Draft Comments: 8-14-08

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS – 1910 – P2
P. O. Box 8010
Baltimore, MD 21244-8110

RE: Proposed Rule – Medicare Program; Changes in Conditions of Participation Requirements and Payment Provisions for Rural Health Centers and Federally Qualified Health Centers – CMS – 1910-P2: 73 Federal Register 36696 et seq. (June 27, 2008)

To Whom It May Concern:

The National Association of Community Health Centers (NACHC) is pleased to respond to the above-cited solicitation from the Department of Health and Human Services (DHHS). NACHC is the national membership organization for federally-supported and federally recognized health centers (hereinafter interchangeably referred to as "health centers" or FQHCs) throughout the country, and is an Internal Revenue Code Section 501(c)(3) organization. NACHC also serves as a source of information, analysis, education, training, and advocacy regarding medically underserved people and communities.

1. BACKGROUND

There are, at present, approximately 1150 health center entities nationwide, which serve as the health care homes to more than seventeen (17) million persons at more than 7,000 sites located in all fifty (50) states, Puerto Rico, the District of Columbia, the U.S. Virgin Islands and the Pacific Islands. Most of these health centers receive federal grants under Section 330 of the Public Health Service Act (42 U.S.C. §254b) from the Bureau of Primary Health Care (BPHC), within the HRSA. Under this authority, health centers fall into four general categories: (1) those centers serving medically underserved areas (invariably poor communities), (2) those serving homeless populations within a particular community or geographic area, (3) those serving migrant or seasonal farm worker populations within similar community or geographic areas, and (4) those serving residents of public housing. Although there are some slight differences in the grant requirements for each of these four program types, for all intents and purposes, the ways in which these health centers operate are identical.

BPHC's grants are intended to provide funds to assist health centers with the costs of providing comprehensive preventive and primary care and enabling services to uninsured and underinsured low-income patients, as well as to maintain the health center's infrastructure. Patients from

eligible communities who are not low-income or who have insurance (whether public or private) are expected to pay for the services rendered. [1]

Currently, health centers serve more than one million Medicare beneficiaries, the vast majority of whom have income below 200% of the Federal Poverty Level (FPL).

2. COMMENTS ON PROPOSED RULES

Definition of an FQHC: Proposed Rule 42 CFR 405.2401— In the Deficit Reduction Act of 2005, Congress made a technical correction to the definition of an FQHC to clarify that Homeless Health Centers qualify as FQHCs in the Medicare program. In this proposed rule, CMS would amend the definition of an FQHC so that it is consistent with the DRA change, i.e., so that the regulation also includes Homeless Health Centers as Medicare FQHCs. NACHC supports this correction.

FQHC Reimbursement: Proposed Rule 42 CFR 405.2410 and 405.2466(b)(1)(iii)—The effect or intent of these changes is not very clear in the actual language of the proposed rules. However, if NACHC correctly understands the explanations of these proposed changes in the preamble to the rule, specifically at 73 Fed. Reg 36704-36705, we must object to such proposed revisions as contrary to and inconsistent with CMS's historic interpretation and application of that law, and equally inconsistent and contrary to the requirements of Section 330 of the Public Health Service Act (Section 330). As we understand them, the proposed changes relate to the fact that the Medicare FQHC statute and regulations provide that health centers are to be reimbursed on the basis of reasonable cost, that Medicare will pay them no more than 80% of their reasonable cost, and that the law and regulations allow the centers to collect from their patients up to 20% of their reasonable **charge.** CMS appears to be concerned that a health center can receive in excess of its reasonable cost when the Medicare payment of 80% of cost is combined with the patient's payment of 20% of the center's reasonable **charge**. For example: a health center's current per visit cost **and** charge for a visit may be $135. It may collect a 20% co-payment from a patient, which, in this case, would be $27. If this is an urban center, the Medicare per visit cap (the legality of which is not conceded by NACHC) is $117.41. Medicare would pay 80% of $117.41= $93.93. Consequently, the FQHC could collect, in total, $93.93 + $27 = $120.93, which is $3.52 over the Medicare FQHC cap. We understand CMS to be saying that this payment would result in the health center receiving $3.52 in excess of its reasonable cost and that if such payments resulted in the health center receiving more than its cost such reimbursement would exceed what the statute allows. If we understand this proposed change correctly, we suggest it is flawed for the following reasons:

1. The 80% of reasonable cost payment limit from CMS to an FQHC, found in 42 USC 1395l(a)(3)(A), should be read as separate from that statute's co-payment limit of 20% of reasonable charge. The provision states that "in no case may the payment for such

