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NATIONAL RURAL HEALTH ASSOCIATION

Regulatory Guide: RHC/FQHC Proposed Rule

On June 27, 2008, the Centers for Medicare and Medicaid Services (CMS) published a proposed rule to change the conditions of participation of Rural Health Clinics (RHC) and make payment changes for RHCs and Federally Qualified Health Centers (FQHCs) under Medicare. The proposed rule could have a radical impact on rural and frontier safety net providers. The NRHA provides this regulatory guide to explain the proposed rule and the proposed changes, to share the initial concerns NRHA will offer to CMS regulators and to give details on how rural advocates can submit their own comments on the proposed rule.

Sections in this guide:

Background

The Rural Health Clinic (RHC) program was created in 1977 to provide incentives for providers to serve rural and frontier underserved communities. One of these incentives was a cost-based reimbursement rate with a payment limit under Medicare. In addition, Congress sought to increase the number of non-physician providers that worked in rural communities in order to increase the team approach and cross-discipline interaction in rural communities. In an effort to encourage providers to participate and to open facilities in rural America, Congress allowed a facility that received RHC status to remain an RHC even if the facility no longer met the location requirements. For a little more than the first decade of the program's existence, the number of providers that were certified as a RHC remained small.

In the early 1990s, the program exploded in number of clinics (see figure 1) participating in the program and the amount spent by the Medicare and Medicaid programs. This explosion was driven in large part due to the change in the Medicare system to a fee schedule that left many rural providers unable to stay financially viable without cost-based reimbursement. In the mid-1990s, a number of federal studies and reports (Office of the Inspector General (OIG) 1996, Government Accountability Office (GAO) 1996, and GAO testimony 1997) on the RHC program were released. These reports tended to be critical of the program and questioned whether the program actually led to an increase in rural beneficiary access to care. They recommended that Congress, CMS and Health Resources and Services Administration (HRSA) revise policies so that RHCs would be subject to review of their status and encourage greater need assessment within the program.

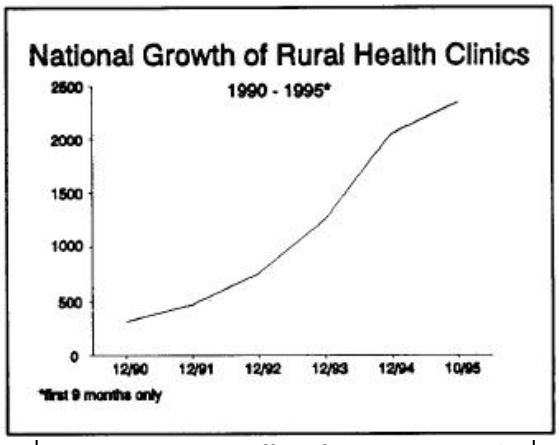

Figure 1. *Source – Office of Inspector General, "Rural Health Clinics: Growth, Access and Payment," July 1996, OEI-05-94-00040.*

As part of the Balanced Budget Act of 1997 (BBA), Congress changed the statute or law regarding RHCs. RHCs would be required to undergo review of their location requirements every three years. In addition, provider-based RHCs were no longer automatically given a waiver to the payment limit. Instead, an RHC would have to be owned by another provider with less than 50 beds. Once legislation creates law, the administration must put out regulations or guidance on how this law will be implemented. Whenever regulations are released, an open comment period is created to allow all interested parties to submit information, data or suggested changes to improve the regulation. This is what is happening today with an open comment period until August 26th at 5 PM ET to respond to this CMS released proposed rule to implement the changes in the BBA.

Previously, CMS changed the provider-based rule. Today, only those hospitals with less than 50 beds see their payment limit waived. However, recertification of RHCs based on the location requirements has not been implemented. A proposed rule in 2000 indicated how CMS would like to implement the BBA. It was finalized in 2003. But due to changes in the law in the meantime, which required a final rule within three years of it first being proposed, CMS withdrew the rule in September 2006. During this

time, OIG released a second report (2005) that continued to push for the reduction in the number of RHCs in existence. This is CMS' second attempt to indicate how they will implement the 1997 legislation that mandates RHCs renew their status. Details on the rule are below:

Changes to the Location Requirements for an RHC

By law, RHCs must be located in non-urbanized shortage areas. Non-urbanized areas are defined by the Census Bureau as communities under 50,000 in population. Shortage areas refer to either a geographic Health Professional Shortage Area (HPSA), population HPSA, Medically Underserved Area (MUA) or Governor's designated and Secretary certified areas (hereafter, these will be collectively referred to as shortage designations unless a specific designation is specified). In the proposed rule, CMS is making little change on how a new RHC would be certified.

CMS, however, is implementing the BBA requirement that all RHCs must recertify their status every three years. This means that to remain a RHC, a facility must continue to be in a non-urbanized area and be designated as an area with a shortage of health professionals. Previously, an RHC only needed to meet these criteria to join in the program. This proposed rule would make it so that RHCs have to keep these designations or risk losing their RHC status. While there is an exception process, the most basic way to continue with the program is to demonstrate that you are both in a non-urbanized area and a shortage designation. Both are discussed in the next few sub-sections.

