CMS Has Yet To Enforce A Statutory Provision Related To Rural Health Clinics
EXECUTIVE SUMMARY: CMS HAS YET TO ENFORCE A STATUTORY PROVISION RELATED TO RURAL HEALTH CLINICS
OEI-05-13-00290

WHY WE DID THIS STUDY
The Rural Health Clinic (RHC) certification was created in 1977 to address the shortage of physicians in rural areas. RHCs had to meet two location requirements: (1) being located in rural areas and (2) being located in areas that have a shortage of health care providers. RHCs receive enhanced Medicare and Medicaid reimbursements for most services.

Prior to the enactment of the Balanced Budget Act of 1997 (BBA), RHCs retained their certifications indefinitely. However, the BBA removed their permanent status and allowed for the termination of RHCs that no longer met the location requirements as long as they were not determined to be “essential provider” RHCs.

A 2005 Office of Inspector General report found that nearly 300 RHCs did not meet the location requirements and that the Centers for Medicare & Medicaid Services (CMS) had not issued regulations that would allow RHCs to apply as essential-provider RHCs.

HOW WE DID THIS STUDY
We plotted RHC locations onto a digital map to determine whether RHCs met the two location requirements in 2013. Additionally, we used 2012 claims data to calculate the amount Medicare paid to the RHCs we determined did not meet the location requirements. Finally, we reviewed Federal regulations and interviewed CMS staff to determine whether essential-provider criteria had been established or were in the process of being established.

WHAT WE FOUND
Approximately 12 percent of RHCs no longer met the location requirements in 2013. Pursuant to the BBA, these RHCs should continue to qualify as RHCs—and receive enhanced reimbursement—only if they are determined to be essential providers. However, CMS has yet to issue final regulations that would allow RHCs that do not meet the location requirements to qualify as essential-provider RHCs.

WHAT WE RECOMMEND
More than 16 years have elapsed since Congress directed CMS to issue regulations that would allow RHCs that no longer meet location criteria to qualify as essential providers. Without these regulations, CMS can neither terminate RHCs nor identify them as essential providers in accordance with the BBA provision. Consequently, RHCs that no longer meet location criteria continue to receive enhanced reimbursement. To ensure that CMS can enforce the BBA provisions relating to RHCs, we recommend that CMS issue regulations to ensure that RHCs determined to be essential providers remain certified as RHCs. CMS responded to the report but neither concurred nor nonconcurred with our recommendation.
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OBJECTIVES

1. To determine the extent to which Rural Health Clinics (RHCs) no longer meet the location requirements.

2. To determine whether the Centers for Medicare & Medicaid Services (CMS) has taken steps to address a prior Office of Inspector General (OIG) recommendation to issue regulations defining the criteria for RHCs to be deemed “essential providers.”

BACKGROUND

Rural Health Clinics

The RHC certification was created in 1977 to address the shortage of physicians in rural areas by providing enhanced reimbursement. To ensure that RHCs could be located only in rural areas with documented physician shortages, CMS specified two location-based criteria (hereinafter known as the location requirements) in the RHC Conditions of Participation. RHCs had to be (1) located in nonurbanized areas, as defined by the Census Bureau (hereafter referred to as rural areas), and (2) located in one of the following types of health care shortage areas, as defined by the Health Resources and Services Administration (HRSA):

- Primary Care Geographic Health Professional Shortage Area (HPSA)
- Primary Care Population Group HPSA
- Medically Underserved Area (MUA)
- Governor-designated and Secretary-certified shortage area under the Omnibus Budget Reconciliation Act of 1989

For a detailed description of each type of shortage area, see Appendix A.

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2 Conditions of Participation are requirements that providers must meet to participate in Medicare.
3 Social Security Act, § 1861(aa)(2); 42 U.S.C. § 1395x(aa)(2); CMS, Rural Health Clinic: Rural Health Fact Sheet Series, January 2013. HPSAs are subject to annual reviews (76 Fed. Reg. 68198 (Nov. 3, 2011)). MUAs are not subject to regular reviews (Negotiated Rulemaking Committee on the Designation of Medically Underserved Populations and Health Professional Shortage Areas: Final Report to the Secretary, October 31, 2011, p.18).
5 PHS Act, § 332(a)(1)(B).
6 PHS Act, § 330(b)(3).
7 Section 6213(c).
Most of the information that the RHC location requirements draw on is updated periodically. Census-defined urbanized areas are updated every 10 years, following the decennial Census. HPSAs are updated approximately once every 4 years; HRSA prioritizes designations that are more than 3 years old for recertification. Currently, MUAs are never updated.