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[1] In addition to those health centers receiving grant funds pursuant to one or more of the Section 330 funding programs, there are certain entities that are designated by the Centers for Medicare and Medicaid Services (CMS) as FQHCs, by virtue of the fact that they meet all of the requirements to receive a Section 330 grant, but do not receive funding from HRSA. For purposes of this comment, unless otherwise noted, we do not distinguish between grantees and FQHC look-alike entities, collectively referring to both types of organizations as "FQHCs" or "health centers."

services…exceed 80 percent of such costs“ and that payment clearly refers to CMS's payment to the FQHC. The statute does not state that this payment plus the reasonable charge collected by the center cannot equal more that the center's reasonable cost. If Congress intended such a limitation it could have stated as much and, most likely, would have limited the FQHC to collecting only 20% of its reasonable cost.

Notably, the statutory language that CMS looks to in order to justify its change in rule and policy reads the same in its relevant part as it did in 1992 and 1996 when the agency promulgated its Medicare FQHC rules in interim final and final form, respectively. It is difficult to understand upon what legal basis CMS can now revise its earlier interpretation of this rule. Moreover, CMS cannot maintain that a rule that would prohibit an FQHC from collecting from CMS and its Medicare beneficiary an amount that might total in excess of CMS's reasonable cost limit is not a change in its FQHC policy since in its preamble to its final FQHC regulations published in the Federal Register on April 3, 1996, the agency responded to comments on the rule as follows:

> Consequently, our regulations provide that an FQHC may not charge beneficiaries more than 20 percent of the charge for the service furnished regardless of the payment the FQHC receives from Medicare .
>
> We believe that, on average, many FQHCs will recover their costs under this provision. While it is possible that, in situations involving minimal services, the FQHC will recover less than its cost**, it will recover more than its costs in certain other visits involving high charge services.**
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> 61 Fed. Reg. 14644 (April 3, 1996). (emphasis added)

Clearly, CMS understood the federal law (which reads the same today as it did in 1996) to allow for situations in which a health center might collect an FQHC payment from CMS and a co-insurance from the beneficiary that together might exceed the health center's cost for that visit.

This understanding by CMS would also explain why it made no comparable change to this rule when it promulgated final regulations on December, 24, 2003, implementing changes in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA)(Pub. L. 108-173) . In the preamble to the current proposed rules, CMS presents its proposed changes essentially as a continuation and update of the 2003 final rules (which CMS was required to suspend because it had not finalized them within three years from the date they were first promulgated). Yet those suspended rules contained no proposal similar to the one that NACHC is addressing in this comment. Thus, as recently as December, 2003—seven years after promulgating final FQHC regulations and 13 years after it promulgated interim final FQHC regulations in 1992, CMS made no mention of the policy it is currently suggesting is required by a law enacted in 1990.

2. An additional reason for NACHC's opposition to this proposed rule change relates to CMS' Medicare FQHC per visit payment limit or “cap”. In reality, CMS' proposed rule will not have the effect of limiting an FQHC to receipt of it reasonable costs. Instead, it will have the

effect of limiting an FQHC to a payment based on an artificial, inaccurate, outdated, and arguably illegal FQHC per visit cap. When CMS first promulgated the Medicare FQHC cap in 1992, NACHC commented that the rule had no legal basis. Equally important, we pointed out then, and in a number of subsequent written communications to and meetings with CMS, that the methodology used by CMS to construct the cap in 1992 was flawed for a number of reasons, including, but not limited to, the agency's use of the Congressionally-mandated Rural Health Clinic per visit cap as the base for the construction of the FQHC cap. We have pointed out to CMS that our research indicates that at least 50%, and as many as 70%, of FQHCs incur cost for their Medicare patients in excess of the Medicare cap, even though they are applying Medicare cost principles per 42 CFR 413 and 405.2400 in determining their allowable, reasonable costs. NACHC, and numerous members of Congress, also have asked CMS on a number of occasions to recalculate the FQHC cap as the agency stated it would in its 1992 and 1996 regulatory preambles, in which it stated:

> This approach is an interim approach. Actual cost report data for FQHCS will be gathered and analyzed during this period of time. The limits imposed in the regulation will be evaluated and adjusted as necessary based on these data.
> 57 Fed Reg.24973 (June 12, 1992)
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> We will collect and analyze FQHC cost report data to determine if a payment limit adjustment is necessary. If after analysis, we find it necessary to adjust the methodology used to determine the FQHC limits currently in place, we will issue a proposed notice and the public will have an opportunity to comment.
> 61 Fed. Reg.14653 (April 3, 1996).

