients and staff continue to experience the highest degree of fire safety possible. All Medicare and Medicaid participating providers and suppliers are currently subject to the requirements of the 2012 edition of the LSC and the 2012 edition of the Health Care Facilities Code as adopted by CMS.

Therefore, in this rule we propose to incorporate by reference the NFPA 101® 2012 edition of the LSC, issued August 11, 2011, and all Technical Interim Amendments issued (TIA) April 16, 2014; and the NFPA 99®2012 edition of the Health Care Facilities Code, issued August 11, 2011, and all TIA issued prior to April 16, 2014. (1) NFPA 101, LSC, 2012 edition, issued August 11, 2011; (i) TIA 12-1 to NFPA 101, issued August 11, 2011. (ii) TIA 12-2 to NFPA 101, issued October 30, 2012. (iii) TIA 12-3 to NFPA 101, issued October 22, 2013. (iv) TIA 12-4 to NFPA 101, issued October 22, 2013. (2) NFPA 99, Standards for Health Care Facilities Code of the NFPA 99, 2012 edition, issued August 11, 2011. (i) TIA 12-2 to NFPA 99, issued August 11, 2011. (ii) TIA 12-3 to NFPA 99, issued August 9, 2012. (iii) TIA 12-4 to NFPA 99, issued March 7, 2013. (iv) TIA 12-5 to NFPA 99, issued August 1, 2013. (v) TIA 12-6 to NFPA 99, issued March 3, 2014. The materials that are incorporated by reference are available to interested parties and can be inspected at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02169, www.nfpa.org, 1 (617) 770-3000. If any changes in this edition of the Code are incorporated by reference, CMS will publish a document in the **Federal Register** to announce the changes.

The 2012 Edition of the Health Care Facilities Code

The 2012 edition of the NFPA 99, "Health Care Facilities Code," addresses requirements for both health care occupancies and ambulatory care occupancies and serves as a resource for

those who are responsible for protecting health care facilities from fire and associated hazards. The purpose of this Code is to provide minimum requirements for the installation, inspection, testing, maintenance, performance, and safe practices for health care facility materials, equipment and appliances. This Code is a compilation of documents that have been developed over a 40-year period by NFPA, and is intended to be used by those persons involved in the design, construction, inspection, and operation of health care facilities, and in the design, manufacture, and testing of appliances and equipment used in patient care areas of health care facilities. It provides information on subjects, for example, medical gas and vacuum systems, electrical systems, electrical equipment, and gas equipment. The NFPA 99 applies specific requirements in accordance with the results of a risk-based assessment methodology. A risk-based approach allows for the application of requirements based upon the types of treatment and services being provided to patients or residents rather than the type of facility in which they are being performed. In order to ensure the minimum level of protection afforded by NFPA 99 is applicable to all patient and resident care areas within a health care facility, we are proposing to adopt the 2012 edition of NFPA 99, with the exception of chapters 7—Information Technology and Communications Systems for Health Care Facilities; 8—Plumbing; 12—Emergency Management; and 13—Security Management.

REH Proposed Requirements

At § 485.544(a) we propose that the REH be constructed, arranged, and maintained to ensure the safety of the patient and to provide facilities for diagnosis and treatment and for special hospital services appropriate to the needs of the community. Specifically, we propose that the condition of the physical plant and the overall REH environment must be developed and maintained in such a manner that the safety and well-being of patients are assured. This would include emergency power and lighting in at least all areas serviced by the emergency supply source, including but not limited to, the operating, recovery, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source the REH would be required to have battery lamps and flashlights available. In addition, we propose to require the REH to have facilities for emergency gas and water supply and a safe and sanitary environment, that is

properly constructed, equipped and maintained to protect the health and safety of all patients.

At § 485.544(b), we propose that the REH be required to maintain adequate facilities for its services that includes diagnostic and therapeutic facilities that are located in a manner that ensures the safety of patients. We also would require the REH to maintain facilities, supplies, and equipment in a manner that ensures an acceptable level of safety and quality. We propose further that the facility be designed and maintained to reflect the scope and complexity of the services it offers in accordance with accepted standards of practice and that there must be proper ventilation, light, and temperature controls in pharmaceutical, food preparation, and other appropriate areas.

At § 485.544(c), we propose that REHs meet the provisions applicable to Ambulatory Health Care Occupancies in the 2012 edition of the LSC, regardless of the number of patients the facility serves. We believe the protection provided in the Ambulatory Health Care Occupancies chapter is necessary to protect the health and safety of patients who are incapable of caring for themselves at any point in time. We propose at § 485.544(c)(2) to implement requirements related to the Secretary's waiver authority for periods deemed appropriate, which would result in unreasonable hardship, but only if the waiver will not adversely affect the health and safety of patients. We propose at § 485.544(c)(3) that the provisions of the LSC would not apply in a state if CMS finds that a fire and safety code imposed by state law adequately protects patients. We also propose at § 485.544(c)(4) requirements related to protection against inappropriate access for alcohol-based hand rub dispensers. At § 485.544(c)(5), we propose to require that a REH with a sprinkler system that is out of service for more than 10 hours in a 24-hour period to evacuate the building or portion of the building affected by the system outage, or establish a fire watch until the system is back in service, notwithstanding the lower standard of the 2012 LSC.

Lastly, at § 485.544(d) we propose to require REHs to comply with the 2012 edition of the NFPA 99. We propose that chapters 7, 8, 12, and 13 would not apply to REHs. We also propose to allow for waivers of these provisions under the same conditions and procedures that we currently use for waivers of applicable provisions of the LSC.

23. Condition of Participation: Skilled Nursing Facility Distinct Part Unit (Proposed § 485.546)

Section 1861(kkk)(2)(D)(vi) of the Act allows REHs to establish a unit that is a distinct part licensed as a SNF to furnish post-REH or post-hospital (in the event the services were provided at a hospital or a CAH) extended care services (or SNF services). A distinct part SNF is an area that is separately licensed and certified to provide SNF services at all times. A distinct part SNF 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 at 42 CFR part 483, subpart B. Medicare payment for SNF services furnished in these distinct part SNFs of an REH would be under the SNF prospective payment system as required under section 1834(x)(4) of the Act. We note that a distinct part SNF of an REH is not subject to the REH's length of stay limits of less than an annual per patient average of 24 hours.

According to a policy brief published by RUPRI Center for Rural Health Policy Analysis, there were 472 nursing home closures between 2008 and 2018 in nonmetropolitan counties in the U.S.²⁸ The policy brief noted that 10.1 percent of the country's nonmetropolitan counties had no nursing homes. Given the closures of rural nursing homes and the lack of nursing homes in rural communities, residents living in rural areas may not have adequate access to SNF services. The provision of these services in distinct part units of REHs may help address this access issue.

We highlight that a distinct part SNF unit is not the same as a CAH or hospital utilizing swing-beds. CAHs and hospitals may provide swing-bed services, allowing them to use their beds for acute inpatient care or for post-hospital or CAH SNF care. These facilities must be certified by CMS to provide swing-bed services. CAHs or hospitals utilizing swing-beds are not required to have their swing-beds in a special unit or area within the facility.

To implement that statutory provision allowing REHs to establish distinct part SNFs, we are proposing at § 485.546 to require REHs choosing to establish such a distinct part unit to meet the

²⁸ RUPRI Center for Rural Health Policy Analysis. (2021). Trends in Nursing Home Closures in Nonmetropolitan and Metropolitan Counties in the United States, 2008–2018. <https://rupri.public-health.uiowa.edu/publications/policybriefs/2021/Rural%20NH%20Closure.pdf>.

requirements for long-term care facilities at 42 CFR part 483, subpart B.

B. Proposed Changes for Critical Access Hospital Conditions of Participation

1. Condition of Participation: Status and Location (§ 485.610(c))

a. Adding the Definition of “Primary Roads”

Generally, a CAH must meet certain criteria for designation, as outlined in section 1820(c)(2)(B) of the Act. These criteria specify certain “distance requirements” relative to other hospitals or CAHs, and specifically require that a CAH be (1) “located 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 (2) “certified before January 1, 2006, by the State as being a necessary provider of health care services to residents in the area”. The current regulatory requirement at § 485.610(c) sets forth the distance requirements for CAHs relative to other CAHs and hospitals, and specific definitions as related to the distance requirements are found in the SOM, Chapter 2, Section 2256A.

In 2013, the HHS OIG released a report entitled *Most Critical Access Hospitals Would Not Meet the Location Requirements If Required to Re-Enroll in Medicare* (OEI-05-12-00080) which found that approximately 63 percent of CAHs would not meet the distance requirement if required to re-enroll in Medicare. The report also found that CMS does not have the authority to decertify most of these CAHs based on failure to meet the distance requirement, as a majority of these CAHs are “necessary provider” CAHs and therefore exempt from the distance requirement as noted in section 1820(h)(3) of the Act. The report also included a recommendation for CMS to ensure that CAHs’ compliance with the location-related CoPs is periodically reassessed. In response, CMS began evaluating its policies concerning the definitions of several key concepts used in enforcing the CAH regulations at § 485.610, which are further described in the SOM, Chapter 2, Section 2256A for enforcement of the distance requirements. The COVID-19 PHE put a hold on CAH certifications, and CMS has used this opportunity to work with interested parties to continue to review how it applies the distance requirements for CAH eligibility. In this proposed rule, CMS outlines how it will apply the CAH distance requirements as a result of its review. We recognize the impact of these criteria on rural communities and we aim to minimize

any disruption to CAHs based on these requirements.

The distance requirements are uniquely important to CAH designations, as they must continually be met to maintain status as a CAH, by statutory design. As such, CMS anticipates certain facilities may lose or gain eligibility for CAH designation depending on the locations of hospitals and CAHs established within relevant distance of the CAH. Thus, 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.

CMS publishes guidance related to the distance requirements in the SOM, Chapter 2, Section 2256A. One of the distance criteria, as described in section 1820(c)(2)(B)(i) of the Act and set forth in § 485.610(c), requires CMS to determine what constitutes a secondary road, and by extension a primary road. In 2015, CMS refined the definition of “primary road” in the SOM. The purpose of this refinement was, first, to make the definition of what constitutes a “primary road” more consistent across regions of the U.S., and, second, to make measuring the distances between facilities more consistent. It was not anticipated that this refinement in the definition of primary road would have any significant impact on the eligibility of existing CAHs to maintain their certification, but certain providers and interested parties raised concern in anticipation of their re-certification. Specifically, they were concerned about certain aspects of the 2015 refinements from the previous SOM update that would no longer afford them eligibility as a CAH, even though the existing CAH did not change location and there were no other CAHs or hospitals that moved within a relevant distance. Thus, CMS is further refining and codifying the definition to offer maximum flexibility to providers in meeting these distance criteria.

Presently, primary roads are defined as any U.S. highway, including; (1) any road in the National Highway System, as codified at 23 U.S.C. 103(b); or (2) in the Interstate System, as defined at 23 U.S.C. 103(c); or (3) 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. Currently, there is no regulatory language that references primary roads or outlines the definition of this term.

We propose to incorporate the definition of primary road in the CAH distance requirement regulations, both as part of the 35-mile drive requirement, and as applicable through the secondary roads definition for the 15-mile drive requirement. Specifically, we propose to revise § 485.610(c) to clarify that the location distance for a CAH is one for more than a 35-mile drive *on* primary roads (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH. In addition, at § 485.610(c)(2), we propose to specify that primary road of travel for determining the driving distance of a CAH and its proximity to other providers as a numbered Federal highway, including interstates, intrastates, expressways or any other numbered Federal highway; or a numbered state highway with two or more lanes each way. We are also soliciting comments regarding the description of a numbered Federal highway in this proposed definition. Specifically, we are interested in feedback on whether the definition of primary roads should include numbered Federal highways with two or more lanes, similar to the description of numbered state highways, and exclude numbered Federal highways with only one lane in each direction.

We believe that codifying the definition of primary roads in the regulations will provide clarity and consistency regarding the distance requirements.

Furthermore, if finalized, to support these proposed regulatory changes we are planning to establish a centralized, data-driven review procedure that focuses on hospitals being certified in proximity to a CAH, rather than focusing specifically on road classifications. CMS would review all hospitals and CAHs within a 50-mile radius of the CAH during each review of eligibility, and then subsequently on a 3-year cycle. Following the initial review of distance and location, further investigations would focus 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 with no new hospitals within 50 miles would be immediately recertified. Those CAHs with new hospitals within 50 miles will receive additional review

based on the distance from the new hospital and the definitions for Primary Roads and Mountainous Terrain. To facilitate this review, the CAH Distance Analysis Committee and the CMS Survey Operations Group (SOG) Locations will utilize the geocoding of hospitals to identify those CAHs that are located within 50 miles of another certified hospital. Those CAHs that do not meet the regulatory distance and location requirements at the time of review would be identified as non-compliant and may face enforcement actions. We believe this change would help surveyors to make evidence-based and objective determinations of continued CAH eligibility. We expect the new distance review procedure, coupled with regulatory clarity on the proposed primary roads definition, would provide greater consistency in evaluating if CAHs meet the statutory 35 or 15-mile distance requirements from other acute care hospitals and CAHs as well greater adherence to statutory language by ensuring that CAHs operate under the CAH designation until, or unless, a hospital moves within 35 miles or 15 miles of the existing CAH.

2. Condition of Participation: Patient's Rights (§ 485.614)

We believe that it is imperative for patients to have the ability to exercise certain rights and protections while seeking and receiving necessary care and services at a CAH. Ensuring that patients and family members are aware of their rights and how to exercise them are vital components of improving overall CAH quality and patient satisfaction. We believe that having patient's rights requirements for CAHs creates transparency between the provider and patient. In addition, adding patient's rights requirements for CAHs is consistent with other providers and suppliers similar to CAHs, including those proposed in this rule for REHs. As previously mentioned, behavioral health is very important in the treatment and safety of patients and staff. Behavioral health is a challenge in rural areas, due to the accessibility, affordability, acceptability and availability of these services, therefore we believe it is important to have policies and procedures in place for CAHs and REHs in the event of a mental health crisis and the need for the use of restraints and seclusions.

We have received feedback from interested parties stating that CAHs should have patient rights requirements in place to protect the patient. Therefore, we are mirroring these proposed requirements for CAHs after the hospital patient's rights

requirements found at § 482.13. However, we note that some of the provisions in this section for CAHs, and also for REHs (as discussed earlier) have requirements that are less prescriptive than those for hospitals because are proposing to allow for these providers to develop policies and procedures based on the scope of services they provide and patient populations they serve.

For example, we believe that CAHs will have a lower volume of patients than hospitals and the use of restraints and seclusion would not be as frequent as other providers. CAHs do not currently have any patient rights CoPs so our proposed requirements aim to increase accountability and provide patient protections in the event restraints and seclusion are used. We are specifically soliciting comments on the appropriateness of the patient's rights requirements proposed for restraint and seclusion, the potential need to require standards that are more stringent to address patient protections, and the feasibility of implementing such requirements in rural communities.

Specifically, we propose to establish a CoP for patient's rights at § 485.614 that would set forth the rights of all patients to receive care in a safe setting and provide protection for a patient's emotional health and safety as well as their physical safety. This would include proposed requirements for the CAH to inform patients of and exercise their rights; address privacy and safety; adhere to the confidentiality of patient records; responsibilities for the use of restraint and seclusion; and adherence to patient visitation rights.

Notice of Rights

At § 485.614(a), we propose that a CAH must inform each patient, or when appropriate, the patient's representative (as allowed under state law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible. This includes a proposal to require the CAH to establish a process for the oversight and prompt resolution of patient grievances and for informing each patient whom to contact to file a grievance.

Exercise of Rights

At § 485.614(b), we propose to specify those rights a patient has regarding their medical care, which includes the right to participate in the development and implementation of their plan of care, to make informed decisions regarding their care, to be fully informed about such care, and the right to request or refuse treatment, and finally the right to have a family member or representative of their choice and their own physician

notified promptly of their admission to the hospital. We note that this right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate. In addition, we propose to specify that the patient also has the right to formulate advance directives and to have CAH staff and practitioners who provide care in the CAH comply with these directives.

Privacy, Safety, and Confidentiality of Patient Records

At § 485.614(c), we propose to specify that the patient has the right to personal privacy, receive care in a safe setting, and be free from all forms of abuse or harassment. At § 485.614(d), we propose to specify that patients have the right to the confidentiality of their medical records and the right to access their medical records. When requested, we propose that the CAH must provide the patients with their records in a form and format requested by the requestor and within a reasonable timeframe, as not to frustrate the legitimate efforts of individuals to gain access to their own medical records.

Use of Restraints and Seclusion

At § 485.614(e), we propose those patient's rights relating to the use of restraints and seclusion. We are proposing requirements that are less burdensome than those existing restraint and seclusion requirements for hospitals because given the level of services provided by CAHs and their patient volume, we expect the likelihood of their need to utilize restraints and seclusion to be relatively low.

Specifically, we propose to specify that all patients have the right to be free from physical or mental abuse, and from corporal punishment and from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. We propose that restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time. We propose to define restraint as any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move their arms, legs, body, or head freely; or a drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition. A restraint does not include devices, such as orthopedically

prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, off of a stretcher, or out of a chair, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort). We propose to define seclusion as the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

At § 485.614(e)(2), we propose to require that the restraint or 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 at § 485.614(e)(3) 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. At § 485.614(e)(4) we propose that the CAH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice. These proposed requirements would allow for the CAH to use restraints and seclusion in the event that it is necessary and as a last resort to respond to immediate safety concerns, but lessens the burden and allows for more flexibility than the current hospital CoPs. We believe that allowing the CAH the flexibility to develop their own policies and procedures for restraints and seclusion based on the scope of services they provide is necessary given their patient volumes, populations, and access to resources. The policies and procedures that are developed need to be consistent with current standards of practice. As noted, we are soliciting comments on the appropriateness of the patient's rights requirements proposed for restraint and seclusion, the potential need to require standards that are more stringent to address patient protections, and the feasibility of implementing such requirements in rural communities.

Staff Training Requirements for the Use of Restraints or Seclusion

The following staff training requirements are not as prescriptive as the existing hospital requirements, and we are proposing these same requirements for REHs in this rule. At § 485.614(f) we propose to establish staff training requirements for the use of restraints and seclusion. Specifically,

we propose that the patient has the right to safe implementation of restraint or seclusion by trained staff. We propose that the CAH must provide competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the use of restraint and seclusion. To ensure that the use of restraint and seclusion for patients receiving services in a CAH is respectful of, and responsive to, individual patient preferences, needs and values, we propose to require that the training be patient-centered. Additionally, to ensure that staff are educated and trained on using the least restrictive intervention necessary for the safety of the patients and CAH staff, we propose at § 485.614(f)(2) to require that the CAH train their staff in alternatives to the use of restraint and seclusion. For example, we believe that staff should have trauma-informed knowledge competencies and be aware of effective de-escalation techniques that can be used to avoid the use of restraint and seclusion so not to trigger any previous mental health issues because of the use of restraints and seclusion. Trained peer workers (people who share similar experiences of being diagnosed with mental health conditions, substance use disorders, or both) and CHWs may also serve a useful role in assisting patients and other staff. This could include helping to monitor use of restraint and seclusion, deescalating interactions with patients and contributing to a positive and supportive environment for patients, family members, and CAH staff. CAHs are encouraged to consider the use of peer workers and CHWs in their staffing plans. For further information, please see the 2007 guidance on use of peers in the Medicaid program (<https://www.medicaid.gov/federal-policy-guidance/downloads/SMD081507A.pdf>) and resources from the Substance Abuse and Mental Health Services Administration (<https://www.samhsa.gov/brss-tacs/recovery-support-tools/peers>). In addition, facilities are encouraged to consider any nutritional needs while a patient is restrained, such as a need to provide food and water.