RHCs receive enhanced reimbursements from Medicare and Medicaid. These enhanced reimbursements are based on costs. Medicare reimbursements to RHCs are subject to a per-visit payment limit, which was approximately $80 in 2013. Per-visit Medicare payment limits do not apply to RHCs that are part of a hospital with fewer than 50 beds.

In 2013, there were 4,019 RHCs providing services in 44 States in the United States. Medicare and beneficiaries paid approximately $1 billion for services provided at these RHCs.

**Creation of “Essential Provider” RHCs**

In 1996, both OIG and the Government Accountability Office (GAO) recommended that CMS ensure that the RHC certification apply only to facilities in areas that would otherwise be underserved, rather than in rural areas that are designated as health care shortage areas but have high concentrations of medical providers.

In response to the OIG and GAO recommendations, the Balanced Budget Act of 1997 (BBA) removed RHCs’ permanent status and allowed for the creation of an exemption process for RHCs that would otherwise be

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10 Negotiated Rulemaking Committee on the Designation of Medically Underserved Populations and Health Professional Shortage Areas: Final Report to the Secretary, October 31, 2011, p. 18. In March 2014, HRSA staff stated that they are in the process of promulgating an interim final rule that would set a recertification schedule for MUAs.


terminated from the Medicare program. Prior to the BBA, RHCs that initially met the location requirements retained their RHC certifications indefinitely, effectively making the RHC certification permanent. The BBA specified the RHCs that were in areas that no longer qualified as nonurbanized areas or shortage areas would continue to qualify as RHCs only if they were determined to be “essential to the delivery of primary care services that would otherwise be unavailable in the geographic area served by the clinics” (hereafter referred to as essential-provider RHCs). Further, the BBA specified that the Secretary of Health and Human Services should issue regulations that would establish the criteria used to determine essential-provider RHCs, and that those regulations should take effect no later than January 1, 1999.

Rulemaking Process

Agencies like CMS must follow the Administrative Procedure Act, which governs rulemaking. Typically, an agency must publish a proposed rule in the Federal Register and invite the public to comment on it. The agency uses the proposed rule and public comments as the basis for the final rule, which it publishes—along with the date the rule goes into effect—in the Federal Register.

The Medicare Prescription Drug, Improvement, and Modernization Act (MMA), which became law on December 8, 2003, made a change to the rulemaking process for all agencies within the Department of Health and Human Services, including CMS. Specifically, the MMA established that no more than 3 years may pass between the publication of a proposed rule or interim final and the publication of a final rule except under exceptional circumstances. In the event of such circumstances, a notice of the different timeline must be published in the Federal Register.

Related Work

OIG has a body of work that examines the location of RHCs. In addition to its 1996 report, OIG issued a report in 2005 that found that, in 2003, 279 RHCs were not located in rural areas or in health care shortage areas and that RHCs were often located near other health care providers. OIG recommended on the basis of these findings that CMS issue regulations

16 Balanced Budget Act of 1997, P.L. No. 105-33 § 4205(d)(3)(A). New RHCs are still required to meet the original location requirements—that is, they must be located in rural areas and in designated health care shortage areas.
defining essential-provider criteria for RHCs. In its May 2005 comments on our report, CMS concurred with the recommendation and stated that it intended to issue new rules for RHCs in early 2006.

METHODOLOGY

Scope
We analyzed RHC locations to identify those that in 2013 were no longer located in rural areas or in health care shortage areas. We excluded RHCs with locations that we were unable to confidently determine. We also calculated the amount that Medicare and beneficiaries paid to RHCs in 2012.

We focused on the 2005 OIG report’s recommendation that CMS issue regulations defining essential-provider criteria for RHCs.

Data Collection and Analysis
We requested from HRSA a list of RHC addresses and corresponding latitudes and longitudes. HRSA created this list using a three-step process: (1) compiling addresses for all RHCs enrolled in Medicare in 2013, using CMS’s Certification and Survey Provider Enhanced Reports (CASPER); (2) running these addresses through the address standardizer Trillium 13.5;21,22 and (3) identifying latitudes and longitudes for these standardized addresses using Esri’s StreetMap Premium 2013.23 There were 4,019 RHCs on this list.

We excluded 498 RHCs from our analysis because they were geocoded only to the city, State, or ZIP Code level, rather than to the address level.24 We felt that these levels of geocoding were not precise enough to determine whether these RHCs met the location requirements.