Sixteen years after its initial pledge in 1992 to review the adequacy of the FQHC cap and twelve years after renewing this commitment in 1996, CMS has yet to review or revise its methodology and provide the public an opportunity to comment on a proposed revision. Notably, in Section 151 of the recently-enacted Medicare Improvements for Patients and Providers Act of 2008 (Pub. L 110-275— July 15, 2008), Congress registered its frustration with CMS' shortcoming by charging the Comptroller General with the task of studying and reporting to Congress on the adequacy of the reimbursement to FQHC's under the Medicare cap and by mandating that CMS raise the cap by $5 effective in 2010.

In short, an important basis for NACHC's opposition to the proposed rule change is that it is premised on a per visit cap that was flawed, and possibly illegal, at the outset, and is grossly and harmfully out-of –date today.

3. Should CMS decide to finalize the reasonable cost/reasonable charge policy as proposed in its June 27, 2008 publication, NACHC believes it is critical that it distinguish between a health center's <u>billed</u> co-insurance charges and the <u>actual payments</u> the health center receives from its Medicare patients, and **include only the latter payments** in determining whether a health center has been reimbursed in excess of its reasonable cost. The practical reason for such an approach is obvious—if a health center did not collect the full co-insurance amount then its total payment does not exceed even CMS' restrictive per visit cap. The relevant section of the Medicare statute supports this interpretation in that it refers to the amount of the co-insurance

“a provider **may** charge”. 42 USC 1395l(a)(3)(A). (emphasis added). Indeed, Congress acknowledged this distinction in its Conference Report relating to Section 237 of the Medicare Modernization Act of 2003, in stating: “Services provided by FQHCs to Medicare enrollees are reimbursed at no more than 80% of the reasonable cost of providing such services less any beneficiary cost sharing amounts **collected.**”H.R. Conf Rep. 108-391, at 560 (2003), reprinted in 2004 U.S.C.C.A.N 1808, 1929. (emphasis added).

Equally important, treating billed charges as having been actually collected is directly at odds with the long-standing statutory requirements of Section 330, and equally long-standing DHHS implementing regulations. Both the statute and the rule require that, as a condition of receipt of its Section 330 grant, a health center apply a sliding fee schedule of discounts to charges for all of its patients based on ability to pay, and the rule specifically defines those patients as individuals or families whose annual incomes are at or below 200% of the Federal Poverty Line (FPL) allowing for the collection of no fee or at best a “nominal” fee from those whose annual incomes are at or below 100% of the FPL. (42 USC § 254b(k)(3)(G)(i); codified in federal regulation at 42 CFR § 51c.303(f)). In fact, Congress recognized and provided further support for this regulatory requirement when it mandated a specific safe harbor under the federal anti-kickback law for FQHCs that allows the health center to waive or reduce the amount of Medicare co-insurance payments collected from patients who qualify for these sliding fee charges. (42 USC 1320a-7b (b)(3)(D)).

It is totally illogical for CMS to treat **billed** co-insurance amounts as funds actually collected by an FQHC for purposes of determining if the health center has received in excess of its reasonable cost, when the law and rules of HRSA - its sister agency within DHHS - specifically **prohibit** the health centers from collecting the full co-insurance from their low-income Medicare patients. Indeed, such a policy is in complete conflict with the fact that a center must comply with the HRSA requirement as a condition of receiving a Section 330 grant or being designated as an FQHC look-alike entity, the receipt of either of which is the basis upon which the health center qualifies as an FQHC under Medicare and thereby qualifies for reasonable cost reimbursement. Thus, the best way to reconcile these Medicare and Section 330 statutory requirements is to read the latter as qualifying the former, i.e. in no event can a health center collect an amount that exceeds what it is permitted under its patient-adjusted payment obligations, which would be the amount collected not the amount billed.

In summary, the above CMS proposed rule—as it is explained in the preamble to the proposal—would revise CMS’s 16 year old application and understanding of the law although there has been no change in that law; would result in health centers being subjected even more adversely to an artificial, flawed, outdated, legally questionable per visit cap which Congress basically rejected last month; and would assume the actual collection of co-insurance payment amounts that federal law and DHHS prohibits the centers from collecting from their low-income Medicare patients. Finally, this proposal undercuts the clear intent of Congress in legislating reasonable cost reimbursement for FQHCs, which was to assure that Medicare (and separately, Medicaid) reimburse health centers their cost of serving these patients so that they can use their Section 330 grant funds to subsidize the cost of services to their uninsured patients. For all of these reasons, NACHC urges that CMS drop this proposed rule change.