Determine if you qualify to remain a RHC

As stated, to remain classified as an RHC, your facility must be located in both a non-urbanized area and a shortage designation. The easiest way to determine this is to follow the following instructions for each of the participating requirements:

1. **Not classified by the Census Bureau as an urban area**. This means you can be either located in an Urban Cluster or an area that is neither classified as an Urbanized Area nor an Urban Cluster. You can determine this by going to Census Bureau's website and doing an address search. You will then see information on your community as displayed in Figure 2, 3, or 4:

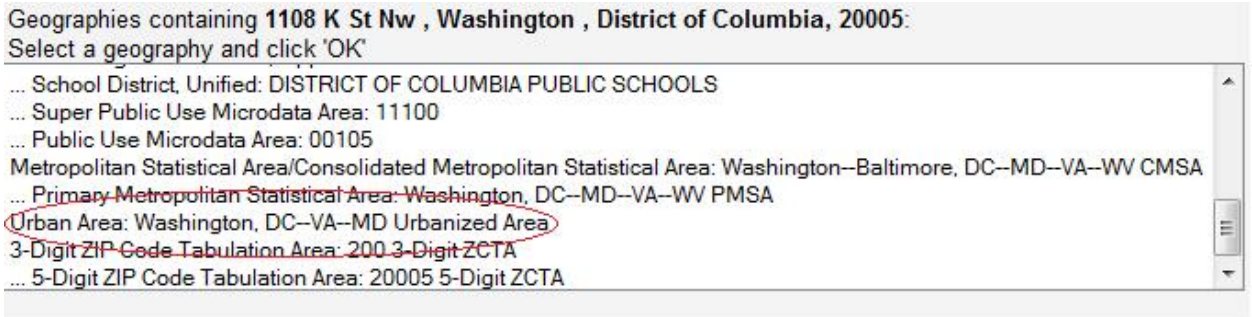

Figure 2. *Example of an Urbanized Area that would not qualify a facility for RHC designation. Notice that the "Urban Area" line item is below the Metropolitan Statistical Area information but above the 3-Digit Zip Code*

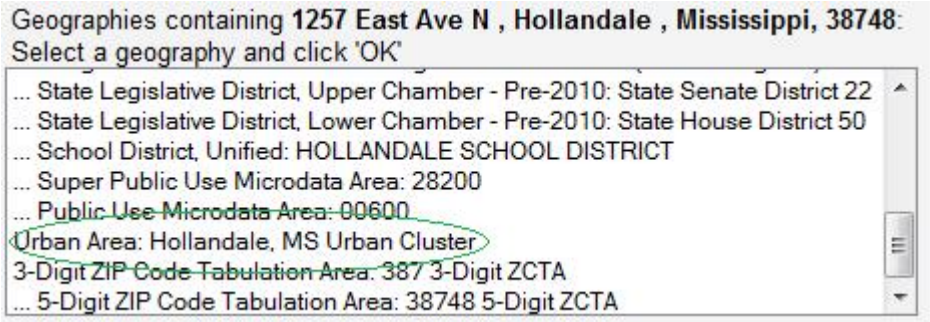

Figure 3. *Example of an Urban Cluster that would qualify a facility for RHC designation. Notice that the Urban Cluster is at the end of the line that is entitled "Urban Area." The Census Bureau displays Urban Area as the line title. You actually find out that the facility is in an Urban Cluster at the end of the line.*

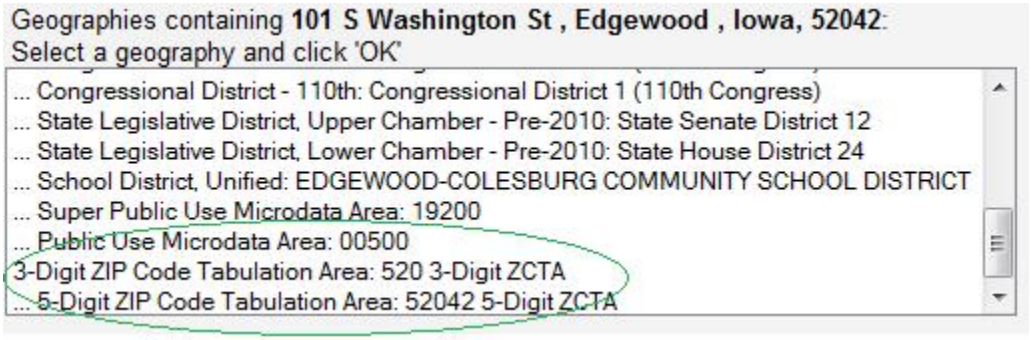

Figure 4. *For facilities that are not located in an Urbanized Area nor an Urban Cluster, there will not be a line entitled "Urban Area." These facilities also qualify for RHC designation*

As demonstrated, a facility needs to be located in an Urban Cluster (figure 3) or neither an Urbanized Area nor an Urban Cluster (figure 4). If your facility is located in an Urbanized Area (figure 2), you may be able to keep your designation, if you can secure an exception to the location requirements, as explained in the next sub-section.