Death Reporting Requirements

The following requirements are similar to the hospital requirements at § 482.13. At § 485.614(g), we propose to establish requirements that CAHs must follow when reporting deaths associated with the use of seclusion or restraint. Specifically, we propose to require that the CAH must report to CMS, by

telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day the following information— (1) Each death that occurs while a patient is in restraint or seclusion; (2) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion; (3) Each death known to the CAH that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. We note that "reasonable to assume" in this context would include, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

For instances when no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the CAH staff must record in an internal log or other system, the following information—(1) Any death that occurs while a patient is in such restraints; (2) Any death that occurs within 24 hours after a patient has been removed from such restraints. Furthermore, we propose that staff must also document in the patient's medical record the date and time the death was reported to CMS or recorded in the internal log or other system. Also, for instances when no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), we propose to require that entries into the internal log or other system must be documented no later than seven days after the date of death of the patient, include the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es), and to be made available in either written or electronic form to CMS immediately upon request.

Patient Visitation Rights

We propose to redesignate § 485.635(f) as § 485.614(h). At § 485.614(h), we propose to establish requirements related to a patient's visitation rights. Specifically, we propose to require that a CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH

may need to place on such rights and the reasons for the clinical restriction or limitation. A CAH must inform each patient (or support person, where appropriate) of their visitation rights, including any clinical restriction or limitation on such rights, when they are informed of their other rights, inform each patient (or support person, where appropriate) of the right, subject to their consent, to receive the visitors whom they designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and their right to withdraw or deny such consent at any time, not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability, and ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

3. Condition of Participation: Staffing and Staff Responsibilities (§ 485.631)

Unified and Integrated Medical Staff for a CAH in a Multi-Facility System

In alignment the current standards for hospitals, we are proposing at § 485.631(e) to allow for either a unique medical staff for each CAH or for a unified and integrated medical staff shared by multiple hospitals, CAHs, and REHs within a health care system. We propose to hold a CAH responsible for showing that it actively addresses its use of a system unified and integrated medical staff model. We are also proposing to require that the medical staff members holding privileges at each separately certified CAH in the system have voted either to participate in a unified and integrated medical staff structure or to opt out of such a structure, and to maintain a CAH-specific separate and distinct medical staff for their respective CAH.

In addition, we propose to require that the unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified CAH (that is, all medical staff members who hold specific privileges to practice at that CAH) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their CAH. We propose that the unified

and integrated medical staff must be established in a manner that takes into account each CAH's unique circumstances, and any significant differences in patient populations and services offered in each CAH. Lastly, we propose that the unified and integrated medical staff give due consideration to the needs and concerns of members of the medical staff, regardless of practice or location, and the CAH has mechanisms in place to ensure that issues localized to particular CAHs are duly considered and addressed.

In proposing this allowance for CAHs in the requirements here, we considered this past rulemaking experience with those multi-hospital systems using the single governing body and unified and integrated medical staff model for separately certified hospitals within their systems, as well as our decision to also propose this flexibility for REHs (as discussed in section II.A.7. of this rule), and applied the same model to CAHs within single governing body systems. As we continue to do with hospitals, we believe that it is in the best interest of CAHs, medical staff members, and patients to propose this requirement allowing for the use of a unified and integrated medical staff for a multi-facility system and its member CAHs, in order to enable the medical staff of each CAH to voluntarily integrate itself into a larger system medical staff. We welcome comments on the proposed applicability of these changes for CAHs.

4. Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Programs (§ 485.640)

Unified and Integrated Infection Prevention and Control and Antibiotic Stewardship Programs for a CAH in a Multi-Facility System

Similar to a standard in the hospital CoPs, we propose a standard at § 485.649(h) for CAHs that would allow for the governing body of a CAH that is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a single system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, to elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities, including any CAHs, after determining that such a decision is in accordance with all applicable state and local laws. The system's single governing body would be responsible for ensuring that each of its separately certified CAHs meets all of the requirements of this section. We note that each separately certified CAH

subject to the system's single governing body would need to demonstrate that the unified and integrated infection prevention and control and antibiotic stewardship programs:

- Are established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each CAH;
- Establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified CAHs, regardless of practice or location, are given due consideration; and
- Have mechanisms in place to ensure that issues localized to particular CAHs are duly considered and addressed.

The CAH would also need to demonstrate that it has designated a qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship at the CAH to be responsible for:

- Communicating with the system's unified infection prevention and control and antibiotic stewardship programs;
- Implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs; and
- Providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to CAH staff.

5. Condition of Participation: Quality Assessment and Performance Improvement Program (§ 485.641)

Unified and Integrated QAPI Program for a CAH in a Multi-Facility System

Consistent with the standard included at § 482.21(f) in the hospital CoPs for QAPI programs, we are proposing at § 485.641(f) to allow CAHs that are part of a multi-facility system consisting of multiple separately certified hospitals, CAHs, and/or REHs to elect to have a unified and integrated QAPI program after determining that such a decision is in accordance with all applicable state and local laws. Specifically, we propose to specify that the system's governing body is responsible and accountable for ensuring that each of its separately certified CAHs meets the proposed QAPI program requirements. We expect this allowance, if finalized, would be beneficial to CAHs that may lack time, resources, or staff to implement a QAPI program. The CAH would be able to

benefit from the resources and expertise of a multi-hospital system in implementing their QAPI program, as well as potentially reducing the time and labor investments required to enact and maintain the program.

We are interested in input from the public regarding unintended consequences that could occur as a result of allowing CAHs to participate in a unified and integrated QAPI program. We are interested in feedback regarding how the integrated health system's governing body will ensure that they take into account the CAH's unique circumstances and any significant differences in patient populations and services offered at the CAH. We also seek comments regarding how the integrated health system's governing body will ensure that a CAH participating in a unified and integrated QAPI program provides the appropriate level of care to patients being treated in the CAH, including being appropriately transferred to another facility when necessary.

C. Conforming Amendments and Technical Corrections

1. Technical Correction to § 485.635(b)(2)

We are proposing to make a technical correction to the laboratory services CAH CoP at § 485.635(b)(2). In the September 1, 1994, final rule entitled "Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1995 Rates" (59 FR 45403), we revised the CAH laboratory services requirement to require the CAH laboratory services to meet the standards imposed under section 353 of the Public Health Service Act (42 U.S.C. 236a). We inadvertently included an error in the referenced Public Health Service Act standard. The referenced standard at § 485.635(b)(2) should read, ". . . 353 of the Public Health Service Act (42 U.S.C. 263a)."

2. Conforming Amendments §§ 489.2(b) and 489.24(b)

The provider agreement and supplier approval requirements for Medicare-participating providers and suppliers are located at 42 CFR part 489. Section 489.2 sets forth the basic requirements for submittal and acceptance of a provider agreement under Medicare, with the providers that are subject to the provisions of this part listed at § 489.2(b). We are proposing to add REHs to the list of applicable providers at § 489.2(b) and therefore require REHs to adhere to the requirements for submittal and acceptance of provider

agreements under Medicare as defined by § 489.3.

The requirements at 42 CFR part 489 also set forth requirements for Medicare hospitals in emergency cases. These provisions apply to hospitals that have emergency departments. Under this section, a hospital includes a critical access hospital as defined in section 1861(mm)(1) of the Act. The CAA amends Section 1867(e)(5) of the Act by including REHs, as defined in 1861(kkk)(2), as hospitals that have emergency departments. As a result, we are proposing to add REHs to the definitions at § 489.24(b) for Medicare hospitals in emergency cases under the hospital definition and to the definition of a participation hospital.

III. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement (ICR) is submitted to the Office of Management and Budget (OMB) for review and approval.

In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs):

A. Factors Influencing ICR Burden Estimates

Under this proposed rule, an REH's ICR may differ from that of a hospital or CAH, given that REHs would be providers of outpatient services and would not provide inpatient services. We based the ICRs for REHs on the ICRs for hospitals and CAHs in some cases because, in accordance with section 1861(kkk) of the Act, REHs must convert from either a rural hospital with not more than 50 beds or a CAH. In the discussion that follows, we rely heavily on the study of the North Carolina Rural Health Research Program's (NC RHRP's)

study titled, "How Many Hospitals Might Convert to a Rural Emergency Hospital (REH)?"²⁹ This study examined data on existing rural hospitals (Medicare-funded through both the prospective payment system and cost-reimbursements to CAHs) to determine how many might meet three key criteria (1) three years of negative total financial margins; (2) average daily census of acute and swing beds of less than three persons; and (3) net patient revenue of less than \$20 million annually. The study further assumed that all the statutory and regulatory requirements would be met by every REH. The NC RHRP study assumes that hospitals and CAHs meeting the necessary requirements would apply for election of coverage under the new REH program. The study did not address the potential caseload, cost, or revenue changes from electing conversion and implicitly assumed that the net effects would be positive.

We note that another study from consulting firm CLA also examines the number of facilities likely to convert to REHs titled, "A Path Forward: CLA's Simulations on Rural Emergency Hospital Designation."³⁰ The CLA study estimated that between 11 and 600 CAHs would benefit from conversion to REH status—based on estimated REH reimbursement and several financial assumptions (estimated average facility payment, estimated outpatient fee schedule payment, estimated average skilled nursing facility payment rates by state, presence or loss of swing bed payments, and continuance or cessation of 340B eligibility) and four simulation methods. A key takeaway from both studies is that available data support a possible wide range of conversion decisions. In addition, we note that these results and the calculations on which they rely are subject to a wide range of uncertainty as illustratively shown in the CLA study's summary estimate and the NC RHRP study makes the same point in describing its central estimate set of results. In the analysis that follows, we use for simplicity of exposition the NC RHRP study results, which depend on data and calculations presented in the study at a level of detail that allows reader analysis and present our

²⁹ This study can be accessed here: <https://www.shepscenter.unc.edu/product/how-many-hospitals-might-convert-to-a-rural-emergency-hospital-reh/>.

³⁰ CLA, "A Path Forward: CLA's Simulations on Rural Emergency Hospital Designation", 2/8/22, at <https://www.claconnect.com/resources/articles/2022/a-path-forward-clas-simulations-on-rural-emergency-hospital-designation>.

summary estimates based on the NC RHRP study’s central estimate.

In total, the NC RHRP study estimated that there are 1,673 hospitals (mostly CAHs) eligible to convert to an REH and of these, 68 would convert to REH status. The reasons why some would convert are presented in the NC RHRP study and include low levels of inpatient revenue, low levels of swing bed nursing care revenue, and negative financial margins over a period of years.

The finances of individual rural hospitals and CAHs vary widely, as do the local economic and demographic circumstances of the communities served by these facilities (for example some rural areas are gaining population even as most face declining populations). Competition from other hospitals either in the rural area or in nearby cities also varies widely, with the only certainty in forecasting REH

conversion is that seemingly similar hospitals and CAHs will make widely different decisions. What the NC RHRP did, in essence, was predict that the hospitals and CAHs facing the most severe financial difficulties would be the most likely to convert.

For purposes of our analysis, we use the NC RHRP estimate of 68 conversions though acknowledge that the number of conversions could be less than or significantly greater than this estimate. In addition, when considering the PRA burden for REHs, given that the proposed CoPs align closely with existing standards, we considered both the existing burden estimates for CAHs and hospitals, as well as our ongoing experience with these provider types. We also considered that REHs would only be furnishing outpatient services, which would lessen their burden. We request comments on our estimates,

particularly the conversion assumption. The final rule could utilize different estimates based on these comments.

B. Sources of Data Used in Estimates of Burden Hours and Cost Estimates

For the estimated costs contained in the analysis below, we used data from the U.S. Bureau of Labor Statistics (BLS) to determine the mean hourly wage for the positions used in this analysis.³¹ For the total hourly cost, we doubled the mean hourly wage for a 100 percent increase to cover overhead and fringe benefits, according to standard HHS estimating procedures. If the total cost after doubling resulted in 0.50 or more, the cost was rounded up to the next dollar. If it was 0.49 or below, the total cost was rounded down to the next dollar. The total costs used in this analysis are indicated in Table 1.

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TABLE 1: Summary Information of Estimated Mean Hourly and Adjusted Hourly Wages

Occupation Code	BLS Occupation Title	Associated Position Title in this Regulation	Mean Hourly Wage (\$/hour)	Adjusted Hourly Wage (with 100% markup for fringe benefits & overhead) (\$/hour) (rounded to nearest dollar)
29-1228	Physicians, All Others; and Ophthalmologist, except Pediatric) (General Medical and Surgical Hospitals)	Physician	\$105.22	\$210
29-1141	Registered Nurses	Registered Nurse, Clinical Trainer	\$39.27	\$79
11-9111	Medical and Health Services Managers (General Medical and Surgical Hospitals)	Administrator, Medical director, Director of nursing	\$61.22	\$122
29-1071	Physician Assistants	Physician Assistant	\$55.34	\$111
29-1171	Nurse Practitioners	Nurse Practitioner	\$53.51	\$107
43-6013	Medical Secretaries and Administrative Assistants	Clerical Staff	\$18.75	\$38
11-3010	Administrative Services and Facilities Managers	Facilities Director	\$51.98	\$104
29-1000	Healthcare Diagnosing or Treating Practitioners	Mid-Level Practitioner	\$50.58	\$101

³¹ BLS. *May 2020 National Occupational Employment and Wage Estimates United States.*

United States Department of Labor. Accessed at

https://www.bls.gov/oes/current/oes_nat.htm. Accessed on August 25, 2021.

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C. Rural Emergency Hospitals

1. ICRs Regarding Condition of Participation: Provision of Services (§ 485.514)

Proposed § 485.514(a) would require REHs to furnish health care services in accordance with appropriate written policies that are consistent with applicable state law. In addition, proposed § 485.514(b) would require REHs to develop the policies with the advice of members of the REH's professional health care staff, while § 485.514(d) would require REHs to conduct a biennial review of all its policies and procedures. We have not designated any specific process or format for REHs to use in developing their policies or conducting a review of their policies because we believe they need the flexibility to determine how best to accomplish these tasks.

In accordance with the section 1861(kkk)(3) of the Act, REHs must have been either a CAH or a rural hospital with not more than 50 beds as of the date of enactment of the CAA, December 27, 2020, to convert to an REH. We estimate that 68 facilities will convert to an REH and we believe that they will be developing REH-specific policies that are based on policies that were utilized when the facility was a rural hospital or CAH. As a result, we estimate that it would take an REH approximately 80 hours for administrative and clinical staff to develop policies. If there are 68 REHs to comply with the policy development requirement and each REH uses 80 hours to comply: (16 hours for a physician + 16 hours for an administrator + 16 hours for a mid-level practitioner + 16 hours for a nurse + 16 hours for a clerical staff person), then the burden hours are 5,440 (68 REHs × 80 hours). The cost is \$8,800 per REH (\$3,360 for a physician (16 hours × \$210) + \$1,952 for an administrator (16 hours × \$122) + \$1,616 for a mid-level practitioner (16 hours × \$101) + \$1,264 for a nurse (16 hours × \$79) + \$608 for a clerical staff person (16 hours × \$38)). The total cost is 598,400 (68 REHs × \$8,800). We estimate that it would take an REH's professional personnel 16 hours to review and make changes to policies and procedures biennially. Therefore, for all 68 REHs to comply with the policy review requirement it would require an estimated 16 burden hours biennially, or 8 hours annually (1.5 hours for a physician + 2 hours for an administrator + 1.5 hours for a mid-level practitioner + 1.5 hours for a nurse + 1.5 hours for a clerical staff person). The burden hours are 544 (8 hours × 68

REHs). The cost per REH is \$886 (\$315 for a physician (1.5 hours × \$210) + \$244 for an administrator (2 hours × \$122) + \$151.50 for a mid-level practitioner (1.5 hours × \$101) + \$118.50 for a nurse (1.5 hours × \$79) + \$57 for a clerical staff person (1.5 hours × \$38)). The total cost is \$60,248 (\$886 × 68 REHs). Therefore, the total cost for each REH to comply with these requirements would be \$658,648 annually and 5,984 burden hours.

2. ICRs Regarding Condition of Participation: Infection Prevention and Control and Antibiotic Stewardship Programs (§ 485.526)

COVID-19 and Seasonal Influenza Reporting

Consistent with the recent changes we made to the hospital and CAH infection control CoPs related to COVID-19 and the declared public health emergency (PHE), we are proposing to require REHs, after the conclusion of the current COVID-19 PHE, to report COVID-19 and seasonal influenza-related reporting. The proposed requirements would apply upon conclusion of the COVID-19 PHE and would continue until April 30, 2024, unless the Secretary establishes an earlier ending date. The proposed data elements align closely with those COVID-19 reporting requirements for long-term care (LTC) facilities that were finalized on November 9, 2021 (86 FR 62421), and are representative of the guidance provided to hospitals and CAHs for reporting. Therefore, we do not expect that these categories of data elements would require REHs to report any information beyond that which they have already been reporting as existing rural hospitals or CAHs. Furthermore, similar to the requirements for LTC facilities, this proposal would also allow for the scope and frequency of data collection to be reduced and limited responsive to the evolving clinical and epidemiological circumstances.

Based on our experience with those existing hospitals and CAHs and the current COVID-19 and related reporting requirements, we believe that this will primarily be the responsibility of a registered nurse and we have used this position in this analysis at an average hourly salary of \$79. According to the most recent COVID-19 hospital reporting guidance (available at <https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf>), hospitals are reporting COVID-19 and influenza-related data on a daily basis, with backdating permitted for weekends and holidays, except psychiatric and

rehabilitation hospitals who report weekly. Some data element reporting fields are inactive for data collection, and therefore, hospitals can optionally report data for these fields. The inactive fields and active fields together reflect what is listed in this proposed rule for COVID-19 and influenza-related reporting as well as future reporting in the event of a declared PHE, which we discuss next. We do not expect, nor have we proposed, daily reporting for COVID-19 or influenza outside of a declared PHE.

If we were to assume a weekly reporting frequency, we would anticipate that there are reduced cases and fewer data elements (with no line level patient data) being reported. Based on these assumptions, we estimate that total annual burden hours for REHs to comply with these requirements would be 5,304 hours based on weekly reporting of the required information by 68 REHs × 52 weeks per year and at an average weekly response time of 1.5 hours for a registered nurse with an average hourly salary of \$79. Therefore, the estimate for total annual costs for all hospitals and CAHs to comply with the required reporting provisions weekly would be \$419,016 or approximately \$6,162 per facility annually. We acknowledge that the data elements and reporting frequency could increase or decrease over the next two years, and those changes would impact this burden estimate.