The Medicare Cap: Proposed Rule 42 CFR 405.2462-- In this proposed revision, CMS includes a clause stating that RHCs and FQHCs are paid on the basis of an all-inclusive rate per visit "subject to a payment limit." For the reasons explained in the previous section of our comments, NACHC cannot support the provision of a per visit cap when both the legality of any cap is questionable and the inadequacy of the current cap is evident not only to NACHC and health centers (of which at least 50% incur cost in excess of the amount) but to Congress as well.

Payment for Services in Skilled Nursing Facilities (SNF)—In the preamble to its proposed rule, CMS acknowledges that an amendment to the Medicare statute legislated in the MMA of 2003 excludes FQHCs (and RHCs) from Medicare's SNF consolidated billing provision, thereby allowing FQHCs to bill Medicare for services provided to its patients in a nursing home. CMS states in the preamble, however, that only the following services are covered under this rule: physician, physician assistant, nurse practitioner, clinical psychologist and certified nurse midwife. It states that "[o]nly this subset of RHC and FQHC services may be covered and paid through the RHC and FQHC benefit" and that "any cost associated with…other services by the RHC or FQHC are excluded from coverage and payment when furnished to a Part A SNF patient." 73 Fed Reg. 36706. This proposed rule appears to be too limiting in that the Medicare statute's definition of FQHC services also includes clinical social worker, medical nutritional therapy, and diabetes outpatient self-management training services. (42 USC 1395x(aa)(3).) We ask CMS to add these services to the above list of services for which an FQHC can bill when they are provided to a health center patient at an SNF.

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Payment for Screening Mammography: Proposed rule 42 CFR 405.2448—CMS proposes to eliminate (d) of this section, so that the rule is now consistent with current policy that screening mammography is a covered FQHC service. We agree with and support this proposed rule change.

Proposed Changes to Conditions of Participation Rule: Proposed rule 42 CFR 491.5(a)(2) and 491.3(b)(3)--This proposed rule includes a modification to the general location requirements for a facility to obtain certification to participate in Medicare. (42 CFR §491.5(a)(2)). While the existing rule requires an FQHC to be located in a rural or urban area that is designated either as a shortage area or an area that has a medically underserved population (MUP), the proposed rule requires the FQHC **to be located** in a rural or urban area that is either designated as a medically underserved area (MUA) or includes an MUP. As explained below, the existing and the proposed requirement that the FQHC be located either in an MUA or in an area with an MUP are inconsistent with, and contrary to, Section 330, which requires that health centers either be located in **or serve** an MUA/MUP.

Section 330(a) defines a health center as an entity that serves an MUP. An MUP is defined in Section 330(b)(3) as either a specific population designated as such or the population of an area that is designated as an MUA. In the latter case, if serving the population of an MUA, the health center would be serving effectively the MUA itself. Further, the health center implementing

regulations require all health center applications to include, among other things, a description of the area which will be served by the health center, including the MUP(s) within the service area (42 CFR § 51c.104(b)(2)). Since neither Section 330 nor its implementing regulations require health centers to be located in an MUA (or in an area which includes an MUP) in order to serve it, it is clear that clearly both Congress and DHHS did not consider the actual physical location of the facility to be as determinative as the FQHC organization's ability to provide services to populations in need.

As noted above, under Section 330-related requirements, service and location are not necessarily linked as they are under the proposed Medicare participation requirements. One of the primary focuses of Section 330 is ensuring that a health center organization can appropriately serve an MUA/MUP and that the individuals can reasonably access such services, regardless of whether the health care facilities at which services are provided are physically located in the respective area. Given potential geographic (and other) barriers to care faced by the underserved populations served by health centers, reasonable access and location often are not linked in reality and, thus, should also not be linked in regulation.

Compounding this issue is CMS's proposed modification to 42 CFR § 491.3(b)(3) (general certification requirements), which adds the following to the existing requirement that multi-site FQHCs obtain approval for each site independently: "and [each unit independently] must meet the location requirements based on the physical location of the clinic or center." Since the proposed location requirements require the FQHC to be located in an MUA/MUP, the proposed modification to Section 491.3(b)(3) would require **each site** of the health center to be located in the MUA/MUP – contrary to longstanding HRSA policy which requires health centers to meet eligibility and service requirements on an organizational (and not site-by-site) basis.