2. **Located in a shortage area**. As stated, a RHC must remain in a current shortage designated area including Geographic HPSA, Population HPSA, Medically Underserved Area and Governor's designated shortage area (Secretary-Certified). By current, CMS means that the designation has to have been made within the last three years. To determine if you meet this criteria, follow these steps, being careful that you are looking at the census track information and not the entire county:
    a. *Determine if you are in a HPSA* - Go to the HRSA website and enter your address. You will see a chart that looks like this:

In a Primary Care Health Professional Shortage Area: Yes	
Primary Care HPSA Name:	Homeless - Downtown Washington
Primary Care HPSA ID:	1119991108
Primary Care HPSA Status:	Designated
Primary Care HPSA Score:	13
Primary Care HPSA Designation Last Update Date:	07/29/2005
In a Mental Health Professional Shortage Area: No	
In a Dental Care Health Professional Shortage Area: Yes	
Dental Health HPSA Name:	Homeless - Downtown D.C.
Dental Health HPSA ID:	6119991103
Dental Health HPSA Status:	Designated
Dental Health HPSA Score:	16
Dental Health HPSA Designation Last Update Date:	07/29/2005
In a Medically Underserved Area/Population: Yes	
MUA/P Service Area Name:	D C Service Area
MUA/P ID:	00498

Figure 5. *From the HRSA HPSA Finder website. This example shows a facility located in a Primary Care HPSA that was designated in 2005 and a location that may be an MUA, which qualifies, or an MUP, which does not.*

If your facility has a "Primary Care Health Professional Shortage Area" within the last three years, your current site meets the shortage designation requirement for RHC designation as either a Geographic or Population HPSA. RHC certification does not accept Mental Health or Dental Health HPSAs. If you are not located in a currently designated Primary Care HPSA within three years, proceed to the next step.

b. *Determine if you are in a MUA* – The proceeding chart will tell you if you have a MUA or an MUP. Unfortunately, it does not specify which one and to be a RHC, it needs to be an MUA and not an MUP. Go to the MUA Finder website and enter your state, county and your MUA/P Id (the bottom item in the example chart above). If your designation date for an MUA is within three years, your current site meets the shortage designation requirement for RHC designation. If you are not located in a currently designated MUA or are located in a MUP, proceed to the next step.

c. *Determine if you are in a Governor's designated shortage area (Secretary-Certified)* – Unlike HPSAs and MUAs, there is not a national online tool to look up your shortage designation for a Governor's designation. Instead, you will need to visit your state primary care office's (PCO) website, call your state PCO, or call the HRSA Shortage Designation Branch at 301-594-0816 to find out if you are in a governor designated and secretary-certified area. If you have received such a designation within the last three years, your current site meets the shortage designation requirement for RHC designation. If you are not currently designated as a Governor's shortage area, then you will need to seek an exception as detailed in the next sub-section.

Exceptions to the Location Requirements

CMS is proposing that if you do not meet one of the two criterion and you are an RHC existing facility, you can apply for an exception. To be clear, you have to be both an existing RHC designated facility and meet one of the two criteria to consider an exception. New RHC designations must meet both criterion and an RHC located in an urban area that is not currently considered underserved would not be eligible to remain in the program under the proposed rule.

In addition, if the RHC is located in a Census Bureau defined Urbanized Area the facility would have to demonstrate the following items before applying for an exception:

- **A shortage designation** – as previously stated, an exception cannot be sought if an RHC is in both an Urbanized Area and a non-shortage designated area. These RHCs will be decertified if the rule is finalized.
- **Rural Urban Commuting Area (RUCA) level 4 or higher** – RUCA is one way of defining whether or not a community is rural or not. It is based on commuting patterns of the population and densities. If your facility is located in an Urbanized Area, you can find out whether or not you are located in a RUCA level 4 or higher by downloading the scores and zip codes in your home state at the WWAMI website.
- **Demonstrate at least 51 percent of your patients reside in an adjacent non-urbanized area** – CMS did not specify how this must be demonstrated. The NRHA's assumption is that a facility would submit collected data on the facility's patient locations and whether or not they live in an Urban Cluster or in an area that is neither an Urbanized Area nor an Urban Cluster.