We note that this estimate is assumed to be a one-day snapshot of reporting information as opposed to a cumulative weekly report accounting for information based on each day of that week. If we assumed a cumulative weekly account, we can assume reduced burden related to the actual reporting time, but anticipate that the estimate would be slightly higher to account for the need to track closely to daily reporting. We also acknowledge that respondents may have to track and invest in infrastructure in order to timely and accurately report on the specified frequency. Thus, respondents may face ongoing burdens associated with this collection even in the case of reduced frequency of submissions. We solicit comment on this potentiality.

Furthermore, we note that this estimate likely overestimates the costs associated with reporting because it assumes that all REHs will report manually. Efforts are underway to automate reporting that have the potential to significantly decrease reporting burden and improve reliability.

Future Reporting in the Event of a Future PHE Declaration

In addition, we are proposing to establish reporting requirements for future PHEs related to epidemics and pandemics by requiring REHs to electronically report information on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection), SARS-CoV-2/COVID-19, and other viral and bacterial pathogens or infectious diseases of pandemic or epidemic potential only when the Secretary has declared a PHE directly related to such specific pathogens and infectious diseases. Specifically, when the Secretary has declared a PHE, we propose to require REHs to report specific data elements to the CDC's National Health Safety Network (NHSN), or other CDC-supported surveillance systems, as determined by the Secretary. The proposed requirements of this section would apply to local, state, and national PHEs as declared by the Secretary. Relevant to the declared PHE, the categories of data elements that this report would include are as follows: suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff; total deaths attributed to the relevant infectious disease pathogen among patients and staff; personal protective equipment and other relevant supplies in the facility; capacity and supplies in the facility relevant to the immediate and long term treatment of the relevant infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies; total REH bed and intensive care unit bed census, capacity, and capability; staffing shortages; vaccine administration status of patients and staff for conditions monitored under this section and where a specific vaccine is applicable; relevant therapeutic inventories and/or usage; isolation capacity, including airborne isolation capacity; and key comorbidities and/or exposure risk factors of patients being treated for the pathogen or disease of interest in this section that are captured with interoperable data standards and elements.

We are also proposing to require that, unless the Secretary specifies an alternative format by which a REH must report each applicable infection (confirmed and suspected) and the applicable vaccination data in a format that provides person-level information, to include medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant

comorbidities for affected patients, unless the Secretary specifies an alternative format by which the REH would be required report these data elements. We are also proposing in this provision to limit any person-level, directly or potentially individually identifiable, information for affected patients and staff to items outlined in this section or otherwise specified by the Secretary. We note that the provided information obtained in this surveillance system that would permit identification of any individual or institution is collected with a guarantee that it will be held in strict confidence, will be used only for the purposes stated, and will not otherwise be disclosed or released without the consent of the individual, or the institution in accordance with sections 304, 306, and 308(d) of the Public Health Service Act (42 U.S.C. 242b, 242k, and 242m(d)). Lastly, we are proposing that a REH would provide the information specified on a daily basis, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's National Healthcare Safety Network (NHSN) or other CDC-supported surveillance systems as determined by the Secretary.

For purposes of this burden collection, we acknowledge the unknown and the ongoing burdens that may exist even if CMS is not collecting information outside of a declared PHE. We recognize that considerations such as building and maintaining the infrastructure to support readiness are necessary to ensure compliance with this requirement. Therefore, we are soliciting comment on the burden associated with these proposed requirements given the intended flexibility provided in reducing or limiting the scope and frequency of reporting based on the state of the PHE and ongoing circumstances. We are specifically asking for comment on the potential burden associated with the proposed reporting requirements as they might relate to any differences in the public health response to one specific pathogen or infectious disease versus another that would be directly related to the declared PHE. We are also interested in public comments addressing burden estimates (and the potential differences in those estimates) for variations in the required reporting response for a local PHE versus a regional PHE versus a national PHE that might be declared by the Secretary based on the specific circumstances at the time of the declaration.

CMS will pursue an emergency collection of information in the case of a declared PHE and use such burden

estimate to inform its approach at that time. CMS will also publish an accompanying **Federal Register** Notice concurrent with its submission of a request to collect information, in addition to all other actions consistent with 5 CFR 1320.13. CMS commits to ensuring that respondents are well aware in advance of the intention to collect such information and solicits comment on the appropriate timeline and notification process for such actions.

3. ICRs Regarding Condition of Participation: Staffing and Staff Responsibilities (§ 485.528)

We proposed that the emergency department of the REH be staffed 24 hours a day, 7 days a week, and we propose this requirement at § 485.6528(a) and that a doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant must be available to furnish services in the REH in the facility 24 hours a day. The burden associated with this requirement is the time it takes to review the REH's written policies and make appropriate changes or updates regarding its staffing and staff responsibilities for the services it furnishes. In conjunction with a mid-level practitioner, the physician develops, executes, and periodically reviews the REH's written policies governing the services it furnishes. We estimate that it will take the physician and mid-level practitioner 1 hour each to review the REH written policies and make the appropriate changes. We also estimate that a REH will utilize the services of one clerical person for half an hour to process any changes or updates, for a total of 2.5 burden hours and an estimated cost per REH of \$ 330 ((1 hour × \$210 for a physician) + (1 hour × \$101 for a mid-level practitioner) + (0.5 hours × \$38 for clerical staff)). Therefore, the burden associated with this requirement is an estimated 170 burden hours (2.5 hours × 68 REHs) at an estimated cost of \$22,440 (\$330 × 68 REHs).

4. ICRs Regarding Condition of Participation: Patient's Rights (§ 485.534) Standard: Notice of Rights: § 485.534(a)(1) and (2)

Proposed § 485.534(a) would require REHs to notify a patient of their rights and of whom to contact to file a grievance. We allow REHs the flexibility to use different approaches to meet this CoP. We have set forth general elements that should be common to all grievance processes, but have not delineated strategies and policies for implementing this system. We believe that in large

measure, REHs would be able to use existing systems for providing patients with information and handling complaints, and the elements listed in the regulation only serve to give basic assurance that these systems are responsive to patient grievances and act effectively. A less specific approach would permit a nominal, non-functional system that in essence did not serve the very purpose intended by the regulation. Costs associated with formalizing a process and modifying any existing notices or processes will most likely be partially offset by a reduction in patient-initiated lawsuits regarding care, and should provide a valuable tool for targeting internal quality assurance mechanisms.

We asked that the patient be provided with written notice containing a contact person's name, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion. Steps taken on behalf of the patient need not include a detailed description of who was spoken to and when. It might merely be that the appropriate staff were interviewed and that records were reviewed to investigate the grievance, and that the investigation found the grievance to be either unsubstantiated or substantiated. Second, the figures represented are estimates. We know of no existing system that tracks how many complaints are lodged in aggregate in hospitals or CAHs each year; however, for REHs, we believe that the grievance response can largely rely on standardized language with only relevant information filled in, or could be created in a check-sheet format, or in many other ways.

Thus, the burden associated with this requirement is the time and effort necessary to modify any existing notices to include the proposed grievance process requirements. We believe that an office assistant may be tasked with drafting or updating the notices and distributing or posting, as appropriate, the information. We estimate that this would require no more than two hours of the clerical staff time. Based on this we estimate that this will create a one-time cost of \$5,168 (68 REHs \times 2 hours \times \$38 clerical staff hourly wage). In addition, we estimate that it will require the office assistant 2 minutes (.0333 hours) to provide the notice per REH patient on an annual basis. The number of notices required will depend on the number of patients received at the REH. Therefore, the per facility burden associated with providing the notice will vary based on the unique factors of the REH. According to an OIG report,

there were 2,316,675 outpatient visits in 2011 at CAHs.³² Based on this estimate, we assume that the REH will have an average of 1,743 outpatient/emergency department visits per year that would require informing each patient of their rights which would take 58 hours (.0333 hours \times 1,743 notices). The cost is \$149,872 (\$38 clerical staff wage \times 58 hours \times 68 REHs).

In its resolution of a grievance, a REH must provide the patient with written notice of its decision that contains the name of the REH contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

The burden associated with this requirement is the time and effort necessary to disclose the written notice to each patient who filed a grievance. We estimate that on average it will take each REH 15 minutes to develop and disseminate the required notice and estimate that an REH may have to provide 50 notices on an annual basis for a total annual burden. The burden hours would be 13 hours (0.25 hours \times 50 notices). The total burden hours would be 884 hours (13 hours \times 68 REHs) at the cost of \$33,592 (\$38 \times 884 hours). Therefore, the total burden associated with this requirement is \$188,632 (\$5,168 to update notices, \$149,872 to provide the notices, and \$33,592 to provide the results of a grievance investigation).

Standard: Confidentiality of Patient Records (§ 485.534(d))

Proposed § 485.534(d), which sets forth the patient's right to access information in their records, will involve minimal burden as many states' existing laws cover this point. We have not proposed to require disclosure of all records, inasmuch as we recognize that there are situations where such a release could be harmful to the patient or another individual. Furthermore, we have not taken a prescriptive approach in specifying how quickly this information must be provided to the patient, or by setting a rate that the REH can charge. In the absence of state law, the REH should charge whatever is reasonable and customary in its community for duplication services (based on rates at local commercial copy centers, post offices, or other venues in which one could make photocopies). Therefore, while this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA, as defined in

³² <https://oig.hhs.gov/oei/reports/oei-05-12-00081.pdf>.

5 CFR 1320.3(b)(2) and (3) because this requirement is considered standard industry practice and/or is required under state or local law.

Standard: Restraint and Seclusion (§ 485.534(e))

Section 485.534(e) requires that REH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice. While the requirement is subject to the PRA, we believe the associated burden is exempt in accordance with 5 CFR 1320.3(b)(2) because the time, and effort, and financial resources necessary to comply with this requirement would be incurred by persons in the normal course of their activities. These are reasonable and customary state practices based on current standards of practice and the state would impose this standard for efficient utilization of Medicare or Medicaid services in the absence of a Federal requirement. However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden on those providers eligible to convert to an REH.

Standard: Restraint and Seclusion: Staff Training Requirements (§ 485.534(f))

Section 485.534(f) requires facilities to establish staff training requirements for the use of restraints and seclusion. The REH must provide competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the use of restraint and seclusion. While these information collection requirements are subject to the PRA, we believe the burden associated with them are exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities. However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden on those providers eligible to convert to an REH.

Standard: Death Reporting Requirements (§ 485.534(g))

Section 485.534(g) requires the facility to report the death of a resident associated with restraint or seclusion to the CMS regional office. A report must include the name of the resident involved in the serious occurrence, a description of the occurrence, and the name, street address, and telephone number of the facility.

We estimate it will take 5 minutes to report each death to the CMS regional office and to document that report. We estimate fewer than 10 deaths annually for all 68 facilities. Five (5) minutes \times 10 deaths annually would equate to a national burden of 50 minutes per year.

The hourly adjusted rate for a Medical and Health Service Manager responsible for notifying the CMS regional office of a death a documenting the report is \$122/hour. Multiplying the total burden of 0.83 hours by the hourly wage yields an associated cost of about \$101.67.

Standard: Patient Visitation Rights (§ 485.534(h))

Section 485.534(h) requires a REH to have written policies and procedures regarding the visitation rights of patients, including any clinically necessary or reasonable restriction or limitation that the REH may need to place on such rights and the reasons for the clinical restriction or limitation. Specifically, the written policies and procedures must contain the information listed in § 485.534(h)(1) through (4). Given that the statute requires a REH to have been either a CAH or rural hospital as of the date of enactment of the CAA, we expect these facilities to already have a visitation policy in accordance with the CAH and hospital CoPs at §§ 485.635(f) and 482.13(h), respectively. Therefore, the ICR burden associated with this requirement would be the time and effort necessary for a REH to review and make any necessary updates given its conversion to an REH and to distribute that information to patients. We expect that an office secretary or other clerical staff would update and distribute, or post as appropriate, the information and could accomplish this task in 15 minutes for an estimated one-time burden total of 17 hours (0.25 hours \times 68 REHs) and at the cost of \$646 (\$38 \times 17 hours).

5. ICRs Regarding Condition of Participation: Transfer Agreements (Proposed § 485.538)

At § 485.538, we propose that each REH must have a transfer agreement in effect with at least one certified hospital that is a level I or level II trauma center for the referral and transfer of patients requiring emergency medical care beyond the capabilities of the REH. We estimate that it would require an REH administrator and a clerical person 2 hours each to develop the initial agreement and obtain the appropriate approvals. According to Table 1, the REH administrator's total hourly cost is \$122 per hour. The clerical staff person's total hourly cost is \$38. We

estimate that for each REH to comply with the requirements in this section it would require 4 burden hours which would be a total of 272 hours (4 hours \times 68 REHs). The cost is \$320 (\$244 (2 hours \times \$122 for an administrator) + \$76 (2 hours \times \$38 for a clerical staff person)) for each REH. The total cost is \$21,760 (\$320 \times 68 REHs). This is a one-time cost.

6. ICRs Regarding Condition of Participation: Medical Records (Proposed § 485.540)

There is no burden attributed to this task. The REH's health care services are furnished in accordance with appropriate written policies that are consistent with applicable state law. The policies include a description of the services the REH furnishes directly and those furnished through agreement or arrangement; policies and procedures for emergency medical services and guidelines for medical management of health problems that include the conditions requiring medical consultation and/or patient referral and the maintenance of health care records.

We are not including burden associated with certain patient related activities such as health care plans, patient records, medical records, etc., because prudent institutions already incur this burden in the course of doing everyday business. As stated in 5 CFR 1320.3(b)(2), the burden associated with usual and customary business practices is exempt from the PRA. However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden on those providers eligible to convert to an REH. Further, state laws require providers to maintain patient records. (For example, the annotated Code of Maryland (§ 10.11.03.13) requires a provider to be responsible for maintaining patient records for services that it provides.) State law requires record information that should include: documentation of personal interviews; diagnosis and treatment recommendations; records of professional visits and consultations; and consultant notes which shall be appropriately initialed or signed.

7. ICRs Regarding Condition of Participation: Quality Assessment and Performance Improvement Program (QAPI) (Proposed § 485.536)

At proposed § 485.536, we require REHs to develop, implement, and maintain an effective, ongoing, REH-wide, data-driven quality assessment and performance improvement (QAPI) program. The REH's governing body must ensure that the program reflects

the complexity of the REH's organization and services; involves all REH departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The REH must maintain and demonstrate evidence of its QAPI program for review by CMS. In addition, REHs must comply with all of the requirements set forth in proposed § 485.536(a) through (e). We believe that the REH QAPI leadership (consisting of a physician, and/or administrator, mid-level practitioner, and a nurse) would need to have at least one and potentially two meetings to ensure that the current QAPI program that the provider has established is in accordance with the proposed requirements at § 485.536. The first meeting would be to discuss the current QAPI program and what, if anything, needs to be revised based on the proposed QAPI requirements at § 485.536. The second meeting, if needed, would be to discuss strategies to update the current policies, and then to discuss the process for incorporating those changes. We believe that these meetings would take approximately 2 hours each. We estimate that the physician would have a limited amount of time, approximately 1 hour to devote to the QAPI activities. Additionally, we estimate these activities would require 4 hours of an administrator's time, 4 hours of a mid-level practitioner's time, 8 hours of a nurse's time, and 2 hours of a clerical staff person's time for a total of 19 burden hours. We believe that the REH's QAPI leadership would need to meet periodically to review and discuss the changes that would need to be made to their program. We also believe that a nurse would likely spend more time developing the program with the mid-level practitioner. The physician would likely review and approve the program. The clerical staff member would probably assist with the program's development and ensure that the program was disseminated to all of the necessary parties in the REH.

Based on these factors, we estimate that for each REH to comply with the requirements in this section it would require annually 19 burden hours (1 hour for a physician + 4 hours for an administrator + 4 hours for a mid-level practitioner + 8 hours for a nurse + 2 hours for a clerical staff person) at a cost of \$1,810 (\$210 for a physician (1 hour \times \$210) + \$488 for an administrator (4 hours \times \$122) + \$404 for a mid-level practitioner (4 hours \times \$101) + \$632 for a nurse (8 hours \times \$79) + \$76 for a

clerical staff person (2 hours × \$38)). Therefore, for all 68 REHs to comply with these requirements, it would require 1,292 burden hours (19 hours × 68 REHs) at a cost of approximately \$123,080 (\$1,810 × 68 REHs).

8. ICRs Regarding Condition of Participation: Emergency Preparedness (§ 485.542)

Section 485.542 sets forth the proposed emergency preparedness requirements for REHs. We note that these emergency preparedness standards are consistent national parameters that all Medicare and Medicaid participating providers and suppliers must meet. This includes both rural hospitals and CAHs and therefore facility that converts to an REH would have already incurred the costs to develop and implement their emergency preparedness plan. Based on this, the burden associated with these requirements would be the on-going costs to review, maintain and implement the emergency preparedness program to ensure ongoing compliance with the requirements and as such we have developed this collection of information (COI) section based largely on the existing COI burden for CAHs and hospitals.

Standard: Risk Assessment and Planning (§ 485.542(a))

We propose to require REHs to develop and maintain an emergency preparedness plan that must be reviewed and updated at least biennially. We expect that each REH facilities director (\$104 per hour) would conduct a thorough risk assessment that will consider its location and geographical area; patient population, including those with special needs; and the type of services they have the ability to provide in an emergency (12 hours biennially or 6 hours annually) based on the services that they are now providing as an REH. They each would also need to review the measures needed to ensure continuity of its operation, including delegations and succession plans. We estimate that ongoing compliance with this requirement would require 6 burden hours annually (12 biennially) from the REH facilities director. Therefore, for all 68 REHs to comply with this requirement, it would require 408 burden hours (6 × 68 REHs) at a cost of approximately \$42,432 (408 hours × \$104).

Standard: Policies and Procedures (§ 485.542(b))

REHs are required to maintain emergency preparedness policies and procedures in accordance with their

emergency plan, risk assessment, and communication plan. Each needs to review their emergency preparedness policies and procedures and revise, or in some cases, develop new policies and procedures that would ensure that the emergency preparedness plans address the specific requirements of the regulations.

We believe that the requirement for REHs to review and update their policies and procedures annually constitutes a usual and customary business practice and is not subject to the PRA in accordance with 5 CFR 1320.3(b)(2). However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden on those providers eligible to convert to an REH.

Standard: Communication Plan (§ 485.542(c))

REHs are required to develop and maintain an emergency preparedness communication plan that complies with both Federal and state law and must be reviewed and updated at least annually. The burden associated with this requirement would be the time and effort necessary to review, revise, and if necessary, develop a new communications plan to ensure that it complies with the requirements of this regulation. However, we believe that most REHs have some type of emergency preparedness communication plan based on their prior status as a CAH or rural hospital. It is standard practice in the health care industry to have and maintain contact information for both staff and outside sources of assistance; alternate means of communications in case there is an interruption in phone service to the facility, such as cell phones; and a method for sharing information and medical documentation with other health care providers to ensure continuity of care for their patients.