We mapped the latitudes and longitudes of the remaining 3,521 RHCs onto a digital map using ArcGIS. We used this map, along with the 2013 boundaries of urbanized areas and health care shortage areas, to identify RHCs that did not meet the location requirements.

21 The CASPER database includes data generated from certification surveys and includes information such as provider addresses and enrollment dates.
22 Trillium 13.5 standardizes name and address elements and corrects spelling and other errors.
23 StreetMap Premium is an enriched street dataset that works with Esri’s ArcGIS software to allow for geocoding, routing, and turn-by-turn directions. Geocoding is the process of turning standard addresses into latitude and longitude coordinates.
24 These 498 RHCs had complete addresses but the geocoding software could map their locations with confidence only to the center of a city, State, or ZIP Code.
Using data from CMS’s 2012 Outpatient Standard Analytic Files—the most recent complete claims data—we calculated the amount Medicare and beneficiaries paid to RHCs that did not meet the location requirements.

Finally, we reviewed Federal regulations and interviewed CMS staff to determine whether essential-provider criteria had been established or were in the process of being established.

**Standards**

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.
**FINDINGS**

Approximately 12 percent of RHCs no longer meet the location requirements

Of the 3,521 RHCs included in our analysis, 434 no longer meet the location requirements. Fifty-nine percent of these RHCs are located in areas not designated as shortage areas. Another 39 percent of these RHCs are located in urbanized areas. The final 2 percent were located in areas that were neither rural nor designated as shortage areas. Medicare and beneficiaries paid approximately $132 million to these RHCs in 2012. Table 1 provides the number of RHCs that do not meet the location requirements and the amounts paid by Medicare and beneficiaries in 2012.

Table 1: Number of RHCs that did not meet the location requirements and amounts paid to them by Medicare and beneficiaries

<table>
<thead>
<tr>
<th>Characteristics of RHCs that did not meet the location requirements</th>
<th>Number of RHCs</th>
<th>Amount paid by Medicare and beneficiaries to these RHCs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Located in a rural area but not in a health care shortage area</td>
<td>257</td>
<td>$84.6 million</td>
</tr>
<tr>
<td>Located in a health care shortage area but not in a rural area</td>
<td>169</td>
<td>$46.7 million</td>
</tr>
<tr>
<td>Located in neither a health care shortage area nor a rural area</td>
<td>8</td>
<td>$0.8 million</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>434</strong></td>
<td><strong>$132.1 million</strong></td>
</tr>
</tbody>
</table>


The number of RHCs that no longer meet the location requirements has increased by approximately 56 percent since 2003, when OIG found that 279 RHCs did not meet the location requirements.

RHCs may no longer meet location requirements because health care shortage areas and urbanized areas change periodically. HPSAs are updated approximately every 4 years; urbanized areas are updated every 10 years, following the decennial Census.

Pursuant to the BBA, RHCs that no longer meet the location requirements should continue to qualify as RHCs only if they are determined to be essential providers.

**CMS has yet to issue final regulations that would allow RHCs that do not meet the location requirements to qualify as essential providers**

Sixteen years have passed since Congress directed CMS to issue regulations outlining the criteria that RHCs could use to qualify as essential providers, and CMS has not finalized such regulations. CMS has
twice promulgated proposed rules, but neither rule was finalized by the Department of Health and Human Services. There remains no final rule establishing essential-provider criteria for RHCs. As such, RHCs continue to operate without the option to apply as essential providers.

In addition, the CMS staff who are responsible for developing and overseeing RHC-related policies state that they are not currently planning to reissue the more recent of the two proposed rules or to develop a replacement. Because CMS did not finalize the most recent proposed rule within 3 years of its publication date, the agency would need to reissue the proposed rule and go through the rulemaking process again.
More than 16 years have elapsed since Congress directed CMS to issue regulations to ensure that only RHCs determined to be essential providers remain certified as RHCs, and more than 8 years have elapsed since CMS told OIG that it planned to issue the regulations. Although CMS has promulgated proposed rules regarding essential-provider criteria for RHCs, it has yet to publish a final rule establishing these criteria. Meanwhile, the number of RHCs that do not meet the location requirement has increased by 56 percent since 2003.