The RHC would have to collect all information needed to seek an exception within 90 days from the date you no longer meet the location requirements and would then be notified by CMS within another 90 days, as detailed in the timeline sub-section of this guide. The proposed exceptions and the necessary information and criteria for each are as follows:

- **Sole Community Provider –** the RHC meets either of the following requirements:
    - The RHC is at least 25 miles from the nearest participating primary care provider, which for the purpose of all exceptions is defined as another RHC, FQHC or primary care provider that is actively accepting and treating Medicare beneficiaries, Medicaid recipients, low-income patients, and the uninsured (regardless of their ability to pay); OR
    - The RHC is at least 15 miles but less than 25 miles from the nearest participating primary care provider and can demonstrate that it is more than 30 minutes from the nearest primary care provider based on local topography, predictable weather conditions, or posted speed limits.
- **Major Community Provider –** The RHC meets both of the following requirements:

  - Has a Medicare, Medicaid, low-income and uninsured patient utilization rate greater than or equal to 51 percent (CMS has clarified in calls that this can be patients or visits), or a low-income patient utilization rate greater than or equal to 31 percent; AND
  - Is actively accepting and treating a major share of Medicare, Medicaid, low-income and uninsured patients (regardless of their ability to pay) compared to other participating primary care providers that are within 25 miles of the RHC. CMS left "major share" undefined so that you can make the case for your own facility.
- **Extremely Rural Community Provider -** The RHC meets both of the following requirements:
  - Is located in a frontier county (6 or less persons per square mile) or in a RUCA code 10; AND
  - Is actively accepting and treating Medicare, Medicaid, low-income and uninsured patients (regardless of their ability to pay).
- **Specialty Clinic Provider: Obstetrics/Gynecology (Ob/Gyn) or Pediatrics –** The RHC meets all of the following requirements:
  - Exclusively provides Ob/Gyn or pediatric health services (as applicable), which does not mean it must provide all Ob/Gyn or pediatric services, just that the clinic itself only provides these types of services; AND
  - Is actively accepting and treating Medicare, Medicaid, low-income, and uninsured patients; AND
  - Has a Medicare, Medicaid, low-income patient and uninsured utilization rate greater than or equal to 31 percent; AND
  - Provides Ob/Gyn (including prenatal care) or pediatrics services onsite to clinic patients; AND
  - Is the sole or major source of Ob/Gyn or pediatrics for Medicare (where applicable), Medicaid, and uninsured patients (regardless of their ability to pay) and is either of the following:
    - At least 25 miles from the nearest participating provider of Ob/Gyn or pediatric services; OR
    - At least 15 miles but less than 25 miles from the nearest participating provider of Ob/Gyn or pediatric services, and can demonstrate that it is more than 30 minutes from the nearest participating primary care provider providing these services based on local topography, predictable weather conditions, or posted speed limits.

CMS has said that they have attempted to make the exceptions as open as they can to allow as many RHCs as possible to meet their stated criteria. They estimated in the proposed rule that most of the RHCs that seek an exception will be granted and CMS believes that most of the 500 RHCs that they estimate to not meet either or both of the location requirements will seek such an exception. CMS was unable to estimate how many facilities would meet these exception requirements as that would take a survey of each individual clinic. It is imperative, that you find out whether or not your facility will meet the location requirements and then determine if you may be able to seek an exception. If not, the NRHA

will be proposing in our comment letter additional exceptions that should be allowed. **Please pass on information on what type of exception that your facility would need to NRHA staff.**

Second, in the previous final rule, CMS had proposed a Mental Health Specialty Clinic exception. However, statute limits the amount of mental health care an RHC can offer patients at a ceiling of 50 percent. CMS has specifically asked how they can offer such an exception and what criteria should be used to allow this in light of the need of mental health care in most rural communities but also meet statute. Any thoughts on this should be shared to NRHA staff to prepare for our comment letter and in any comment letter that you submit to CMS.

Timeline for review of RHC status and decertification

In the proposed rule, CMS is proposing a timeline for an RHC to renew their designation as an RHC. If an RHC has a current shortage designation and is located in a non-Urbanized Area, as explained in the proceeding sub-sections, no action is needed. However, if an RHC loses their designation or the state has not renewed their shortage designation within three years, the RHC must take action within 90 days after the 3-year designated period to request an exception.

CMS will then process such a request within 90 days to determine whether or not an RHC is going to be granted an exception. If the request is accepted, the RHC will not need to take further action for 3 years, when they must again submit a request for an exception. If the request is not accepted, CMS is proposing that the RHC will be decertified at the beginning of the next month that comes ninety days after the date of notification. If the RHC does not seek an exception, the RHC is decertified the first of the month following 180 days after the 3-year designation process ends.