If any revisions or additions are necessary to satisfy the requirements as an REH, we expect the revisions or additions would be those incurred during the course of normal business and thereby impose no additional burden. Thus, the ICRs related to the communication plan would constitute a usual and customary business practice as stated in the implementing regulations of the PRA at 5 CFR 1320.3(b)(2) and we did not include this activity in the burden analysis. We are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden on those providers eligible to convert to an REH.

Standard: Training and Testing (§ 485.542(d))

REHs are required to develop and maintain an emergency preparedness training and testing program. The training program must include initial training in emergency preparedness policies and procedures for all new and existing staff, individuals providing services under arrangement, and volunteers, consistent with their expected roles and must be documented. The testing program must include participation in a full-scale exercise that is community-based or when a community-based exercise is not accessible, an individual, facility-based. If an actual natural or man-made emergency that requires activation of the emergency plan is experienced, then this requirement is exempt for 1 year following the onset of the actual event. In addition, the testing program must include one additional testing exercise, which may be determined by the REH. The training must be provided biennially and two testing exercises must be conducted annually.

We expect that all REHs will review their current training programs in their current capacity as hospitals or CAHs, and compare them to their risk assessments and emergency preparedness plans, emergency policies and procedures, and emergency communication plans. The CAHs will need to revise and, if necessary, develop new sections or materials to ensure their training and testing programs complied with our requirements. We anticipate that ongoing compliance with this requirement will require the involvement of an administrator, the mid-level practitioner, the facilities director, and clerical staff. We expect that a mid-level practitioner will perform the initial review of the training program (4 hours), brief the administrator and the director of facilities (2 hours), and clerical staff to revise or develop new sections for the training program (1 hour), based on the group's decisions, if necessary. This will result in a cost of \$894 (\$404 for a mid-level practitioner (4 hours × \$101) + \$244 for an administrator (2 hours × \$122) + \$208 for a director of facilities (2 hours × \$104) + \$38 for a clerical staff person (1 hour × \$38)) for each REH. Therefore, for all REHs to comply with this requirement it will require an estimated 476 burden hours (7 hours × 68 REHs) at a cost of \$60,792 (\$894 × 68 REHs).

9. ICRs Regarding Conditions of Participation: Physical Environment (§ 485.544)
Standard: Life Safety Code (§ 485.544)

The REH must meet the applicable provisions of the 2012 edition of the Life Safety Code (LSC) of the National Fire Protection Association. If CMS finds that the state has a fire and safety code imposed by the state law that adequately protects patients, CMS may allow the state survey agency to apply the state’s fire and safety code instead of the LSC if waiving the provisions of

the LSC does not adversely affect the health and safety of patients. This regulation requires a REH to maintain written evidence of regular inspections and approval by state fire control agencies. We estimate that the burden associated with maintaining written evidence of state inspections and approval would be an average of 30 minutes for clerical personnel to file the documentation, for a total of 34 burden hours (0.5 hours × 68 REHs) and a cost of \$1,292 (34 hours × \$38). The burden will be accounted for in the Information

Collection Request under OMB control number 0938–XXXX.

The table that follows summarizes our estimates of burden hours and costs for REHs. We emphasize that these estimates assume 68 conversions and that the number actually converting could be a fraction of this figure, or much higher, which as discussed earlier is an uncertainty addressed in both the NC RHRP and CLA study that estimated likely conversions. Our estimates of the cost per entity, however, would not be affected by the number of conversions.

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TABLE 2: Total COI Burden for Rural Emergency Hospitals

COI Requirement	Burden Hours	Costs
Condition of Participation: Provision of Services (§ 485.514)	5,984	\$658,648
Condition of Participation: Infection prevention and control and antibiotic stewardship programs (§485.526)	5,304	\$419,016
Condition of Participation: Staffing and Staff Responsibilities (§ 485.528)	170	\$22,400
Standard: Notice of Rights: (§ 485.534(a)(1) and (2))	4,981	\$188,632
Standard: Restraint and Seclusion (§485.534(e))	0	\$0
Standard: Restraint and seclusion: Staff training requirements (§ 485.534(f))	0	\$0
Standard: Death reporting requirements (§ 485.534(g))	0.83 hours	\$101.67
Standard: Patient visitation rights (§ 485.534(h))	17	\$646
Condition of participation: Agreements (Proposed § 485.538)	272	\$21,760
Condition of Participation: Quality assessment and performance improvement program (QAPI) (Proposed § 485.536)	1292	\$123,080
Standard: Risk Assessment and Planning (§485.542(a))	408	\$42,432
Standard: Training and testing (§485.542(d))	476	\$60,792
Standard: Life Safety Code (§ 485.544)	34	\$1,292
TOTALS	18,939	\$1,538,800

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D. Critical Access Hospitals

1. ICRs Regarding Condition of Participation: Patient’s Rights (§ 485.614)

Standard: Notice of Rights: § 485.614(a)(1) and (2)

Proposed § 485.614(a) proposes to require CAHs to notify the patient of

their rights and of whom to contact to file a grievance. We allow REHs the flexibility to use different approaches to meet this CoP. We have set forth general elements that should be common to all grievance processes, but have not delineated strategies and policies for implementing this system. We believe that in large measure, CAHs would be

able to use existing systems for providing patients with information and handling complaints, and the elements listed in the regulation only serve to give basic assurance that these systems are responsive to patient grievances and act effectively. A less specific approach would permit a nominal, non-functional system that in essence did not serve the very purpose intended by the regulation. Costs associated with formalizing a process and modifying any existing notices or processes will most likely be offset by a reduction in patient-initiated lawsuits regarding care, and should provide a valuable tool for targeting internal quality assurance mechanisms.

We propose that the patient be provided with written notice containing a contact person's name, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion. Steps taken on behalf of the patient need not include a detailed description of who was spoken to and when. It might merely be that the appropriate staff were interviewed and that records were reviewed to investigate the grievance, and that the investigation found the grievance to be either unsubstantiated or substantiated. Second, the figures represented are estimates. We know of no existing system that tracks how many complaints are lodged in aggregate in CAHs each year; however, we believe that the grievance response can largely rely on standardized language with only relevant information filled in, or could be created in a check-sheet format, or in many other ways.

Thus, the burden associated with this requirement is the time and effort necessary to modify any existing notices to include the proposed grievance process requirements. We believe that an office assistant may be tasked with drafting or updating the notices and distributing or posting, as appropriate, the information. We estimate that this would require no more than two hours of the clerical staff time. The burden hours are 2,720 (2 hours \times 1,360). Based on this we estimate that this will create a one-time cost of \$103,360 (2,720 hours \times \$38). In addition, we estimate that it will require the office assistant 2 minutes (.0333 hours) to provide the notice per CAH patient on an annual basis. The number of notices required will depend on the number of patients received at the CAH. Therefore, the per facility burden associated with providing the notice will vary based on the unique factors of the CAH. According to a 2013 OIG report, there were approximately 1,753 patient visits

per CAH in 2011.³³ Based on this estimate, the burden hours would be 58 hours (.0333 hours \times 1,753 notices). The total burden hours would be 78,880 hours (58 hours \times 1,360 CAHs). Therefore, we estimate that the CAH would have had to inform each of these patient of their rights at a cost of \$2,997,440 (\$38 \times 78,880 hours).

In its resolution of a grievance, a CAH must provide the patient with written notice of its decision that contains the name of the CAH contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

The burden associated with this requirement is the time and effort necessary to disclose the written notice to each patient who filed a grievance. We estimate that on average it will take each REH 15 minutes to develop and disseminate the required notice and estimate that a CAH may have to provide 50 notices on an annual basis. The burden hours for each CAH will be 12.5 (0.25 hour \times 50 notices) for a total of 17,000 burden hours (12.5 hours \times 1,360 CAHs). The total annual burden cost is \$646,000 (\$38 \times 17,000).

Therefore, the total burden hours are 98,600 (78,880 + 17,000 + 2,720) and the total cost associated with this requirement is \$3,746,800 (\$103,360 to update notices, \$2,997,440 to provide the notices, and \$646,000 to provide the results of a grievance investigation).

Standard: Confidentiality of Patient Records (§ 485.614(d))

Proposed § 485.614(d), which sets forth the patient's right to access information in their records, will involve minimal burden as many states' existing laws cover this point. We have not proposed to require disclosure of all records, inasmuch as we recognize that there are situations where such a release could be harmful to the patient or another individual. Furthermore, we have not taken a prescriptive approach in specifying how quickly this information must be provided to the patient, or by setting a rate that the CAH can charge. In the absence of state law, the REH should charge whatever is reasonable and customary in its community for duplication services (based on rates at local commercial copy centers, post offices, or other venues in which one could make photocopies). Therefore, while this requirement is subject to the PRA, we believe that the burden associated with this requirement is exempt from the PRA, as defined in

³³ <https://oig.hhs.gov/oei/reports/oei-05-12-00081.pdf>.

5 CFR 1320.3(b)(2) and (3) because this requirement is considered standard industry practice and/or is required under state or local law.

Standard: Restraint and Seclusion (§ 485.614(e))

Proposed § 485.614(e) requires that each CAH have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice. While the requirement is subject to the PRA, we believe the associated burden is exempt in accordance with 5 CFR 1320.3(b)(2) because the time, and effort, and financial resources necessary to comply with this requirement would be incurred by persons in the normal course of their activities. These are reasonable and customary state practices and the state would impose this standard for efficient utilization of Medicare and Medicaid services in the absence of a Federal requirement. However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden.

Standard: Restraint and Seclusion: Staff Training Requirements (§ 485.614(f))

Proposed § 485.614(f) requires facilities to establish staff training requirements for the use of restraints and seclusion. The CAH must provide competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the use of restraint and seclusion. While these information collection requirements are subject to the PRA, we believe the burden associated with them are exempt as defined in 5 CFR 1320.3(b)(2) because the time, effort, and financial resources necessary to comply with the requirement are incurred by persons in the normal course of their activities. However, we are soliciting comment on whether this is a customary business practice or whether this would impose an additional burden.

Standard: Death Reporting Requirements (§ 485.614(g))

Proposed § 485.614(g) requires the facility to report the death of a resident associated with seclusion or restraint to the CMS regional office. A report must include the name of the resident involved in the serious occurrence, a description of the occurrence, and the name, street address, and telephone number of the facility.

We estimate it will take 5 minutes to report each death to the CMS regional

office and to document that report. We estimate fewer than 10 deaths annually for all 1,360 facilities. Five (5) minutes × 10 deaths annually would equate to a

national burden of 50 minutes per year. The hourly adjusted rate for a Medical and Health Service Manager responsible for notifying the CMS regional office of

a death a documenting the report is \$122/hour. Multiplying the total burden of 0.83 hours by the hourly wage yields an associated cost of about \$101.26.

TABLE 3: Total COI Burden for Critical Access Hospitals

COI Requirement	Burden Hours	Costs
Standard: Notice of Rights (§ 485.614(a)(1) and (2))	98,600	\$3,746,800
Standard: Restraint and Seclusion (§ 485.614 (c))	0	\$0
Standard: Restraint and seclusion: Staff training requirements (§ 485.614(f))	0	\$0
Standard: Death reporting requirements (§ 485.614(g))	0.83 hours	\$101
TOTALS	98,601	\$3,746,901

The burden for the proposed CAH provisions will be accounted for in the Information Collection Request under OMB control number 0938–XXXX.

If you comment on these information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements, please submit your comments electronically as specified in the **ADDRESSES** section of this proposed rule.

Comments must be received by August 29, 2022.

IV. Response to Comments

Because of the large number of public comments, we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

V. Regulatory Impact Statement

We have examined the impact of this proposed rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999), and the Congressional Review Act (5 U.S.C. 804(2)).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A Regulatory Impact Analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This proposed rule addresses the CoPs required for REH designation, which in accordance with the statute, may be sought by CAHs and small rural hospitals. It also proposes several new CAH requirements that we believe are appropriate under the existing program as well as to REHs. However, note that the costs of these CAH proposals are not attributable to the new REH program (except where such costs are experienced by entities that remain open due to the REH option but would have closed otherwise). The baseline for the estimates of REH costs is the status quo had the new program had not been created. Because the proposed CoPs for the new REH provider type are similar to those already met by the facilities that will potentially convert to REH status, and assuming that the estimated number of hospitals converting to the new program is approximately correct, the provisions of this proposed rule do not reach the economic threshold and thus it is not considered a major rule. This would remain the case if the number converting were to be significantly higher or lower. This is also an upper bound for these costs on a per facility

basis, since for collection of information purposes we did not subtract offsetting savings from providers who would already meet these standards and who decide to make little change when updating their status. Payment policies for REHs will be developed under separately proposed rulemaking, and we expect that the total economic impact of the new program including both Conditions of Participation and payment costs will exceed the threshold for an economically significant impact, and will be addressed at that time.

The RFA requires agencies to analyze options for regulatory relief of small entities, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other healthcare providers and suppliers are small entities, either by nonprofit status or by having revenues of less than \$8.0 million to \$41.5 million in any 1 year. Individuals and states are not included in the definition of a small entity. We estimate that almost all of the new REH facilities, and the great majority of CAHs, are or would be small entities on the basis of legal status, revenues, or both. The North American Industry Classification System Code for the converting hospitals is 622110 (General Medical and Surgical Hospitals), and for the REHs to which they convert the closest Code is 621493 (Freestanding Ambulatory Surgical and Emergency Centers).

HHS uses an increase in costs or decrease in revenues of more than 3

percent as its threshold for “significant economic impact”. Our collection of information estimates are that the 68 facilities converting to REH status (as estimated by the NC RHRP study referenced in the COI section) would face average annual costs of about \$22,600 each ($68 \times \$22,600 = \$1,537,000$ (COI burden estimate)). The North Carolina Rural Health Research Program estimated that the 68 hospitals it thought most likely to convert to REH status had average patient revenues of \$7.3 million. For these facilities, the 3 percent threshold would be about \$219,000, almost ten times our estimated cost of information collection. The CLA study does not present average facility revenues. However, we note that while it reaches a broad range of conversion estimates, we do not believe that it would have reached different conclusions had it presented such calculations. These relationships between revenues and costs would not be substantially different if the number of conversions was substantially fewer or substantially greater in number. More importantly, these facilities would be converting voluntarily to the new program. We expect that the costs any facility faces would be less than the anticipated gains of conversion, or it would not convert. This positive relationship of expected gains from conversion compared to current costs and revenues is explicit in the CLA modeling.

The effects of the proposed policy changes on CAHs are even smaller. The average annual cost per CAH for the new Conditions of Participation would be about \$2,755 each ($1,360 \text{ facilities} \times \$2,755 = \text{the } \$3,747,000 \text{ COI estimate}$), a tiny fraction of 1 percent of annual patient revenues estimated in the NC RHRP study at about \$24 million a year. Moreover, the proposed change in the definition of primary roads could prevent the loss of the CAH designation for 3 to 4 CAHs. We note that we propose no change in rural hospital standards, so they are not directly regulated by this proposed rule.

For these reasons, an Initial Regulatory Flexibility Analysis (IRFA) is not required. Furthermore, as described provision by provision earlier in this preamble, we carefully sought to keep regulatory burdens on REH providers to a reasonable minimum, taking into account our obligation to reduce health care inequities, their small size, and the statutory and practical limitations on their status as providers. For example, we propose to allow systems composed of multiple and separately certified hospitals, CAHs, and/or REHs to have unified or integrated governing bodies,

unified infection prevention and control and antibiotic stewardship programs, and unified and integrated medical staff. Taking all these factors into account, this analysis and the preamble as a whole meet the scope and content required for IRFAs.

Accordingly, we are not preparing an analysis under the RFA because we have determined, and the Secretary certifies, that this proposed rule would not have a significant economic impact on a substantial number of small entities. We do, however, request comments on our estimates and analysis, and on any alternatives that would reduce unnecessarily costly effects.

In addition, section 1102(b) of the Act requires us to prepare an RIA if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this proposed rule would not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of \$100 million in 1995 dollars, updated annually for inflation. In 2022, that threshold is approximately \$165 million. This proposed rule would not impose a mandate that will result in the expenditure by state, local, and Tribal Governments, in the aggregate, or by the private sector, of more than \$165 million in any 1 year.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. Since this regulation does not impose any costs on state or local governments, the requirements of Executive Order 13132 are not applicable.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

Chiquita Brooks-LaSure,
Administrator of the Centers for

Medicare & Medicaid Services, approved this document on June 9, 2022.

List of Subjects

42 CFR Part 485

Grant programs—health, Health facilities, Incorporation by reference, Medicaid, Privacy, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR chapter IV as set forth below:

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 1. The authority citation for part 485 continues to read as follows:

Authority: 42 U.S.C. 1302 and 1395hh.

■ 2. Subpart E is added to read as follows:

Subpart E—Conditions of Participation: Rural Emergency Hospitals (REHs)

Sec.

- 485.500 Basis and scope.
- 485.502 Definitions.
- 485.504 Basic requirements.
- 485.506 Designation and certification of REHs.
- 485.508 Condition of participation: Compliance with Federal, state, and local laws and regulations.
- 485.510 Condition of participation: Governing body and organizational structure of the REH.
- 485.512 Condition of participation: Medical staff.
- 485.514 Condition of participation: Provision of services.
- 485.516 Condition of participation: Emergency services.
- 485.518 Condition of participation: Laboratory services.
- 485.520 Condition of participation: Radiologic services.
- 485.522 Condition of participation: Pharmaceutical services.
- 485.524 Condition of participation: Additional outpatient medical and health services.
- 485.526 Condition of participation: Infection prevention and control and antibiotic stewardship programs.
- 485.528 Condition of participation: Staffing and staff responsibilities.
- 485.530 Condition of participation: Nursing services.
- 485.532 Condition of participation: Discharge planning.
- 485.534 Condition of participation: Patient's rights.
- 485.536 Condition of participation: Quality assessment and performance improvement program.

- 485.538 Condition of participation: Agreements.
- 485.540 Condition of participation: Medical records.
- 485.542 Condition of participation: Emergency preparedness.
- 485.544 Condition of participation: Physical environment.
- 485.546 Condition of participation: Skilled nursing facility distinct part unit.

Subpart E—Conditions of Participation: Rural Emergency Hospitals (REHs)

§ 485.500 Basis and scope.

Section 1861(kkk) of the Act requires the Secretary to establish the conditions REHs must meet in order to participate in the Medicare program and which are considered necessary to ensure the health and safety of patients receiving services at these entities.

§ 485.502 Definitions.

As used in this subpart, *Rural Emergency Hospital* or *REH* means 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.

§ 485.504 Basic requirements.

Participation as an REH is limited to facilities that—

- (a) Meet the definition in § 485.502.
- (b) Have in effect a provider agreement as defined at § 489.3 of this chapter to provide services.
- (c) Meet the conditions of participation set out in this subpart.