To ensure that CMS can enforce the BBA provisions relating to RHCs, we recommend that CMS:

**Issue regulations to ensure that RHCs determined to be essential providers remain certified as RHCs.**

The BBA requires that RHCs that no longer meet the location requirements and that are not determined to be essential providers be terminated from the program. However, CMS has yet to issue regulations defining essential-provider criteria for RHCs; consequently, all RHCs remain certified as RHCs and continue to receive enhanced Medicare and Medicaid reimbursements. CMS should issue these regulations so that only RHCs determined to be essential providers continue to receive enhanced reimbursements.
AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

CMS responded to the report but neither concurred nor nonconcurred with our recommendation.

We continue to encourage CMS to issue regulations to ensure that RHCs determined to be essential providers remain certified as RHCs, as doing so will help protect Medicare and Medicaid dollars from going to providers that no longer qualify for the enhanced reimbursements that RHCs receive. Without regulations that define essential provider criteria, all RHCs—including those that no longer meet the location requirements—remain certified and continue to receive enhanced Medicare and Medicaid reimbursements. We will routinely follow up with CMS about implementing this recommendation.

For the full text of CMS’s comments, see Appendix B.
APPENDIX A

Definitions and Criteria for Health Care Shortage Areas

1. A Primary Care Geographic Health Professional Shortage Area (HPSA) must:
   o Be a rational area for the delivery of primary care medical services;
   o Meet one of the following conditions:
     ▪ Have a population to full-time-equivalent primary care physician ratio of at least 3,500:1, or
     ▪ Have a population to full-time-equivalent primary care physician ratio of less than 3,500:1 but greater than 3,000:1 and have unusually high needs for primary health care services or insufficient capacity of existing primary care providers.
   o Demonstrate that primary medical professionals in contiguous areas are overutilized, excessively distant, or inaccessible to the population under consideration.25

2. A Primary Care Population Group HPSA must:
   o Reside in an area in that is rational for the delivery of primary medical care services as defined in the Federal code of regulations.
   o Have access barriers that prevent the population group from use of the area’s primary medical care providers.
   o Have a ratio of persons in the population group to number of primary care physicians practicing in the area and serving the population group ratio of at least 3,000:1.

3. A Medically Underserved Area (MUA) is:
   - Defined by the Index of Medical Underservice (IMU).
     - The IMU scale is from 0 to 100, where 0 represents completely underserved and 100 represents best served or least underserved.
     - Under the established criteria, each service area found to have an IMU of 62.0 or less qualifies for designation as an MUA.
   - The IMU involves four variables—ratio of primary medical care physicians per 1,000 population, infant mortality rate, percentage of the population with incomes below the poverty level, and percentage of the population age 65 or over.
     - The value of each of these variables for the service area is converted to a weighted value, according to established criteria.
     - The four values are summed to obtain the area’s IMU score.

4. A Governor-designated and Secretary-certified shortage area is an area designated by the chief executive office of the State and certified by the Secretary as an area with a shortage of personal health services.

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APPENDIX B
Agency Comments

DATE: AUG 08 2014
TO: Daniel R. Levinson
    Inspector General
FROM: Marilyn Tavenner
    Administrator

Thank you for the opportunity to review and comment on the subject report. Rural Health Clinics (RHCs) were created in 1997 to address the shortage of physicians in rural areas. RHCs must meet two location requirements: 1) they must be located in rural areas, and 2) they must be located in areas that have a shortage of health care providers. RHCs receive enhanced Medicare and Medicaid payment for most services.

The OIG found that approximately 12 percent of RHCs no longer met the location requirements in 2013. Pursuant to the Balanced Budget Act of 1997, OIG indicates that these RHCs should only continue to qualify as RHCs and receive enhanced reimbursement if they are determined to be "essential providers". However, OIG indicated that the Centers for Medicare & Medicaid Services (CMS) has yet to issue final regulations that would allow RHCs that do not meet the location requirements to qualify as essential providers.

The OIG's recommendation and CMS' response to that recommendation are discussed below.

OIG Recommendation

The OIG recommends that CMS issue regulations to ensure that RHCs determined to be essential providers remain certified as RHCs.

CMS Response

The CMS thanks OIG for their efforts on this issue.
ACKNOWLEDGMENTS

This report was prepared under the direction of Ann Maxwell, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, Thomas Komaniecki, Deputy Regional Inspector General, and Laura Kordish, Deputy Regional Inspector General.

Lisa Minich served as the team leader for this study, and Hilary Slover served as the lead analyst. Other Office of Evaluation and Inspections staff from the Chicago regional office who conducted the study include Elliot Curry. Central office staff who provided support include Kevin Farber, Kevin Manley, and Christine Moritz.
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