This timeline can be difficult to understand in written form. Perhaps the best way to describe this is to view the sample timeline chart that CMS included in the proposed rule (Figure 6 on the next page):

Sample Timeline

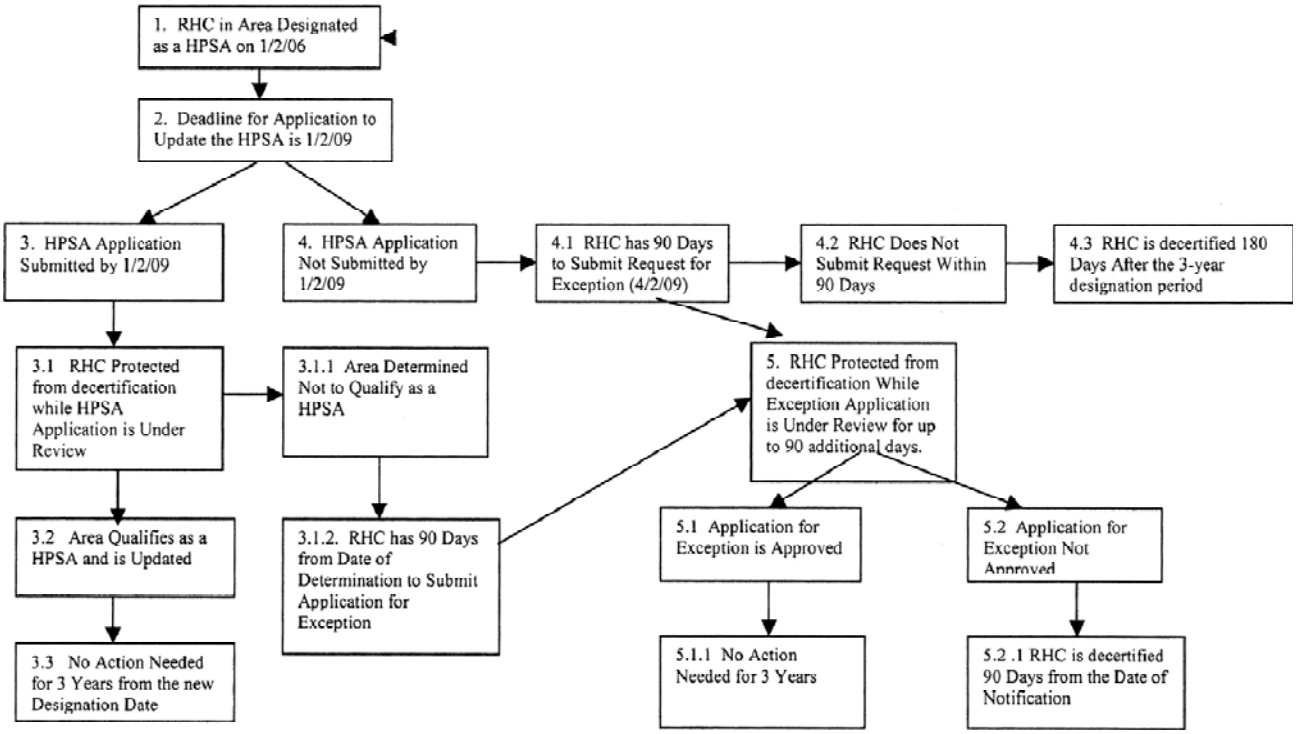

Figure 6. *This sample timeline was provided by CMS in the proposed rule. It shows when an RHC must seek exceptions as they get close to the end of the three-year shortage designation.*

An RHC that seeks an exception should submit all necessary documentation to the Regional Office. An RHC that seeks an exception will not be decertified while its application is under review, as demonstrated above. A facility will not lose their designation until at least 180 days after the end of their shortage designation's three year period. If an RHC is decertified, it can still participate in the Medicare program, under the Part B Physician Fee Schedule payments. Such participation is contingent for provider-based RHCs on a new state survey to join the Medicare program under the Part B system. CMS proposes to offer these provider-based RHCs, which are losing their designation, an additional 120 days of RHC payment while the application is being processed to allow the state to survey the provider. Free-standing RHCs can already participate in Part B billing and no new survey is necessary.

Changes to RHC and FQHC payments

RHC and FQHC payment limit changes impacting total payment

In addition to the RHC location requirement changes, CMS is proposing changes to the RHC and FQHC payment methodology. The payment methodology change will in essence put a hard cap in total payments that is equal to the Medicare payment cap set by Congress and adjusted annually by the Medicare Economic Index. The only major difference between the FQHC and RHC caps is that the FQHC cap is higher (approximately $105 in rural FQHCs to $75 in RHCs). Both are well below the actual costs of operating these facilities and limit the ability of the facilities to offer certain services.

Payment to RHCs and FQHCs for covered services furnished to Medicare beneficiaries is made on the basis of an all-inclusive rate per visit, subject to a payment limit. The all-inclusive rate is determined in accordance with the statute that states that RHCs and FQHCs are paid reasonable costs less the amount a provider may charge but in no case may the payment exceed 80 percent of such costs. Traditionally, the provider have received 80 percent of the allowable capped cost (for RHCs, 80 percent of $75 is $60) plus a co-pay from the beneficiary that is twenty percent of charges. Where the co-pay and the amount paid by CMS have exceeded the capped rate, the provider has been able to use this to help overcome the low cap rate, as demonstrated in figure 7.