§ 485.506 Designation and certification of REHs.

CMS certifies a facility as an REH if the facility was, as of December 27, 2020—

- (a) A critical access hospital; or
- (b) A hospital as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds located in a county (or equivalent unit of local government) that is considered rural (as defined in section 1886(d)(2)(D) of the Act); or
- (c) A hospital as defined in section 1886(d)(1)(B) of the Act with not more than 50 beds that was treated as being located in a rural area that has had an active reclassification from urban to rural status as specified in § 412.103 of this chapter as of December 27, 2020.

§ 485.508 Condition of participation: Compliance with Federal, state, and local laws and regulations.

- (a) The REH must be in compliance with applicable Federal laws related to the health and safety of patients.
- (b) The REH must be located in a state that provides for the licensing of such hospitals under state or applicable local law; and is
 - (1) Licensed in the state as an REH; or
 - (2) Approved as meeting standards for licensing established by the agency of the state or locality responsible for licensing hospitals.
- (c) The REH must assure that 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.

§ 485.510 Condition of participation: Governing body and organizational structure of the REH.

There must be an effective governing body, or responsible individual or individuals, that is legally responsible for the conduct of the REH. If an REH does not have an organized governing body, the person or persons legally responsible for the conduct of the REH must carry out the functions specified in this subpart that pertain to the governing body.

- (a) *Standard: Medical staff.* The governing body must:
 - (1) Determine, in accordance with state law, which categories of practitioners are eligible candidates for appointment to the medical staff.
 - (2) Appoint members of the medical staff after considering the recommendations of the existing members of the medical staff.
 - (3) Ensure that the medical staff has bylaws.
 - (4) Approve medical staff bylaws and other medical staff rules and regulations.
 - (5) Ensure that the medical staff is accountable to the governing body for the quality of care provided to patients.
 - (6) Ensure the criteria for selection are individual character, competence, training, experience, and judgment.
 - (i) Members of the medical staff must be legally and professionally qualified for the positions to which they are appointed and for the performance of privileges granted. The REH grants privileges in accordance with recommendations from qualified medical personnel.
 - (ii) Medical staff privileges must be periodically reappraised by the REH. The scope of procedures performed in the REH must be periodically reviewed and amended as appropriate.
 - (iii) If the REH assigns patient care responsibilities to practitioners other

than physicians, it must have established policies and procedures, approved by the governing body, for overseeing and evaluating their clinical activities.

(7) Ensure that under no circumstances is the accordance of staff membership or professional privileges in the REH dependent solely upon certification, fellowship, or membership in a specialty body or society.

(8) Ensure that, when telemedicine services are furnished to the REH's patients through an agreement with a distant-site hospital, the agreement is written and that it specifies that it is the responsibility of the governing body of the distant-site hospital to meet the requirements in paragraphs (a)(1) through (7) of this section with regard to the distant-site hospital's physicians and practitioners providing telemedicine services. The governing body of the REH whose patients are receiving the telemedicine services may, in accordance with § 485.512(a)(3), grant privileges based on its medical staff recommendations that rely on information provided by the distant-site hospital.

(9) Ensure that when telemedicine services are furnished to the REH's patients through an agreement with a distant-site telemedicine entity, the written agreement specifies that the distant-site telemedicine entity is a contractor of services to the REH and as such, in accordance with paragraph (b) of this section, furnishes the contracted services in a manner that permits the REH to comply with all applicable conditions of participation for the contracted services, including, but not limited to, the requirements in paragraphs (a)(1) through (7) of this section with regard to the distant-site telemedicine entity's physicians and practitioners providing telemedicine services. The governing body of the REH whose patients are receiving the telemedicine services may, in accordance with § 485.512(a)(4), grant privileges to physicians and practitioners employed by the distant-site telemedicine entity based on such REH's medical staff recommendations; such staff recommendations may rely on information provided by the distant-site telemedicine entity.

(10) Consult directly with the individual assigned the responsibility for the organization and conduct of the REH's medical staff, or their designee. At a minimum, this direct consultation must occur periodically throughout the fiscal or calendar year and include discussion of matters related to the quality of medical care provided to patients of the REH. For a multi-facility

system, including a multi-hospital or multi-REH system, using a single governing body, the single multi-facility or multi-REH system governing body must consult directly with the individual responsible for the organized medical staff (or their designee) of each hospital or REH within its system in addition to the other requirements of this paragraph (a).

(b) *Standard: Contracted services.* The governing body must be responsible for services furnished in the REH whether or not they are furnished under contracts. The governing body must ensure that a contractor of services (including one for shared services and joint ventures) furnishes services that permit the REH to comply with all applicable conditions of participation and standards for the contracted services.

(1) The governing body must ensure that the services performed under a contract are provided in a safe and effective manner.

(2) The REH must maintain a list of all contracted services, including the scope and nature of the services provided.

§ 485.512 Condition of participation: Medical staff.

The REH must have an organized medical staff that operates under bylaws approved by the governing body, and which is responsible for the quality of medical care provided to patients by the REH.

(a) *Standard: Eligibility and process for appointment to medical staff.* The medical staff must be composed of doctors of medicine or osteopathy. In accordance with state law, including scope-of-practice laws, the medical staff may also include other categories of physicians (as listed at paragraph (c)(1) of this section) and non-physician practitioners who are determined to be eligible for appointment by the governing body.

(1) The medical staff must periodically conduct appraisals of its members.

(2) The medical staff must examine the credentials of all eligible candidates for medical staff membership and make recommendations to the governing body on the appointment of these candidates in accordance with state law, including scope-of-practice laws, and the medical staff bylaws, rules, and regulations. A candidate who has been recommended by the medical staff and who has been appointed by the governing body is subject to all medical staff bylaws, rules, and regulations, in addition to the requirements contained in this section.

(3) When telemedicine services are furnished to the REH's patients through an agreement with a distant-site hospital, the governing body of the REH whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site hospital when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the REH's governing body ensures, through its written agreement with the distant-site hospital, that all of the following provisions are met:

(i) The distant-site hospital providing the telemedicine services is a Medicare-participating hospital.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site hospital providing the telemedicine services, which provides a current list of the distant-site physician's or practitioner's privileges at the distant-site hospital.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the state in which the REH whose patients are receiving the telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the REH whose patients are receiving the telemedicine services, the REH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site hospital such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the REH's patients and all complaints the REH has received about the distant-site physician or practitioner.

(4) When telemedicine services are furnished to the REH's patients through an agreement with a distant-site telemedicine entity, the governing body of the REH whose patients are receiving the telemedicine services may choose, in lieu of the requirements in paragraphs (a)(1) and (2) of this section, to have its medical staff rely upon the credentialing and privileging decisions made by the distant-site telemedicine entity when making recommendations on privileges for the individual distant-site physicians and practitioners providing such services, if the REH's

governing body ensures, through its written agreement with the distant-site telemedicine entity, that the distant-site telemedicine entity furnishes services that, in accordance with paragraph (d) of this section, permit the REH to comply with all applicable conditions of participation for the contracted services. The REH's governing body must also ensure, through its written agreement with the distant-site telemedicine entity, that all of the following provisions are met:

(i) The distant-site telemedicine entity's medical staff credentialing and privileging process and standards at least meet the standards at § 485.510(a)(1) through (7) and paragraphs (a)(1) and (2) of this section.

(ii) The individual distant-site physician or practitioner is privileged at the distant-site telemedicine entity providing the telemedicine services, which provides the REH with a current list of the distant-site physician's or practitioner's privileges at the distant-site telemedicine entity.

(iii) The individual distant-site physician or practitioner holds a license issued or recognized by the state in which the REH whose patients are receiving such telemedicine services is located.

(iv) With respect to a distant-site physician or practitioner, who holds current privileges at the REH whose patients are receiving the telemedicine services, the REH has evidence of an internal review of the distant-site physician's or practitioner's performance of these privileges and sends the distant-site telemedicine entity such performance information for use in the periodic appraisal of the distant-site physician or practitioner. At a minimum, this information must include all adverse events that result from the telemedicine services provided by the distant-site physician or practitioner to the REH's patients, and all complaints the REH has received about the distant-site physician or practitioner.

(b) *Standard: Medical staff organization and accountability.* The medical staff must be well organized and accountable to the governing body for the quality of the medical care provided to patients.

(1) The medical staff must be organized in a manner approved by the governing body.

(2) If the medical staff has an executive committee, a majority of the members of the committee must be doctors of medicine or osteopathy.

(3) The responsibility for organization and conduct of the medical staff must be assigned only to one of the following:

(i) An individual doctor of medicine or osteopathy.

(ii) A doctor of dental surgery or dental medicine, when permitted by state law of the state in which the hospital is located.

(iii) A doctor of podiatric medicine, when permitted by state law of the state in which the hospital is located.

(4) If an REH is part of a system consisting of multiple separately certified hospitals, critical access hospitals, and/or REHs, and the system elects to have a unified and integrated medical staff for its member hospitals, critical access hospitals, and/or REHs after determining that such a decision is in accordance with all applicable state and local laws, each separately certified REH must demonstrate that:

(i) The medical staff members of each separately certified REH in the system (that is, all medical staff members who hold specific privileges to practice at that REH) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective REH;

(ii) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified REH (that is, all medical staff members who hold specific privileges to practice at that REH) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their REH;

(iii) The unified and integrated medical staff is established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each hospital, CAH, and REH; and

(iv) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, CAHs, and REHs, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals, CAHs, and REHs are duly considered and addressed.

(c) *Standard: Medical staff bylaws.*

The medical staff must adopt and enforce bylaws to carry out its responsibilities. The bylaws must:

(1) Be approved by the governing body.

(2) Include a statement of the duties and privileges of each category of medical staff (for example, active, courtesy, etc.).

(3) Describe the organization of the medical staff.

(4) Describe the qualifications to be met by a candidate in order for the medical staff to recommend that the candidate be appointed by the governing body.

(5) Include criteria for determining the privileges to be granted to individual practitioners and a procedure for applying the criteria to individuals requesting privileges. For distant-site physicians and practitioners requesting privileges to furnish telemedicine services under an agreement with the REH, the criteria for determining privileges and the procedure for applying the criteria are also subject to the requirements in § 485.510(a)(8) and (9) and paragraphs (a)(3) and (4) of this section.

§ 485.514 Condition of participation: Provision of services.

(a) The REH's health care services must be furnished in accordance with appropriate written policies that are consistent with applicable state law.

(b) The policies must be developed with the advice of members of the REH's professional health care staff, including one or more doctors of medicine or osteopathy and one or more physician assistants, nurse practitioners, or clinical nurse specialists, if they are on staff under the provisions of § 485.528(b)(1).

(c) The policies must include the following:

(1) A description of the services the REH furnishes, including those furnished through agreement or arrangement.

(2) Policies and procedures for emergency medical services.

(3) Guidelines for the medical management of health problems that include the conditions requiring medical consultation and/or patient referral, the maintenance of health care records, and procedures for the periodic review and evaluation of the services furnished by the REH.

(4) Policies and procedures that address the post-acute care needs of patients receiving services in the REH.

(d) The policies must be reviewed at least biennially by the group of professional personnel required under

paragraph (b) of this section and updated as necessary by the REH.

§ 485.516 Condition of participation: Emergency services.

The REH must provide the emergency care necessary to meet the needs of its patients in accordance with acceptable standards of practice.

(a) *Standard: Organization and direction.* The emergency services of the REH must be—(1) Organized under the direction of a qualified member of the medical staff; and

(2) Integrated with other departments of the REH.

(b) *Standard: Personnel.* There must be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility.

(c) *Standard: Compliance with CAH requirements.* The REH must meet the requirements specified in § 485.618, with respect to:

(1) 24-hour availability of emergency services (§ 485.618(a)).

(2) Equipment, supplies, and medication (§ 485.618(b)).

(3) Blood and blood products (§ 485.618(c)).

(4) Personnel (§ 485.618(d)).

(5) Coordination with emergency response systems (§ 485.618(e)).

§ 485.518 Condition of participation: Laboratory services.

The REH must provide basic laboratory services essential to the immediate diagnosis and treatment of the patient consistent with nationally recognized standards of care for emergency services. The REH must ensure that—

(a) Laboratory services are available, either directly or through a contractual agreement with a certified laboratory that meets requirements of part 493 of this chapter.

(b) Emergency laboratory services are available 24 hours a day.

§ 485.520 Condition of participation: Radiologic services.

The REH must maintain, or have available, diagnostic radiologic services. If therapeutic services are also provided, the therapeutic services, as well as the diagnostic services, must be furnished by the REH and provided by personnel qualified under state law. The REH must ensure that REH patients or personnel are not exposed to radiation hazards.

(a) *Standard: Radiologic services.* The REH must maintain, or have available, radiologic services according to needs of the patients.

(b) *Standard: Safety for patients and personnel.* The radiologic services,

particularly ionizing radiology procedures, must be free from hazards for patients and personnel.

(1) Proper safety precautions must be maintained against radiation hazards. This includes adequate shielding for patients, personnel, and facilities, as well as appropriate storage, use, and disposal of radioactive materials.

(2) Periodic inspection of equipment must be made and hazards identified must be promptly corrected.

(3) Radiation workers must be checked periodically, by the use of exposure meters or badge tests, for amount of radiation exposure.

(4) Radiologic services must be provided only on the order of practitioners with clinical privileges or, consistent with state law, of other practitioners authorized by the medical staff and the governing body to order the services.

(c) *Standard: Personnel.* (1) The REH must have a full-time, part-time, or consulting qualified radiologist, or other personnel qualified under State law, to interpret only those radiologic tests that are determined by the medical staff to require specialized knowledge. For purposes of this section, a radiologist is a doctor of medicine or osteopathy who is qualified by education and experience in radiology.

(2) Only personnel designated as qualified by the medical staff may use the radiologic equipment and administer procedures.

(d) *Standard: Records.* Records of radiologic services must be maintained.

(1) The radiologist or other practitioner who performs radiology services must sign reports of their interpretations.

(2) The REH must maintain the following for at least 5 years:

(i) Copies of reports and printouts.

(ii) Films, scans, and other image records, as appropriate.

§ 485.522 Condition of participation: Pharmaceutical services.

The REH must have pharmaceutical services that meet the needs of its patients. The REH must have a pharmacy or a drug storage area that is directed by a registered pharmacist or other qualified individual in accordance with state scope of practice laws. The medical staff is responsible for developing policies and procedures that minimize drug errors. This function may be delegated to the REH's registered pharmacist or other qualified individual.

(a) *Standard: Pharmacy management and administration.* The pharmacy or drug storage area must be administered in accordance with accepted

professional principles and in accordance with state and Federal laws.

(1) A pharmacist or competent individual in accordance with state scope of practice laws must be responsible for developing, supervising, and coordinating all the activities of the pharmacy services. The pharmacist or competent individual in accordance with state law and scope of practice must be available for a sufficient time to provide oversight of the REH's pharmacy services based on the scope and complexity of the services offered at the REH.

(2) The pharmaceutical service must have an adequate number of personnel to ensure quality pharmaceutical services for the provision of all services provided by the REH.

(3) Current and accurate records must be kept of the receipt and disposition of all scheduled drugs.

(b) *Standard: Delivery of services.*

Drugs and biologicals must be controlled and distributed in accordance with applicable standards of practice, consistent with Federal and state law, to ensure patient safety.

(1) All compounding, packaging, and dispensing of drugs must be done by a licensed pharmacist or a licensed physician, or under the supervision of a pharmacist or competent individual in accordance with state law and scope of practice and performed consistent with state and Federal laws.

(2) All drugs and biologicals must be kept in a secure area, and locked when appropriate.

(i) All drugs listed in Schedules II, III, IV, and V of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 *et seq.*) must be kept locked within a secure area.

(ii) Only authorized personnel may have access to locked areas.

(3) Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use.

(4) Drugs and biologicals must be removed from the pharmacy or storage area only by personnel designated in the policies of the medical staff and pharmaceutical service, in accordance with Federal and state law.

(c) *Standard: Administration of drugs.* Drugs must be prepared and administered according to established policies and acceptable standards of practice.

(1) Adverse reactions must be reported to the physician responsible for the patient and must be documented in the record.

(2) Blood transfusions, blood products, and intravenous medications must be administered in accordance

with state law and approved medical staff policies and procedures.

(3) Orders given orally for drugs and biologicals must be followed by a written order, signed by the prescribing physician or other authorized prescriber.

(4) There must be an REH procedure for reporting transfusion reactions, adverse drug reactions, and errors in administration of drugs.

§ 485.524 Condition of participation: Additional outpatient medical and health services.

If the REH provides outpatient medical and health services in addition to providing emergency services and observation care, the medical and health services must be appropriately organized and meet the needs of the patients in accordance with acceptable standards of practice.

(a) *Standard: Patient services.* The REH may provide outpatient and medical health diagnostic and therapeutic items and services that are commonly furnished in a physician's office or at another entry point into the health care delivery system that include, but are not limited to, radiology, laboratory, outpatient rehabilitation, surgical, maternal health, and behavioral health services. If the REH provides outpatient and medical health diagnostic and therapeutic items and services, those items and services must align with the health needs of the community served by the REH. If the REH provides outpatient medical and health services in addition to providing emergency services, the REH must—

(1) Provide items and services based on nationally recognized guidelines and standards of practice.

(2) Have a system in place for referral from the REH to different levels of care, including follow-up care, as appropriate.

(3) Have effective communication systems in place between the REH and the patient (or responsible individual) and their family, ensuring that the REH is responsive to their needs and preferences.

(4) Have 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.

(5) Have personnel providing the services in paragraphs (a)(1) through (4) of this section who meet the requirements in paragraph (b) of this section.

(b) *Standard: Personnel for additional outpatient and medical health services.* The REH must—

(1) Assign one or more individuals to be responsible for outpatient services.

(2) Have appropriate professional and nonprofessional personnel available at each location where outpatient services are offered, based on the scope and complexity of outpatient services.

(3) For any specialty services offered at the REH, have a doctor of medicine or osteopathy, nurse practitioner, clinical nurse specialist, or physician assistant providing services with experience and training in the specialty service area and in accordance with their scope of practice.

(c) *Standard: Orders for outpatient medical and health services.* Outpatient medical and health services must be ordered by a practitioner who meets the following conditions:

(1) Is responsible for the care of the patient.

(2) Is licensed in the state where they provide care to the patient.

(3) Is acting within their scope of practice under state law.

(4) Is authorized in accordance with state law and policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services. This applies to the following:

(i) All practitioners who are appointed to the REH's medical staff and who have been granted privileges to order the applicable outpatient services.

(ii) All practitioners not appointed to the medical staff, but who satisfy the requirements of paragraphs (c)(1) through (4) of this section for authorization by the medical staff and the REH for ordering the applicable outpatient services for their patients.

(d) *Standard: Surgical services.* If the REH provides outpatient surgical services, surgical procedures must be performed in a safe manner by qualified practitioners who have been granted clinical privileges by the governing body, or responsible individual, of the REH in accordance with the designation requirements under paragraph (a) of this section.