During its Special Open Door Forum on August 5, 2008, which focused on these proposed rules, CMS staff responded to these specific concerns by stating that the location requirements in the proposed rules apply only to RHCs and are **not i**ntended to apply to FQHCs. NACHC welcomes and is appreciative of this clarification. We believe that in order to insure that there is no misunderstanding or misinterpretation in the future, CMS must (1) change proposed rules 491.5(a)(2) and 491.3(b)(3) to clarify that an FQHC need only be furnishing services to an MUP/MUA, and (2) state such policy clearly in the preamble to its final rule.

Finally, NACHC believes it important to point out that some of the confusion and concern relating to this proposed rule could have been minimized if CMS did not require that FQHCs have each site individually certified. We have noted to CMS on more than one occasion that both in Titles XVIII and XIX (Medicare and Medicaid), an FQHC is defined as an "entity" not as a "facility" (42 USC 1395x(aa)(4) and 1396d(1)(2)(B)). The use of the term "entity" by Congress was neither happenstance nor inadvertent. When the Medicaid FQHC legislation was passed in 1989, an FQHC was referred to in that law as a "facility". However, when Medicare FQHC legislation was enacted by Congress in 1990, the term "entity" was used to define FQHCs, and in that same legislation Congress amended the definition of FQHCs in the Medicaid statute from "facility" to "entity". *See* Sections 4161(a)(2) and 4704(c) of the Omnibus Budget Reconciliation Act of 1990.

In rejecting comments in the past calling for entity certification rather than site-by-site certification, CMS' primary concerns appeared to be that: (1) some sites might not be within the scope of the PHS grant; and (2) site-specific approval allows each site in the entity to continue to operate despite individual problems that may arise in other sites under the same corporate entity. See 61 Fed Reg.14641 (April 3, 1996). It appears that both of these problems can be solved without applying a site-by-site certification requirement. An FQHC could notify CMS that it is opening a new site and provide the agency with documentation of BPHC's approval of such site as being within the FQHC's federally-approved scope of project, or BPHC could notify CMS directly of such site approval. CMS could avoid the second problem—denial of FQHC reimbursement to one site of an FQHC entity if another site does not meet Medicare safety standards—simply by allowing for a policy that did not apply an all-or-nothing rule. CMS could instruct the health center entity that a certain site has not met these standards and that the entity should not include the costs of that site in its cost report nor file a separate cost report for that site until that site is in compliance.

NACHC believes the proposal and finalization of these rules provides CMS with a welcome opportunity to reconsider this policy. We have received numerous calls and letters from health centers over the years telling of delays of many months, and sometimes years between the date that the application for site certification was submitted and the time that the site was approved by CMS. The issue is exacerbated, because CMS' regulations unaccountably singles out FQHCs as one of only two provider groups whose site certification is not effective as of the date of application but rather takes effect as of the date that CMS certifies the site. (42 CFR 489.13(a)(2)). We request and believe it is appropriate that CMS also reconsider this latter regulatory provision and revise it to allow for FQHC reimbursement retroactive to the date the center sought certification for the site.

Patient Health Records: Proposed rule 42 CFR 491.10-- CMS proposes that both RHCS and FQHCs maintain a record for each patient that receives care at the facility and that the record must be "identified and authenticated promptly by the person making the entry." CMS also imposes a 48-hour authentication requirement unless the facility's state enforces a time requirement.

While NACHC understands the value of this proposal, we believe the final rule must allow for some practical considerations with regard to the 48-hour authentication policy. For example, some health centers contract with a transcription service which agrees to transmit all dictation back to the center within 48 hours. As a practical matter, the dictation is transmitted the next business day, at best. If the transcription is recorded and sent to the service on a Friday after close of business, the transcription would not be available until Monday morning, perhaps 60 hours after the service was rendered. Also, a significant number of health center providers work less than full-time at the center and quite often cannot review the record within 48 hours even if the transcription is performed at the center. Certainly if a provider only works one day a week at the center, he or she will not be able to sign off his/her chart within the 48 hour deadline. This also might be the case in multi-site centers in which a provider works at several

different sites during the week. We ask that CMS consider these 48 hour compliance problems and allow for some leeway in its final rules.

Thank you for the opportunity to comment on these proposed rules. If you have any questions about the contents of this document, please call or email me at 202-296-0158; rschwartz@nachc.com .

Sincerely,

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National Association of Community Health Centers