Standard Charge (usually based on cost)	$100
Cost limit	$75
Current Payment	
o Patient pays (20% of charge)	$20
o Medicare pays (80% of cost limit)	$60
Total	**$80**

Figure 7. *How RHCs/FQHCs receive payment to help cushion the inappropriate cost limit.*

Standard Charge (usually based on cost)	$100
Cost limit	$75
Current Payment	
o Patient pays (20% of charge)	$20
o Medicare pays (80% of cost limit)	$60
Sub-total	$80
• Return to CMS	-$5
Total	**$75**

Figure 8. *How the proposed rule would pay RHCs/FQHCs holding them to the inappropriate cost limit, jeopardizing operations.*

Figure 8 demonstrates the change in regulations that CMS Is proposing for the RHC and FQHC payment limits. Instead of simply paying no more than 80 percent of reasonable costs or 80 percent of the payment limit, CMS will also be monitoring how much the facility receives from the patient. So, if the patient's payment plus the Medicare payment exceed the cap, CMS will recoup the difference in the sub-total payments from the capped rate. CMS believes, by making this change, they will be conforming to statute that says that Medicare is not to pay more than 80 percent of reasonable cost to an RHC or FQHC. However, it is a major change of policy and much less clear that the statute ever precluded or

discussed how this Medicare payment should be adjusted based on a co-pay. Such a change is not required by statute and in fact is how Medicare has paid since the inception of the RHC program in 1977 and to FQHCs since 1992.

If CMS proceeds with this proposal, they have suggested such an adjustment will be made in the aggregate and not on each claim. We assume that this will take place in some form of a year end settlement and could lead to large losses for RHCs and FQHCs whose costs exceed the payment cap.

Exceptions to the per visit payment limit for RHCs

Provider-based RHCs that are owned by small, rural hospitals fewer than fifty beds have their payment cap waived to help the hospital and clinic remain financially viable. This means that payments by Medicare are based on reasonable cost with no cap to the payment. Prior to the BBA, all provider-based RHCs had the payment cap waived. CMS responded to the BBA by giving two ways to meet the under fifty bed criteria: a) a count of the number of beds or b) a series of criterion that affect few RHCs (NRHA is only aware of a single RHC that has met this criteria in the past). It is the second waiver to the payment limit that CMS is proposing to change, in order to meet this in the future, an hospital that owns an RHC would have to meet the following criteria:

- The hospital's average daily patient census count does not exceed 40
- Is a sole community hospital
- Is located in a level 9 or 10 RUCA

CMS suggests in the proposed rule that approximately 100 RHCs currently eligible to the exception to the cost limit would no longer be eligible, while 251 previously ineligible facilities would be eligible. The problem with this analysis is that CMS ran all current RHCs with an exception to the cost limit through the new formula, including RHCs that are owned by hospitals owned by less than fifty beds that are not impacted by the proposed rule. If their analysis of the additional RHCs eligible for the waiver is correct, this will allow a number of hospital-owned facilities to receive additional payments.

Commingling and other payment changes

CMS proposes to prohibit commingling relationships of RHCs and other providers when it results in duplicate Medicare or Medicaid reimbursement, either due to the inability of the RHC to distinguish its actual costs from those that are reimbursed on a fee-for-service basis, or due to other reasons. This means an RHC and a Medicare fee-for-service practice may not operate simultaneously in order to prohibit these shared practices from selecting patient encounters for enhanced billing. An RHC may be a part of a multipurpose clinic that houses other non-RHC services, such as a private medical practice, x-ray, lab clinics, dental clinics or emergency rooms in the non-RHC space. The RHC must document which costs are the RHCs or the other providers. This does not prohibit a hospital-based RHC from sharing its practitioners with the hospital emergency department in an emergency nor prohibit an RHC physician from providing on-call services, as long as the RHC continues to meet the RHC conditions for certification in the absence of the practitioner.

In addition, CMS proposes to make the following changes: payment for services to hospital patients, payment for services to skilled nursing facilities, paying physician assistants directly if they own the RHC, and paying FQHCs that provide mammography screening services. In addition, CMS asked for comments on how to pay for high cost drugs. Drug costs are included in the all-inclusive payment rates for RHCs. However, this makes it cost-prohibitive for RHCs to provide services such as outpatient cancer treatments that have a high cost for drugs. CMS is asking for comments on how they may pay for high cost drugs separate from the all inclusive rate. The NRHA will be commenting on this and seeks your suggestions for inclusion.

Changes to the staffing requirements

One of the goals of the RHC program is to encourage non-physician providers to practice as part of a team in rural America. CMS proposes to change the regulation to conform to statute that requires that non-physicians, nurse practitioners, physician assistants or certified nurse midwives, be available to furnish services fifty percent of the time. In addition, CMS proposes to allow for the first time an RHC to contract with non-physician providers in the same way that an RHC could contract with a physician. These contracted providers can then be used to meet the requirement that a non-physician be available fifty percent of the time to provide care. However, an RHC still would be required to have a non-physician on staff, as statute requires an employed non-physician as a condition of participation in the RHC program. Employed could mean that the employee receive a W2 form from the facility, have their health benefits covered or other "normal trademarks" of an employee-employer relationship.