(1) *Designation of qualified practitioners.* The REH designates the practitioners who are allowed to perform surgery for REH patients, in accordance with its approved policies and procedures, and with state scope of practice laws. Surgery is performed only by—

(i) A doctor of medicine or osteopathy, including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(ii) A doctor of dental surgery or dental medicine; or

(iii) A doctor of podiatric medicine.

(2) *Anesthetic risk and evaluation.* (i) A qualified practitioner, as specified in paragraph (a) of this section, must

examine the patient immediately before surgery to evaluate the risk of the procedure to be performed.

(ii) A qualified practitioner, as specified in paragraph (d)(3) of this section, must examine each patient before surgery to evaluate the risk of anesthesia.

(iii) Before discharge from the REH, each patient must be evaluated for proper anesthesia recovery by a qualified practitioner, as specified in paragraph (d)(3) of this section.

(3) *Administration of anesthesia.* The REH designates the person who is allowed to administer anesthesia to REH patients in accordance with its approved policies and procedures and with state scope-of-practice laws.

(i) Anesthesia must be administered by only—

(A) A qualified anesthesiologist;

(B) A doctor of medicine or osteopathy other than an anesthesiologist; including an osteopathic practitioner recognized under section 1101(a)(7) of the Act;

(C) A doctor of dental surgery or dental medicine;

(D) A doctor of podiatric medicine;

(E) A certified registered nurse anesthetist (CRNA), as defined in § 410.69(b) of this chapter;

(F) An anesthesiologist's assistant, as defined in § 410.69(b) of this chapter; or

(G) A supervised trainee in an approved educational program, as described in § 413.85 or §§ 413.76 through 413.83 of this chapter.

(ii) In those cases in which a CRNA administers the anesthesia, the anesthetist must be under the supervision of the operating practitioner except as provided in paragraph (e) of this section. An anesthesiologist's assistant who administers anesthesia must be under the supervision of an anesthesiologist.

(4) *Discharge.* All patients are discharged in the company of a responsible adult, except those exempted by the practitioner who performed the surgical procedure.

(5) *Standard: State exemption.* (i) An REH may be exempted from the requirement for physician supervision of CRNAs as described in paragraph (d)(3) of this section, if the state in which the REH is located submits a letter to CMS signed by the Governor, following consultation with the State's Boards of Medicine and Nursing, requesting exemption from physician supervision for CRNAs. The letter from the Governor must attest that they have consulted with the State Boards of Medicine and Nursing about issues related to access to and the quality of anesthesia services in the state and has

concluded that it is in the best interests of the state's citizens to opt-out of the current physician supervision requirement, and that the opt-out is consistent with state law.

(ii) The request for exemption and recognition of state laws and the withdrawal of the request may be submitted at any time, and are effective upon submission.

§ 485.526 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

The REH must have active facility-wide programs for the surveillance, prevention, and control of healthcare-associated infections (HAIs) and other infectious diseases, and for the optimization of antibiotic use through stewardship. The programs must demonstrate adherence to nationally recognized infection prevention and control guidelines, as well as to best practices for improving antibiotic use where applicable, and for reducing the development and transmission of HAIs and antibiotic-resistant organisms. Infection prevention and control problems and antibiotic use issues identified in the programs must be addressed in collaboration with the facility-wide quality assessment and performance improvement (QAPI) program.

(a) *Standard: Infection prevention and control program organization and policies.* The REH must demonstrate that:

(1) An individual (or individuals), who is qualified through education, training, experience, or certification in infection prevention and control, is appointed by the governing body, or responsible individual, as the infection preventionist(s)/infection control professional(s) responsible for the infection prevention and control program and that the appointment is based on the recommendations of medical staff leadership and nursing leadership;

(2) The infection prevention and control program, as documented in its policies and procedures, employs methods for preventing and controlling the transmission of infections within the REH and between the REH and other health care settings;

(3) The infection prevention and control program include surveillance, prevention, and control of HAIs, including maintaining a clean and sanitary environment to avoid sources and transmission of infection, and that the program also addresses any infection control issues identified by public health authorities; and

(4) The infection prevention and control program reflects the scope and complexity of the services furnished by the REH.

(b) *Standard: Antibiotic stewardship program organization and policies.* The REH must demonstrate that—

(1) An individual (or individuals), who is qualified through education, training, or experience in infectious diseases and/or antibiotic stewardship, is appointed by the governing body, or responsible individual, as the leader(s) of the antibiotic stewardship program and that the appointment is based on the recommendations of medical staff leadership and pharmacy leadership;

(2) The facility-wide antibiotic stewardship program:

(i) Demonstrates coordination among all components of the REH responsible for antibiotic use and resistance, including, but not limited to, the infection prevention and control program, the QAPI program, the medical staff, nursing services, and pharmacy services;

(ii) Documents the evidence-based use of antibiotics in all departments and services of the REH; and

(iii) Documents any improvements, including sustained improvements, in proper antibiotic use;

(3) The antibiotic stewardship program adheres to nationally recognized guidelines, as well as best practices, for improving antibiotic use; and

(4) The antibiotic stewardship program reflects the scope and complexity of the services furnished by an REH.

(c) *Standard: Leadership responsibilities.* (1) The governing body, or responsible individual, must ensure all of the following:

(i) Systems are in place and operational for the tracking of all infection surveillance, prevention and control, and antibiotic use activities, in order to demonstrate the implementation, success, and sustainability of such activities.

(ii) All HAIs and other infectious diseases identified by the infection prevention and control program as well as antibiotic use issues identified by the antibiotic stewardship program are addressed in collaboration with the REH's QAPI leadership.

(2) The infection prevention and control professional(s) are responsible for:

(i) The development and implementation of facility-wide infection surveillance, prevention, and control policies and procedures that adhere to nationally recognized guidelines.

(ii) All documentation, written or electronic, of the infection prevention and control program and its surveillance, prevention, and control activities.

(iii) Communication and collaboration with the REH's QAPI program on infection prevention and control issues.

(iv) Competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the practical applications of infection prevention and control guidelines, policies and procedures.

(v) The prevention and control of HAIs, including auditing of adherence to infection prevention and control policies and procedures by REH personnel.

(vi) Communication and collaboration with the antibiotic stewardship program.

(3) The leader(s) of the antibiotic stewardship program is responsible for:

(i) The development and implementation of a facility-wide antibiotic stewardship program, based on nationally recognized guidelines, to monitor and improve the use of antibiotics.

(ii) All documentation, written or electronic, of antibiotic stewardship program activities.

(iii) Communication and collaboration with medical staff, nursing, and pharmacy leadership, as well as the REH's infection prevention and control and QAPI programs, on antibiotic use issues.

(iv) Competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the practical applications of antibiotic stewardship guidelines, policies, and procedures.

(d) *Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for multi-facility systems.* If a REH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified REHs meets all of the

requirements of this section. Each separately certified REH subject to the system governing body must demonstrate that:

(1) The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each REH;

(2) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified REHs, regardless of practice or location, are given due consideration;

(3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular REHs are duly considered and addressed; and

(4) A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the REH as responsible for communicating with the unified infection prevention and control and antibiotic stewardship programs, for implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs, and for providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to REH staff.

(e) *COVID-19 and Seasonal Influenza reporting.* Beginning at the conclusion of the COVID-19 Public Health Emergency, as defined in § 400.200 of this chapter, and continuing until April 30, 2024, except when the Secretary specifies an earlier end date for the requirements of this paragraph (e), the REH must electronically report information about COVID-19 and seasonal influenza in a standardized format specified by the Secretary.

(1) Related to COVID-19, to the extent as required by the Secretary, this report must include the following data elements:

(i) Suspected and confirmed COVID-19 infections among patients and staff.

(ii) Total COVID-19 deaths among patients and staff.

(iii) Personal protective equipment and testing supplies.

(iv) Ventilator use, capacity, and supplies.

(v) Total patient census and capacity.

(vi) Staffing shortages.
 (vii) COVID-19 vaccine administration data of patients and staff.
 (viii) Relevant therapeutic inventories or usage, or both.

(2) Related to seasonal influenza, to the extent as required by the Secretary, this report must include the following data elements:

- (i) Confirmed influenza infections among patients and staff.
- (ii) Total influenza deaths among patients and staff.
- (iii) Confirmed co-morbid influenza and COVID-19 infections among patients and staff.

(f) *Standard: Reporting of data related to viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential.* The REH must electronically report information on Acute Respiratory Illness (including, but not limited to, Seasonal Influenza Virus, Influenza-like Illness, and Severe Acute Respiratory Infection), SARS-CoV-2/COVID-19, and other viral and bacterial pathogens and infectious diseases of pandemic or epidemic potential only when the Secretary has declared a Public Health Emergency (PHE), as defined in § 400.200 of this chapter, directly related to such specific pathogens and infectious diseases. The requirements of this paragraph (f) will be applicable to local, state, regional, or national PHEs as declared by the Secretary.

(1) The REH must electronically report information about the infectious disease pathogen, relevant to the declared PHE, in a standardized format specified by the Secretary. To the extent as required by the Secretary, this report must include, the following:

- (i) Suspected and confirmed infections of the relevant infectious disease pathogen among patients and staff.
- (ii) Total deaths attributed to the relevant infectious disease pathogen among patients and staff.
- (iii) Personal protective equipment and other relevant supplies in the REH.
- (iv) Capacity and supplies in the REH relevant to the immediate and long term treatment of the relevant infectious disease pathogen, such as ventilator and dialysis/continuous renal replacement therapy capacity and supplies.
- (v) Total patient census, capacity, and capability.

- (vi) Staffing shortages.
- (vii) Vaccine administration data of patients and staff for conditions monitored under this section and where a specific vaccine is applicable.
- (viii) Relevant therapeutic inventories or usage, or both.
- (ix) Isolation capacity, including airborne isolation capacity.

(x) Key co-morbidities or exposure risk factors, or both, of patients being treated for the pathogen or disease of interest in this section that are captured with interoperable data standards and elements.

(2) Unless the Secretary specifies an alternative format by which the REH must report these data elements, the REH must report the applicable infection (confirmed and suspected) and vaccination data in a format that provides person-level information, which must include medical record identifier, race, ethnicity, age, sex, residential county and zip code, and relevant comorbidities for affected patients. Facilities must not report any directly or potentially individually-identifiable information for affected patients (for example, name, social security number) that is not set out in this section or otherwise specified by the Secretary.

(3) The REH must provide the information specified in this paragraph (f) on a daily basis, unless the Secretary specifies a lesser frequency, to the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network or other CDC-supported surveillance systems as determined by the Secretary.

(g) *Standard: COVID-19 Vaccination of REH staff.* Until November 4, 2024, unless the Secretary specifies an earlier end date for the requirements of this paragraph (g), the REH must develop and implement policies and procedures to ensure that all staff are fully vaccinated for COVID-19. For purposes of this section, staff are considered fully vaccinated if it has been 2 weeks or more since they completed a primary vaccination series for COVID-19. The completion of a primary vaccination series for COVID-19 is defined here as the administration of a single-dose vaccine, or the administration of all required doses of a multi-dose vaccine.

(1) Regardless of clinical responsibility or patient contact, the policies and procedures must apply to the following REH staff, who provide any care, treatment, or other services for the REH and/or its patients:

- (i) REH employees;
- (ii) Licensed practitioners;
- (iii) Students, trainees, and volunteers; and
- (iv) Individuals who provide care, treatment, or other services for the REH and/or its patients, under contract or by other arrangement.

(2) The policies and procedures of this section do not apply to the following REH staff:

- (i) Staff who exclusively provide telehealth or telemedicine services

outside of the REH setting and who do not have any direct contact with patients and other staff specified in paragraph (f)(1) of this section; and

(ii) Staff who provide support services for the REH that are performed exclusively outside of the REH setting and who do not have any direct contact with patients and other staff specified in paragraph (f)(1) of this section.

(3) The policies and procedures must include, at a minimum, the following components:

(i) A process for ensuring all staff specified in paragraph (f)(1) of this section (except for those staff who have pending requests for, or who have been granted, exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations) have received, at a minimum, a single-dose COVID-19 vaccine, or the first dose of the primary vaccination series for a multi-dose COVID-19 vaccine prior to staff providing any care, treatment, or other services for the REH and/or its patients;

(ii) A process for ensuring that all staff specified in paragraph (f)(1) of this section are fully vaccinated for COVID-19, except for those staff who have been granted exemptions to the vaccination requirements of this section, or those staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations;

(iii) A process for ensuring the implementation of additional precautions, intended to mitigate the transmission and spread of COVID-19, for all staff who are not fully vaccinated for COVID-19;

(iv) A process for tracking and securely documenting the COVID-19 vaccination status of all staff specified in paragraph (f)(1) of this section;

(v) A process for tracking and securely documenting the COVID-19 vaccination status of any staff who have obtained any booster doses as recommended by the CDC;

(vi) A process by which staff may request an exemption from the staff COVID-19 vaccination requirements based on an applicable Federal law;

(vii) A process for tracking and securely documenting information provided by those staff who have requested, and for whom the REH has granted, an exemption from the staff COVID-19 vaccination requirements based on recognized clinical contraindications or applicable Federal laws;

(viii) A process for ensuring that all documentation, which confirms recognized clinical contraindications to COVID-19 vaccines and which supports staff requests for medical exemptions from vaccination, has been signed and dated by a licensed practitioner, who is not the individual requesting the exemption, and who is acting within their respective scope of practice as defined by, and in accordance with, all applicable state and local laws, and for further ensuring that such documentation contains:

(A) All information specifying which of the authorized COVID-19 vaccines are clinically contraindicated for the staff member to receive and the recognized clinical reasons for the contraindications; and

(B) A statement by the authenticating practitioner recommending that the staff member be exempted from the REH's COVID-19 vaccination requirements for staff based on the recognized clinical contraindications;

(ix) A process for ensuring the tracking and secure documentation of the vaccination status of staff for whom COVID-19 vaccination must be temporarily delayed, as recommended by the CDC, due to clinical precautions and considerations, including, but not limited to, individuals with acute illness secondary to COVID-19, and individuals who received monoclonal antibodies or convalescent plasma for COVID-19 treatment; and

(x) Contingency plans for staff who are not fully vaccinated for COVID-19.

§ 485.528 Condition of participation: Staffing and staff responsibilities.

(a) *Standard: Emergency department staffing.* The emergency department of the REH must be staffed 24 hours a day, 7 days a week to receive patients and activate the appropriate medical resources.

(b) *Standard: Staffing.* (1) The REH must have a professional health care staff that includes one or more doctors of medicine or osteopathy, and may include one or more physician assistants, nurse practitioners, or clinical nurse specialists.

(2) Any ancillary personnel are supervised by the professional staff.

(3) The staff is sufficient to provide the services essential to the operation of the REH.

(4) A registered nurse, clinical nurse specialist, or licensed practical nurse is on duty whenever the REH has one or more patients receiving emergency care or observation care.

(c) *Standard: Responsibilities of the doctor of medicine or osteopathy.* (1)

The doctor of medicine or osteopathy must—

(i) Provide medical direction for the REH's health care activities and consultation for, and medical supervision of, the health care staff.

(ii) In conjunction with the physician assistant and/or nurse practitioner member(s), participate in developing, executing, and periodically reviewing the REH's written policies governing the services it furnishes.

(iii) In conjunction with the physician assistant and/or nurse practitioner members, periodically review the REH's patient records, provide medical orders, and provide medical care services to the patients of the REH.

(iv) Periodically review and sign a sample of outpatient records of patients cared for by nurse practitioners, clinical nurse specialists, certified nurse midwives, or physician assistants only to the extent where state law requires record reviews or co-signatures, or both, by a collaborating physician.

(2) A doctor of medicine or osteopathy must be present for sufficient periods of time to provide medical direction, consultation, and supervision for the services provided in the REH, and is available through direct radio or telephone communication or electronic communication for consultation, assistance with medical emergencies, or patient referral.

(d) *Standard: Physician assistant, nurse practitioner, and clinical nurse specialist responsibilities.* (1) The physician assistant, the nurse practitioner, or clinical nurse specialist members of the REH's staff must—

(i) Participate in the development, execution and periodic review of the written policies governing the services the REH furnishes; and

(ii) Participate with a doctor of medicine or osteopathy in a periodic review of the patients' health records.

(2) The physician assistant, nurse practitioner, or clinical nurse specialist performs the following functions to the extent they are not being performed by a doctor of medicine or osteopathy:

(i) Provides services in accordance with the REH's policies.

(ii) Arranges for, or refers patients to, needed services that cannot be furnished at the REH, and assures that adequate patient health records are maintained and transferred as required when patients are referred.

(3) Whenever a patient is placed in observation care at the REH by a nurse practitioner, physician assistant, or clinical nurse specialist, a doctor of medicine or osteopathy on the staff of the REH is notified of the patient's status.

(e) *Standard: Periodic review of clinical privileges and performance.* The REH requires that—

(1) The quality and appropriateness of the diagnosis and treatment furnished by nurse practitioners, clinical nurse specialists, and physician assistants at the REH must be evaluated by a member of the REH staff who is a doctor of medicine or osteopathy or by another doctor of medicine or osteopathy under contract with the REH.

(2) The quality and appropriateness of the diagnosis and treatment furnished by doctors of medicine or osteopathy at the REH must be evaluated by one of the following—

(i) One Quality Improvement Organization (QIO) or equivalent entity.

(ii) In the case of distant-site physicians and practitioners providing telemedicine services to the REH's patient under an agreement between the REH and a distant-site hospital, the distant-site hospital; or

(iii) In the case of distant-site physicians and practitioners providing telemedicine services to the REH's patients under a written agreement between the REH and a distant-site telemedicine entity, one Quality Improvement Organization (QIO) or equivalent entity.

(3) The REH staff consider the findings of the evaluation and make the necessary changes as specified in paragraphs (b) through (d) of this section.

§ 485.530 Condition of participation: Nursing services.

The REH must have an organized nursing service that is available to provide 24-hour nursing services for the provision of patient care. The nursing services must be furnished and supervised by a registered nurse. Nursing services must meet the needs of patients.

(a) *Standard: Organization and staffing.* Patient care responsibilities must be delineated for all nursing service personnel. Nursing services must be provided in accordance with recognized standards of practice.

(b) *Standard: Nursing leadership.* The director of the nursing service must be a licensed registered nurse. The individual is responsible for the operation of the service, including determining the types and numbers of nursing personnel and staff necessary to provide nursing care for all areas of the REH.

§ 485.532 Condition of participation: Discharge planning.

An REH must have an effective discharge planning process that focuses

on the patient's goals and treatment preferences and includes the patient and their caregivers/support person(s) as active partners in the discharge planning for post-discharge care. The discharge planning process and the discharge plan must be consistent with the patient's goals for care and their treatment preferences, ensure an effective transition of the patient from the REH to post-discharge care, and reduce the factors leading to preventable hospital admissions or readmissions.