As situations change, an RHC may lose their employed non-physician provider or fall below the fifty percent threshold. In these cases, CMS is proposing to allow a one-year waiver to the non-physician provider requirements. In order to receive this waiver, CMS is proposing that an RHC may submit a waiver request that demonstrates that it has been unable in a 90-day period prior to the request to hire one of the providers to meet staffing requirements. CMS left this "demonstration" open to allow a number of activities as described by an RHC. They do note that these could include advertisements in a paper, professional journal or an NP, PA or CNM school. If the waiver is granted, it is for a single year followed by a six-month time period before another waiver can be requested. If the RHC's waiver is denied or if after the year the RHC still does not have a non-physician provider, the RHC may be decertified. If decertified, the RHC could apply to become a physician-directed clinic paid under Medicare Part B.

Changes to the Quality Assessment and facility operations

Quality Assessment and Performance Improvement (QAPI) Program

Currently, each RHC is required to evaluate its total program annually. Since 1997, RHCs have been required by statute to have a QAPI. CMS is proposing to implement the QAPI program in a way would

allow an RHC to determine the most appropriate quality assessment and improvement activities for its own facility. The NRHA will be working with CMS and the nation's RHCs to develop a QAPI framework if and/or when the proposed rule is finalized.

CMS' proposed rule would require that an RHC QAPI would have the following elements:

1. **Objective measures** to evaluate organizational practices and functions, including at least the number of patients served and the volume of services;
2. **Performance measures adopted or developed** that reflect processes of care and RHC operation shown to be predictive of desired patient outcomes or were the outcomes themselves. The RHC would have to conduct distinct improvement projects and maintain records as part of this QAPI program, which could be met if the RHC develops and implements a health information technology system; AND
3. **Address identified priorities in the QAPI plan**. All staff would be required to ensure this happens.

Infection Control requirements for RHCs and FQHCs

CMS proposes to require all RHCs and FQHCs to have appropriate infection control guidelines and an implementation plan. These guidelines and implementation plan should be based on model guidelines that are available from a professional organization. Again, like the QAPI plan, NRHA will be working to provide a framework for meeting the infection control requirements if this proposed rule is finalized. CMS also states that infection control activities should be an integral part of the overall QAPI program.

Other changes to facility operation for an RHC and FQHC

RHCs and FQHCs are currently required to have an emergency plan in order to assess and stabilize a sick or injured person and administer emergency medical treatment while waiting for emergency transport or until a patient could receive an advanced level of care. In the proposed rule, CMS is proposing to revise the requirements to meet current industry standards. Both RHCs and FQHCs would continue to provide care and drugs for emergency situations; however the prescriptive drug list is being removed. Likewise, CMS is not listing all of the appropriate emergency equipment required, instead leaving this to be outcome oriented at the facilities discretion. Staff training for emergencies will be required for health providers to the appropriate levels of training for the facility's own emergency strategy. Finally, CMS is seeking comments in regard to automated external defibrillators (AEDs). The proposed rule would not require AEDs in RHCs or FQHCs but CMS would like to hear from both communities about whether or not such a requirement would make sense in the future.

In addition, CMS is proposing to require RHCs and FQHCs to post their hours of operations outside the facility in plain view of all patients, including those with vision problems and those that are in a wheelchair. Signage needs to clearly delineate times when RHC services are offered and when the facility is only open for administration help. As part of this distinction, CMS is clarifying that times that an RHC is open for reasons other than patient care, such as administrative time or to allow shelter during inclement weather is not considered "in operation" and would not need to have a physician or

non-physician provider present. However, this clarification does not overrule any state laws that prohibit an RHC facility be accessed when an RHC is not in operation or when a provider is not present.

CMS is also requiring that all patient health records be authenticated at RHCs and FQHCs within 48 hours either by electronic methods or manual. All entries must be complete, dated, timed and authenticated by the person that signs for the record. This requirement to happen within 48 hours is not required of other providers and appears to be moving towards electronic record keeping requirements.

NRHA concerns with the proposed rule

The NRHA has grave concerns with the proposed rule's potential impact on RHCs and FQHCs. The most obvious is the location requirements that CMS suggests may require up to 500 RHCs to seek an exception. We believe they are underestimating the impact. In a preliminary review of 422 RHCs, we found that 45 percent of RHCs are either ineligible to continue in the program or that they will have to seek an exception. If this projects out to the approximately 3,700 RHCs in the country, over 1,600 RHCs will have to seek an exception or have their shortage designation reanalyzed to remain a RHC. This could have a devastating effect on rural primary care. We have joined with Congressional champions and other associations, such as the American Medical Association, in calling for an extension to the comment period so that more analysis can be done on the location requirements.

In addition on the location requirement topic, we are very concerned with the timeline and exception process outlined in the proposed rule. The NRHA is not convinced that 90 days is enough time for an RHC to determine whether to seek an exception, collect the required information and then submit an application. Further, while CMS attempts to remain flexible with the exception criteria, it is not clear that the Regional Offices or future interpretative guidelines will be as positive. As such, we are asking NRHA members to look at their own facilities and submit to both CMS and the NRHA information about what exceptions would be appropriate for your own survival as an RHC. We would also appreciate any information from NRHA members on whether they can even collect or show the information CMS is proposing to require in the exception process. NRHA staff is not sure that such information is available even if an RHC works to find it.

Even if an RHC survives the location requirement changes, if they are paid under the payment limited cost-based reimbursement, they and all FQHCs will be subject to changes in the regulation that will significantly reduce payments to facilities whose costs exceed the payment limit. We find this change particularly inappropriate at a time when the RHC cost limit, especially, has not been raised in so long and lags behind true costs. If CMS wants to implement this change, they should wait until the cost limit better reflects true reasonable costs for these facilities.

We also question CMS' suggested impact of the quality, infection control and emergency changes. The paperwork estimates of these programs seem to have been underestimated so that CMS could avoid doing a more in-depth analysis of their proposed changes. While the NRHA supports quality

improvement activities and will work to assure our members participate in the programs, CMS should be more honest with their proposed changes and indicate more accurate impact analyses. We also worry that in CMS' effort to be flexible in the regulatory language, a wide latitude will be left for future interpretative guidelines, Medicare Administrative Contractors (MAC) or Fiscal Intermediaries (FI) to restrict such flexibility and put harmful rules in place when an open comment period is not allowed. CMS should assure that any offered flexibility in this rule remains throughout the sub-regulatory process. CMS should also provide a phase in on any requirement in a formal establishment of quality and infection programs.

The NRHA is also looking at the timelines that are proposed throughout the rule. We already stated our concern at the ninety day window for an RHC to submit an exception to the location requirements. Another timeline that is too short is the 120 days that a decertified provider-based RHC would remain in the Medicare program as an RHC while awaiting a state survey to join the Medicare Part B program, as states are simply way behind in such surveys and could take much longer. We also have concerns about the timeline of the one-year waiver from the RHC's requirement to employ a non-physician provider. We applaud CMS implementing the waiver but question whether their proposal allow enough flexibility for an RHC that seeks a waiver, recruits a non-physician during the year and then loses that provider before the full eighteen month cycle is concluded. Also, if a facility is truly unable to recruit a non-physician, a six month window between requested waivers is inappropriate and should be removed even if this would require a higher burden of proof.

Finally, CMS has proposed to require RHCs to post their hours of operation as opposed to hours that are only for administrative purposes. The language in the regulation is unclear, however, and could be read to say that an RHC must distinguish between hours a physician is present and hours that only a non-physician practitioner is present. CMS should not make this second distinction. Rural RHCs often must be flexible in their week-to-week in their staffing and coverage patterns which could end up more confusing than helpful for patients on a sign. If CMS did not intend to make this second distinction, the language should be cleaned up in any future rulemaking to ensure that it is not interpreted differently than the intent in future sub-regulatory processes.

Information on submitting comments to CMS

Whenever the federal government makes a regulatory change, they offer the general public an open comment period to express their views on the regulation. The agency responsible for the regulation must then respond to each of these comments. This allows rural advocates to express their views on the proposed regulation and make sure that the federal government understands how the rule will impact rural and frontier America. In any final rule, the agency responsible will answer concerns that were presented in the open comment period.

This proposed rule has an open comment period through August 26th, 2008 at 5 PM EST. If you would like to comment, you have the option submitting your comments in the following ways:

1. Electronically - Go to http://www.regulations.gov and click on "Submit electronic comments on HRSA regulations with an open comment period." Follow the instructions on for "Comments or Submission" and enter CMS-1910-P2 to find the document accepting comments. While not stated in the proposed rule, they usually prefer the document in MS Word format but will accept WordPerfect or MS Excel.

2. Through the mail - Send one original and two copies to: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1910-P2, P.O. Box 8010, Baltimore, MD 21244-8010. Allow sufficient time for mailed copies to arrive before the close of the comment period.

3. There is also an option to send overnight mail or by courier. See the regulation for more information on these delivery methods.

Further Information/Questions:

If you have comments, concerns or seek additional information about the proposed changes to the RHC and FQHC programs, please contact NRHA staff contact Tim Fry at Fry@NRHArural.org or 202-639-0550.

Or you can speak directly to CMS by contacting the following individuals:

- Corinne Axelrod, 410-785-5620, on RHC location requirements and exceptions, staffing and payment.
- Mary Collins, 410-786-3189, or Scott Cooper, 410-786-9465, on the QAPI program and health safety standards.

Please note that CMS will only be able to speak directly to the proposed rule and clarify intentions in the rule. If you have concerns with the rules or suggestions to improve it, you should submit a comment letter and also let NRHA staff know so that we can make the strongest case possible to CMS regulators.