(a) *Standard: Discharge planning process.* The REH's discharge planning process must identify, at an early stage of the provision of services, those patients who are likely to suffer adverse health consequences upon discharge in the absence of adequate discharge planning and must provide a discharge planning evaluation for those patients so identified as well as for other patients upon the request of the patient, patient's representative, or patient's physician.

(1) Any discharge planning evaluation must be made on a timely basis to ensure that appropriate arrangements for post-REH care will be made before discharge and to avoid unnecessary delays in discharge.

(2) A discharge planning evaluation must include an evaluation of a patient's likely need for appropriate services following those furnished by the REH, including, but not limited to, hospice care services, post-REH extended care services, home health services, and non-health care services and community-based care providers, and must also include a determination of the availability of the appropriate services as well as of the patient's access to those services.

(3) The discharge planning evaluation must be included in the patient's medical record for use in establishing an appropriate discharge plan and the results of the evaluation must be discussed with the patient (or the patient's representative).

(4) Upon the request of a patient's physician, the REH must arrange for the development and initial implementation of a discharge plan for the patient.

(5) Any discharge planning evaluation or discharge plan required under this paragraph (a) must be developed by, or under the supervision of, a registered nurse, social worker, or other appropriately qualified personnel.

(6) The REH's discharge planning process must require regular re-evaluation of the patient's condition to identify changes that require modification of the discharge plan. The discharge plan must be updated, as needed, to reflect these changes.

(7) The REH must assess its discharge planning process on a regular basis. The assessment must include ongoing periodic review of a representative sample of discharge plans.

(8) The REH must assist patients, their families, or the patient's representative in selecting a post-acute care provider by using and sharing data that includes, but is not limited to, HHA, skilled nursing facility (SNF), inpatient rehabilitation facility (IRF), or long-term care hospital (LTCH) data on quality measures and data on resource use measures. The REH must ensure that the post-acute care data on quality measures and data on resource use measures is relevant and applicable to the patient's goals of care and treatment preferences.

(b) *Standard: Discharge of the patient and provision and transmission of the patient's necessary medical information.* The REH must discharge the patient, and also transfer or refer the patient where applicable, along with all necessary medical information pertaining to the patient's current course of illness and treatment, post-discharge goals of care, and treatment preferences, at the time of discharge, to the appropriate post-acute care service providers and suppliers, facilities, agencies, and other outpatient service providers and practitioners responsible for the patient's follow-up or ancillary care.

§ 485.534 Condition of participation: Patient's rights.

An REH must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* (1) An REH must inform each patient, or when appropriate, the patient's representative (as allowed under state law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The REH must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The REH's governing body or responsible individual must approve and be responsible for the effective operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The REH must establish a clearly explained procedure for the submission

of a patient's written or verbal grievance to the REH.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the REH must provide the patient with written notice of its decision that contains the name of the REH contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) *Standard: Exercise of rights.* The patient has the right to—

(1) Participate in the development and implementation of their plan of care.

(2) Make informed decisions regarding their care, including being informed of their health status, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) Formulate advance directives and to have REH staff and practitioners who provide care in the REH comply with these directives, in accordance with §§ 489.100, 489.102, and 489.104 of this chapter.

(c) *Standard: Privacy and safety.* The patient has the right to—

(1) Personal privacy.

(2) Receive care in a safe setting.

(3) Be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of patient records.* (1) The patient has the right to the confidentiality of their medical records.

(2) The patient has the right to access their medical records, including current medical records, upon an oral or written request.

(i) The records must be provided in the form and format requested by the individual, if it is readily producible in such form and format. This includes in an electronic form or format when such medical records are maintained electronically or if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual.

(ii) The records must be provided within a reasonable time frame. The REH must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its recordkeeping system permits.

(e) *Standard: Restraint or seclusion.*

All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or

seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1)(i) A *restraint* is—

(A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move their arms, legs, body, or head freely; or

(B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, off of a stretcher, or out of a chair, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

(ii) *Seclusion* is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

(2) Restraint or 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.

(3) 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.

(4) The REH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice.

(f) *Standard: Restraint or seclusion: Staff training requirements.* The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) The REH must provide patient-centered competency-based training and education of REH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the REH, on the use of restraint and seclusion.

(2) The training must include alternatives to the use of restraint/seclusion.

(g) *Standard: Death reporting requirements.* REHs must report deaths associated with the use of seclusion or restraint.

(1) With the exception of deaths described under paragraph (g)(2) of this section, the REH must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the REH that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the REH staff must record in an internal log or other system, the following information:

(i) Any death that occurs while a patient is in such restraints.

(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

(3) The staff must document in the patient's medical record the date and time the death was:

(i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or

(ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.

(4) For deaths described in paragraph (g)(2) of this section, entries into the internal log or other system must be documented as follows:

(i) Each entry must be made not later than seven days after the date of death of the patient.

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is

responsible for the care of the patient, medical record number, and primary diagnosis(es).

(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

(h) *Standard: Patient visitation rights.* An REH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the REH may need to place on such rights and the reasons for the clinical restriction or limitation. An REH must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of their visitation rights, including any clinical restriction or limitation on such rights, when they are informed of their other rights under this section.

(2) Inform each patient (or support person, where appropriate) of the right, subject to their consent, to receive the visitors whom they designate, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and their right to withdraw or deny such consent at any time.

(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

§ 485.536 Condition of participation: Quality assessment and performance improvement program.

The REH must develop, implement, and maintain an effective, ongoing, REH-wide, data-driven quality assessment and performance improvement (QAPI) program. The REH's governing body must ensure that the program reflects the complexity of the REH's organization and services; involves all REH departments and services (including those services furnished under contract or arrangement); and focuses on indicators related to improved health outcomes and the prevention and reduction of medical errors. The REH must maintain and demonstrate evidence of its QAPI program for review by CMS.

(a) *Standard: Program scope.* (1) The program must include, but not be limited to, an ongoing program that shows measurable improvement in indicators for which there is evidence that it will improve health outcomes and identify and reduce medical errors.

(2) The REH must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that assess processes of care, REH service and operations.

(b) *Standard: Program data collection and analysis.* The program must incorporate quality indicator data including patient care data, and other relevant data, in order to achieve the goals of the QAPI program.

(c) *Standard: Program activities.* (1) The REH must set priorities for its performance improvement activities that—

(i) Focus on high-risk, high-volume, or problem-prone areas;

(ii) Consider the incidence, prevalence, and severity of problems in those areas; and

(iii) Affect health outcomes, patient safety, and quality of care.

(2) Performance improvement activities must track medical errors and adverse patient events, analyze their causes, and implement preventive actions and mechanisms that include feedback and learning throughout the REH. An *adverse patient event* means an untoward, undesirable, and usually unanticipated event that causes death or serious injury or the risk thereof. *Medical error* means an error that occurs in the delivery of health care services.

(3) The REH must take actions aimed at performance improvement and, after implementing those actions, the REH must measure its success, and track performance to ensure that improvements are sustained.

(d) *Standard: Executive responsibilities.* The REH's governing body (or organized group or individual who assumes full legal authority and responsibility for operations of the REH), medical staff, and administrative officials are responsible and accountable for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety, including the reduction of medical errors, is defined, implemented, and maintained.

(2) That the REH-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety; and that all improvement actions are evaluated.

(3) That clear expectations for safety are established.

(4) That adequate resources are allocated for measuring, assessing, improving, and sustaining the REH's performance and reducing risk to patients.

(e) *Standard: Unified and integrated QAPI program for an REH in a multi-*

facility system. If an REH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have a unified and integrated QAPI program for all of its member facilities after determining that such a decision is in accordance with all applicable state and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified REHs meets all of the requirements of this section. Each separately certified REH subject to the system governing body must demonstrate that—

(1) The unified and integrated QAPI program is established in a manner that takes into account each member REH's unique circumstances and any significant differences in patient populations and services offered in each REH; and

(2) The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified REHs, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular REHs are duly considered and addressed.

§ 485.538 Condition of participation: Agreements.

The REH must have in effect an agreement with at least one certified hospital that is a level I or level II trauma center for the referral and transfer of patients requiring emergency medical care beyond the capabilities of the REH that is—

(a) Licensed as a hospital in a state that provides for the licensing of hospitals under state or applicable local law or approved by the agency of such state or locality responsible for licensing hospitals, as meeting standards established for licensing established by the agency of the state; and

(b) Licensed or designated by the state or local government authority as level I or level II trauma center or is verified by the American College of Surgeons as a level I or level II trauma center.

§ 485.540 Condition of participation: Medical records.

(a) *Standard: Records system.* (1) The REH must maintain a medical records system in accordance with written policies and procedures.

(2) The records must be legible, complete, accurately documented,

readily accessible, and systematically organized.

(3) A designated member of the professional staff is responsible for maintaining the records and for ensuring that they are completely and accurately documented, readily accessible, and systematically organized.

(4) For each patient receiving health care services, the REH must maintain a record that includes, as applicable—

(i) Identification and social data, evidence of properly executed informed consent forms, pertinent medical history, assessment of the health status and health care needs of the patient, and a brief summary of the episode, disposition, and instructions to the patient;

(ii) Reports of physical examinations, diagnostic and laboratory test results, including clinical laboratory services, and consultative findings;

(iii) All orders of doctors of medicine or osteopathy or other practitioners, reports of treatments and medications, nursing notes and documentation of complications, and other pertinent information necessary to monitor the patient's progress, such as temperature graphics, progress notes describing the patient's response to treatment; and

(iv) Dated signatures of the doctor of medicine or osteopathy or other health care professional.

(b) *Standard: Protection of record information.* (1) The REH must maintain the confidentiality of record information and provides safeguards against loss, destruction, or unauthorized use.

(2) The REH must have written policies and procedures that govern the use and removal of records from the REH and the conditions for the release of information.

(3) The patient's written consent is required for release of information not required by law.

(c) *Standard: Retention of records.* The records must be retained for at least 5 years from date of last entry, and longer if required by state statute, or if the records may be needed in any pending proceeding.

(d) *Standard: Electronic notifications.* If the REH utilizes an electronic medical records system or other electronic administrative system, which is conformant with the content exchange standard at 45 CFR 170.205(d)(2), then the REH must demonstrate that—

(1) The system's notification capacity is fully operational and the REH uses it in accordance with all state and Federal statutes and regulations applicable to the REH's exchange of patient health information.

(2) The system sends notifications that must include at least patient name, treating practitioner name, and sending institution name.

(3) To the extent permissible under applicable Federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, at the time of the patient's registration in the REH's emergency department.

(4) To the extent permissible under applicable Federal and state law and regulations, and not inconsistent with the patient's expressed privacy preferences, the system sends notifications directly, or through an intermediary that facilitates exchange of health information, either immediately prior to, or at the time the patient's discharge or transfer from the REH's emergency department.

(5) The REH has made a reasonable effort to ensure that the system sends the notifications to all applicable post-acute care services providers and suppliers, as well as to any of the following practitioners and entities, which need to receive notification of the patient's status for treatment, care coordination, or quality improvement purposes:

- (i) The patient's established primary care practitioner;
- (ii) The patient's established primary care practice group or entity; or
- (iii) Other practitioner, or other practice group or entity, identified by the patient as the practitioner, or practice group or entity, primarily responsible for their care.

§ 485.542 Condition of participation: Emergency preparedness.

The REH must comply with all applicable Federal, state, and local emergency preparedness requirements. The REH must establish and maintain an emergency preparedness program that meets the requirements of this section. The emergency preparedness program must include, but not be limited to, the following elements:

(a) *Emergency plan.* The REH must develop and maintain an emergency preparedness plan that must be reviewed, and updated at least every 2 years. The plan must do the following:

- (1) Be based on and include a documented, facility-based and community-based risk assessment, utilizing an all-hazards approach.
- (2) Include strategies for addressing emergency events identified by the risk assessment.

(3) Address patient population, including, but not limited to, the type of services the REH has the ability to provide in an emergency; and continuity of operations, including delegations of authority and succession plans.

(4) Include a process for cooperation and collaboration with local, tribal, regional, state, and Federal emergency preparedness officials' efforts to maintain an integrated response during a disaster or emergency situation.

(b) *Policies and procedures.* The REH must develop and implement emergency preparedness policies and procedures, based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, and the communication plan at paragraph (c) of this section. The policies and procedures must be reviewed and updated at least every 2 years. At a minimum, the policies and procedures must address the following:

(1) The provision of subsistence needs for staff and patients, whether they evacuate or shelter in place, include, but are not limited to—

- (i) Food, water, medical, and pharmaceutical supplies; and
- (ii) Alternate sources of energy to maintain:

(A) Temperatures to protect patient health and safety and for the safe and sanitary storage of provisions;

(B) Emergency lighting;

(C) Fire detection, extinguishing, and alarm systems; and

(D) Sewage and waste disposal.

(2) A system to track the location of on-duty staff and sheltered patients in the REH's care during an emergency. If on-duty staff or sheltered patients are relocated during the emergency, the REH must document the specific name and location of the receiving facility or other location.

(3) Safe evacuation from the REH, which includes the following:

- (i) Consideration of care and treatment needs of evacuees.
- (ii) Staff responsibilities.
- (iii) Transportation.
- (iv) Identification of evacuation location(s).

(v) Primary and alternate means of communication with external sources of assistance.

(4) A means to shelter in place for patients, staff, and volunteers who remain in the REH.

(5) A system of medical documentation that does the following:

- (i) Preserves patient information.
- (ii) Protects confidentiality of patient information.
- (iii) Secures and maintains the availability of records.

(6) The use of volunteers in an emergency and other staffing strategies, including the process and role for integration of state and federally designated health care professionals to address surge needs during an emergency.

(7) The role of the REH under a waiver declared by the Secretary, in accordance with section 1135 of the Act, in the provision of care and treatment at an alternate care site identified by emergency management officials.

(c) *Communication plan.* The REH must develop and maintain an emergency preparedness communication plan that complies with Federal, state, and local laws and must be reviewed and updated at least every 2 years. The communication plan must include all of the following:

(1) Names and contact information for the following:

(i) Staff.

(ii) Entities providing services under arrangement.

(iii) Patients' physicians.

(iv) Volunteers.

(2) Contact information for the following:

(i) Federal, state, tribal, regional, and local emergency preparedness staff.

(ii) Other sources of assistance.

(3) Primary and alternate means for communicating with the following:

(i) REH's staff.

(ii) Federal, state, tribal, regional, and local emergency management agencies.

(4) A method for sharing information and medical documentation for patients under the REH's care, as necessary, with other health care providers to maintain the continuity of care.

(5) A means, in the event of an evacuation, to release patient information as permitted under 45 CFR 164.510(b)(1)(ii).

(6) A means of providing information about the general condition and location of patients under the facility's care as permitted under 45 CFR 164.510(b)(4).

(7) A means of providing information about the REH's needs, and its ability to provide assistance, to the authority having jurisdiction, the Incident Command Center, or designee.

(d) *Training and testing.* The REH must develop and maintain an emergency preparedness training and testing program that is based on the emergency plan set forth in paragraph (a) of this section, risk assessment at paragraph (a)(1) of this section, policies and procedures at paragraph (b) of this section, and the communication plan at paragraph (c) of this section. The training and testing program must be reviewed and updated at least every 2 years.

(1) *Training program.* The REH must do all of the following:

(i) Provide initial training in emergency preparedness policies and procedures to all new and existing staff, individuals providing on-site services under arrangement, and volunteers, consistent with their expected roles.

(ii) Provide emergency preparedness training at least every 2 years.

(iii) Maintain documentation of all emergency preparedness training.

(iv) Demonstrate staff knowledge of emergency procedures.

(v) If the emergency preparedness policies and procedures are significantly updated, the REH must conduct training on the updated policies and procedures.

(2) *Testing.* The REH must conduct exercises to test the emergency plan at least annually. The REH must do the following:

(i) Participate in a full-scale exercise that is community-based every 2 years.

(A) When a community-based exercise is not accessible, conduct a facility-based functional exercise every 2 years; or

(B) If the REH experiences an actual natural or man-made emergency that requires activation of the emergency plan, the REH is exempt from engaging in its next required community-based or individual, facility-based functional exercise following the onset of the emergency event.

(ii) Conduct an additional exercise at least every 2 years, opposite the year the full-scale or functional exercise under paragraph (d)(2)(i) of this section is conducted, that may include, but is not limited to the following:

(A) A second full-scale exercise that is community-based, or an individual, facility-based functional exercise; or

(B) A mock disaster drill; or

(C) A tabletop exercise or workshop that is led by a facilitator and includes a group discussion using a narrated, clinically-relevant emergency scenario, and a set of problem statements, directed messages, or prepared questions designed to challenge an emergency plan.

(iii) Analyze the REH's response to and maintain documentation of all drills, tabletop exercises, and emergency events and revise the REH's emergency plan, as needed.

(e) *Emergency and standby power systems.* The CAH must implement emergency and standby power systems based on the emergency plan set forth in paragraph (a) of this section.

(1) *Emergency generator location.* The generator must be located in accordance with the location requirements found in the Health Care Facilities Code (National Fire Protection Association

(NFPA) 99 and Technical Interim Amendments (TIA) 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6), Life Safety Code (NFPA 101 and TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4), and NFPA 110, when a new structure is built or when an existing structure or building is renovated.

(2) *Emergency generator inspection and testing.* The CAH must implement emergency power system inspection and testing requirements found in the Health Care Facilities Code, NFPA 110, and the Life Safety Code.

(3) *Emergency generator fuel.* CAHs that maintain an onsite fuel source to power emergency generators must have a plan for how it will keep emergency power systems operational during the emergency, unless it evacuates.

(f) *Integrated healthcare systems.* If an REH is part of a healthcare system consisting of multiple separately certified healthcare facilities that elects to have a unified and integrated emergency preparedness program, the REH may choose to participate in the healthcare system's coordinated emergency preparedness program. If elected, the unified and integrated emergency preparedness program must—

(1) Demonstrate that each separately certified facility within the system actively participated in the development of the unified and integrated emergency preparedness program.

(2) Be developed and maintained in a manner that takes into account each separately certified facility's unique circumstances, patient populations, and services offered.

(3) Demonstrate that each separately certified facility is capable of actively using the unified and integrated emergency preparedness program and is in compliance.

(4) Include a unified and integrated emergency plan that meets the requirements of paragraphs (a)(2) through (4) of this section. The unified and integrated emergency plan must also be based on and include the following:

(i) A documented community-based risk assessment, utilizing an all-hazards approach.

(ii) A documented individual facility-based risk assessment for each separately certified facility within the health system, utilizing an all-hazards approach.

(5) Include integrated policies and procedures that meet the requirements set forth in paragraph (b) of this section, a coordinated communication plan and training and testing programs that meet the requirements of paragraphs (c) and (d) of this section, respectively.

(g) *Incorporation by reference.* The material listed in this paragraph (g) is approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the CMS must publish a document in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at: CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD 21244. For information on the availability of this material at NARA, email: fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html. The material may be obtained from: National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02169; phone: (617) 770-3000; www.nfpa.org.

(1) NFPA 99, Health Care Facilities Code, 2012 edition, issued August 11, 2011.

(2) Technical interim amendment (TIA) 12–2 to NFPA 99, issued August 11, 2011.

(3) TIA 12–3 to NFPA 99, issued August 9, 2012.

(4) TIA 12–4 to NFPA 99, issued March 7, 2013.

(5) TIA 12–5 to NFPA 99, issued August 1, 2013.

(6) TIA 12–6 to NFPA 99, issued March 3, 2014.

(7) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011.

(8) TIA 12–1 to NFPA 101, issued August 11, 2011.

(9) TIA 12–2 to NFPA 101, issued October 30, 2012.

(10) TIA 12–3 to NFPA 101, issued October 22, 2013.

(11) TIA 12–4 to NFPA 101, issued October 22, 2013.

(12) NFPA 110, Standard for Emergency and Standby Power Systems, 2010 edition, including TIAs to chapter 7, issued August 6, 2009.

§ 485.544 Condition of participation: Physical environment.

The REH must be constructed, arranged, and maintained to ensure the safety of the patient, and to provide facilities for diagnosis and treatment and for special services appropriate to the needs of the community.

(a) *Standard: Buildings.* The condition of the physical plant and the overall REH environment must be developed and maintained in such a manner that the safety and well-being of patients are ensured.

(1) There must be emergency power and lighting in at least the operating, recovery, and emergency rooms, and stairwells. In all other areas not serviced by the emergency supply source, battery lamps and flashlights must be available.

(2) There must be facilities for emergency gas and water supply.

(3) The REH must have a safe and sanitary environment, properly constructed, equipped, and maintained to protect the health and safety of patients.

(b) *Standard: Facilities.* The REH must maintain adequate facilities for its services.

(1) Diagnostic and therapeutic facilities must be located for the safety of patients.

(2) Facilities, supplies, and equipment must be maintained to ensure an acceptable level of safety and quality.

(3) The extent and complexity of facilities must be determined by the services offered.

(4) There must be proper ventilation, light, and temperature controls in patient care, pharmaceutical, food preparation, and other appropriate areas.

(c) *Standard: Safety from fire.* (1) Except as otherwise provided in this section, the REH must meet the provisions applicable to Ambulatory Health Care Occupancies, regardless of the number of patients served, and must proceed in accordance with the Life Safety Code (NFPA 101 and TIA 12–1, TIA 12–2, TIA 12–3, and TIA 12–4).

(2) In consideration of a recommendation by the state survey agency or Accrediting Organization or at the discretion of the Secretary, may waive, for periods deemed appropriate, specific provisions of the Life Safety Code, which would result in unreasonable hardship upon an REH, but only if the waiver will not adversely affect the health and safety of the patients.

(3) The provisions of the Life Safety Code do not apply in a state if CMS finds that a fire and safety code imposed by state law adequately protects patients in an REH.

(4) An REH may place alcohol-based hand rub dispensers in its facility if the dispensers are installed in a manner that adequately protects against inappropriate access.

(5) When a sprinkler system is shut down for more than 10 hours, the REH must:

(i) Evacuate the building or portion of the building affected by the system outage until the system is back in service; or

(ii) Establish a fire watch until the system is back in service.

(d) *Standard: Building safety.* Except as otherwise provided in this section, the REH must meet the applicable provisions and must proceed in accordance with the 2012 edition of the Health Care Facilities Code (NFPA 99 and TIA 12–2, TIA 12–3, TIA 12–4, TIA 12–5, and TIA 12–6).

(1) Chapters 7, 8, 12, and 13 of the adopted Health Care Facilities Code do not apply to an REH.

(2) If application of the Health Care Facilities Code required under paragraph (d) of this section would result in unreasonable hardship for the REH, CMS may waive specific provisions of the Health Care Facilities Code, but only if the waiver does not adversely affect the health and safety of patients.

(e) *Incorporation by reference.* The material listed in this paragraph (e) is approved for incorporation by reference by the Director of the Office of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. To enforce any edition other than that specified in this section, the CMS must publish a document in the **Federal Register** and the material must be available to the public. All approved material is available for inspection at CMS and at the National Archives and Records Administration (NARA). Contact CMS at: CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD 21244. For information on the availability of this material at NARA, email: fr.inspection@nara.gov, or go to: www.archives.gov/federal-register/cfr/ibr-locations.html. The material may be obtained from: National Fire Protection Association (NFPA), 1 Batterymarch Park, Quincy, MA 02169; phone: (617) 770–3000; www.nfpa.org.

(1) NFPA 99, Standards for Health Care Facilities Code of the National Fire Protection Association 99, 2012 edition, issued August 11, 2011.

(2) TIA 12–2 to NFPA 99, issued August 11, 2011.

(3) TIA 12–3 to NFPA 99, issued August 9, 2012.

(4) TIA 12–4 to NFPA 99, issued March 7, 2013.

(5) TIA 12–5 to NFPA 99, issued August 1, 2013.

(6) TIA 12–6 to NFPA 99, issued March 3, 2014.

(7) NFPA 101, Life Safety Code, 2012 edition, issued August 11, 2011;

(8) TIA 12–1 to NFPA 101, issued August 11, 2011.

(9) TIA 12–2 to NFPA 101, issued October 30, 2012.

(10) TIA 12–3 to NFPA 101, issued October 22, 2013.

(11) TIA 12–4 to NFPA 101, issued October 22, 2013.

§ 485.546 Condition of participation: Skilled nursing facility distinct part unit.

If the REH provides skilled nursing facility services in a distinct part unit, the services furnished by the distinct part unit must comply with the requirements of participation for long-term care facilities specified in part 483, subpart B, of this subchapter.

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

■ 3. Section 485.610 is amended by revising paragraph (c) to read as follows:

§ 485.610 Condition of participation: Status and location.

* * * * *

(c) *Standard: Location relative to other facilities or necessary provider certification.* (1) The CAH is located more than a 35-mile drive on primary roads (or, in the case of mountainous terrain or in areas with only secondary roads available, a 15-mile drive) from a hospital or another CAH, or before January 1, 2006, the CAH is certified by the State as being a necessary provider of health care services to residents in the area. A CAH that is designated as a necessary provider on or before December 31, 2005, will maintain its necessary provider designation after January 1, 2006.

(2) Primary roads of travel for determining the driving distance of a CAH and its proximity to other providers is defined as:

(i) A numbered Federal highway, including interstates, intrastates, expressways, or any other numbered Federal highway; or

(ii) A numbered State highway with 2 or more lanes each way.

* * * * *

■ 4. Section 485.614 is added to read as follows:

§ 485.614 Condition of participation: Patient's rights.

A CAH must protect and promote each patient's rights.

(a) *Standard: Notice of rights.* (1) A hospital must inform each patient, or when appropriate, the patient's representative (as allowed under State law), of the patient's rights, in advance of furnishing or discontinuing patient care whenever possible.

(2) The hospital must establish a process for prompt resolution of patient grievances and must inform each patient whom to contact to file a grievance. The hospital's governing body must approve and be responsible for the effective

operation of the grievance process and must review and resolve grievances, unless it delegates the responsibility in writing to a grievance committee. The grievance process must include a mechanism for timely referral of patient concerns regarding quality of care or premature discharge to the appropriate Utilization and Quality Control Quality Improvement Organization. At a minimum:

(i) The hospital must establish a clearly explained procedure for the submission of a patient's written or verbal grievance to the hospital.

(ii) The grievance process must specify time frames for review of the grievance and the provision of a response.

(iii) In its resolution of the grievance, the hospital must provide the patient with written notice of its decision that contains the name of the hospital contact person, the steps taken on behalf of the patient to investigate the grievance, the results of the grievance process, and the date of completion.

(b) *Standard: Exercise of rights.* (1) The patient has the right to participate in the development and implementation of their plan of care.

(2) The patient or their representative (as allowed under State law) has the right to make informed decisions regarding their care. The patient's rights include being informed of their health status, being involved in care planning and treatment, and being able to request or refuse treatment. This right must not be construed as a mechanism to demand the provision of treatment or services deemed medically unnecessary or inappropriate.

(3) The patient has the right to formulate advance directives and to have hospital staff and practitioners who provide care in the hospital comply with these directives, in accordance with §§ 489.100, 489.102, and 489.104 of this chapter.

(4) The patient has the right to have a family member or representative of their choice and their own physician notified promptly of their admission to the hospital.

(c) *Standard: Privacy and safety.* (1) The patient has the right to personal privacy.

(2) The patient has the right to receive care in a safe setting.

(3) The patient has the right to be free from all forms of abuse or harassment.

(d) *Standard: Confidentiality of patient records.* (1) The patient has the right to the confidentiality of their clinical records.

(2) The patient has the right to access their medical records, including current medical records, upon an oral or written

request, in the form and format requested by the individual, if it is readily producible in such form and format (including in an electronic form or format when such medical records are maintained electronically); or, if not, in a readable hard copy form or such other form and format as agreed to by the facility and the individual, and within a reasonable time frame. The hospital must not frustrate the legitimate efforts of individuals to gain access to their own medical records and must actively seek to meet these requests as quickly as its record keeping system permits.

(e) *Standard: Restraint or seclusion.* All patients have the right to be free from physical or mental abuse, and corporal punishment. All patients have the right to be free from restraint or seclusion, of any form, imposed as a means of coercion, discipline, convenience, or retaliation by staff. Restraint or seclusion may only be imposed to ensure the immediate physical safety of the patient, a staff member, or others and must be discontinued at the earliest possible time.

(1)(i) A *restraint* is—

(A) Any manual method, physical or mechanical device, material, or equipment that immobilizes or reduces the ability of a patient to move their arms, legs, body, or head freely; or

(B) A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.

(C) A restraint does not include devices, such as orthopedically prescribed devices, surgical dressings or bandages, protective helmets, or other methods that involve the physical holding of a patient for the purpose of conducting routine physical examinations or tests, or to protect the patient from falling out of bed, or to permit the patient to participate in activities without the risk of physical harm (this does not include a physical escort).

(ii) *Seclusion* is the involuntary confinement of a patient alone in a room or area from which the patient is physically prevented from leaving. Seclusion may only be used for the management of violent or self-destructive behavior.

(2) Restraint or 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.

(3) 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.

(4) The CAH must have written policies and procedures regarding the use of restraint and seclusion that are consistent with current standards of practice.

(f) *Standard: Restraint or seclusion: Staff training requirements.* The patient has the right to safe implementation of restraint or seclusion by trained staff.

(1) The CAH must provide patient-centered, trauma informed competency-based training and education of CAH personnel and staff, including medical staff, and, as applicable, personnel providing contracted services in the CAH, on the use of restraint and seclusion.

(2) The training must include alternatives to the use of restraint/seclusion.

(g) *Standard: Death reporting requirements.* Hospitals must report deaths associated with the use of seclusion or restraint.

(1) With the exception of deaths described under paragraph (g)(2) of this section, the hospital must report the following information to CMS by telephone, facsimile, or electronically, as determined by CMS, no later than the close of business on the next business day following knowledge of the patient's death:

(i) Each death that occurs while a patient is in restraint or seclusion.

(ii) Each death that occurs within 24 hours after the patient has been removed from restraint or seclusion.

(iii) Each death known to the hospital that occurs within 1 week after restraint or seclusion where it is reasonable to assume that use of restraint or placement in seclusion contributed directly or indirectly to a patient's death, regardless of the type(s) of restraint used on the patient during this time. "Reasonable to assume" in this context includes, but is not limited to, deaths related to restrictions of movement for prolonged periods of time, or death related to chest compression, restriction of breathing, or asphyxiation.

(2) When no seclusion has been used and when the only restraints used on the patient are those applied exclusively to the patient's wrist(s), and which are composed solely of soft, non-rigid, cloth-like materials, the hospital staff must record in an internal log or other system, the following information:

(i) Any death that occurs while a patient is in such restraints.

(ii) Any death that occurs within 24 hours after a patient has been removed from such restraints.

(3) The staff must document in the patient's medical record the date and time the death was:

(i) Reported to CMS for deaths described in paragraph (g)(1) of this section; or

(ii) Recorded in the internal log or other system for deaths described in paragraph (g)(2) of this section.

(4) For deaths described in paragraph (g)(2) of this section, entries into the internal log or other system must be documented as follows:

(i) Each entry must be made not later than seven days after the date of death of the patient.

(ii) Each entry must document the patient's name, date of birth, date of death, name of attending physician or other licensed practitioner who is responsible for the care of the patient, medical record number, and primary diagnosis(es).

(iii) The information must be made available in either written or electronic form to CMS immediately upon request.

(h) *Standard: Patient visitation rights.* A CAH must have written policies and procedures regarding the visitation rights of patients, including those setting forth any clinically necessary or reasonable restriction or limitation that the CAH may need to place on such rights and the reasons for the clinical restriction or limitation. A CAH must meet the following requirements:

(1) Inform each patient (or support person, where appropriate) of his or her visitation rights, including any clinical restriction or limitation on such rights, in advance of furnishing patient care whenever possible.

(2) Inform each patient (or support person, where appropriate) of the right, subject to his or her consent, to receive the visitors whom he or she designates, including, but not limited to, a spouse, a domestic partner (including a same-sex domestic partner), another family member, or a friend, and his or her right to withdraw or deny such consent at any time.

(3) Not restrict, limit, or otherwise deny visitation privileges on the basis of race, color, national origin, religion, sex, gender identity, sexual orientation, or disability.

(4) Ensure that all visitors enjoy full and equal visitation privileges consistent with patient preferences.

■ 5. Section 485.631 is amended by adding paragraph (e) to read as follows:

§ 485.631 Condition of participation: Staffing and staff responsibilities.

* * * * *

(e) *Standard: Unified and integrated medical staff for a CAH in a multi-facility system.* If a CAH is part of a

system consisting of multiple separately certified hospitals, CAHs, and/or REHs, and the system elects to have a unified and integrated medical staff for its member hospitals, CAHs, and/or REHs after determining that such a decision is in accordance with all applicable State and local laws, each separately certified CAH must demonstrate that:

(1) The medical staff members of each separately certified CAH in the system (that is, all medical staff members who hold specific privileges to practice at that CAH) have voted by majority, in accordance with medical staff bylaws, either to accept a unified and integrated medical staff structure or to opt out of such a structure and to maintain a separate and distinct medical staff for their respective CAH;

(2) The unified and integrated medical staff has bylaws, rules, and requirements that describe its processes for self-governance, appointment, credentialing, privileging, and oversight, as well as its peer review policies and due process rights guarantees, and which include a process for the members of the medical staff of each separately certified CAH (that is, all medical staff members who hold specific privileges to practice at that CAH) to be advised of their rights to opt out of the unified and integrated medical staff structure after a majority vote by the members to maintain a separate and distinct medical staff for their CAH;

(3) The unified and integrated medical staff is established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each hospital, CAH, and REH; and

(4) The unified and integrated medical staff establishes and implements policies and procedures to ensure that the needs and concerns expressed by members of the medical staff, at each of its separately certified hospitals, CAHs, and REHs, regardless of practice or location, are given due consideration, and that the unified and integrated medical staff has mechanisms in place to ensure that issues localized to particular hospitals, CAHs, and REHs are duly considered and addressed.

§ 485.635 [Amended]

■ 6. Section 485.635 is amended—

■ a. In paragraph (b)(2) introductory text by removing the reference “42 U.S.C. 236a” and adding in its place the reference “42 U.S.C. 263a”; and

■ b. By removing paragraph (f).

■ 7. Section 485.640 is amended by adding paragraph (g) to read as follows:

§ 485.640 Condition of participation: Infection prevention and control and antibiotic stewardship programs.

* * * * *

(g) *Standard: Unified and integrated infection prevention and control and antibiotic stewardship programs for a CAH in a multi-facility system.* If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have unified and integrated infection prevention and control and antibiotic stewardship programs for all of its member facilities after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified CAHs meets all of the requirements of this section. Each separately certified CAH subject to the system governing body must demonstrate that:

(1) The unified and integrated infection prevention and control and antibiotic stewardship programs are established in a manner that takes into account each member CAH's unique circumstances and any significant differences in patient populations and services offered in each CAH;

(2) The unified and integrated infection prevention and control and antibiotic stewardship programs establish and implement policies and procedures to ensure that the needs and concerns of each of its separately certified CAHs, regardless of practice or location, are given due consideration;

(3) The unified and integrated infection prevention and control and antibiotic stewardship programs have mechanisms in place to ensure that issues localized to particular CAHs are duly considered and addressed; and

(4) A qualified individual (or individuals) with expertise in infection prevention and control and in antibiotic stewardship has been designated at the CAH as responsible for communicating with the unified infection prevention and control and antibiotic stewardship programs, for implementing and maintaining the policies and procedures governing infection prevention and control and antibiotic stewardship as directed by the unified infection prevention and control and antibiotic stewardship programs, and for providing education and training on the practical applications of infection prevention and control and antibiotic stewardship to CAH staff.

■ 8. Section 485.641 is amended by adding paragraph (f) to read as follows:

§ 485.641 Condition of participation: Quality assessment and performance improvement program.

* * * * *

(f) Standard: Unified and integrated QAPI program for a CAH in a multi-facility system. If a CAH is part of a system consisting of multiple separately certified hospitals, CAHs, and/or REHs using a system governing body that is legally responsible for the conduct of two or more hospitals, CAHs, and/or REHs, the system governing body can elect to have a unified and integrated QAPI program for all of its member facilities after determining that such a decision is in accordance with all applicable State and local laws. The system governing body is responsible and accountable for ensuring that each of its separately certified CAHs meets all of the requirements of this section. Each separately certified CAH subject to the system governing body must demonstrate that:

(1) The unified and integrated QAPI program is established in a manner that takes into account each member CAH's unique circumstances and any

significant differences in patient populations and services offered in each CAH; and

(2) The unified and integrated QAPI program establishes and implements policies and procedures to ensure that the needs and concerns of each of its separately certified CAHs, regardless of practice or location, are given due consideration, and that the unified and integrated QAPI program has mechanisms in place to ensure that issues localized to particular CAHs are duly considered and addressed.

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 9. The authority citation for part 489 continues to read as follows:

Authority: 42 U.S.C. 1302, 1395i-3, 1395x, 1395aa(m), 1395cc, 1395ff, and 1395hh.

■ 10. Section 489.2 is amended by adding paragraph (b)(11) to read as follows:

§ 489.2 Scope of part.

* * * * *

(b) * * *

(11) Rural emergency hospitals (REHs).

* * * * *

■ 11. Section 489.24 is amended in paragraph (b) by revising the definitions of "Hospital" and "Participating hospital" to read as follows:

§ 489.24 Special responsibilities of Medicare hospitals in emergency cases.

* * * * *

(b) * * *

Hospital includes a critical access hospital as defined in section 1861(mm)(1) of the Act and a rural emergency hospital as defined in section 1861(kkk)(2).

* * * * *

Participating hospital means:

- (1) A hospital;
(2) A critical access hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act; or

- (3) A rural emergency hospital as defined in section 1861(kkk)(2) of the Act.

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Xavier Becerra,

Secretary, Department of Health and Human Services.

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