Department of Health and Human Services
Centers for Medicare & Medicaid Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Ave. SW
Washington, DC 20201

April 8, 2013

Re: CMS-3267-P (Proposed Rule, Medicare and Medicaid Programs, Part II – Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction)

To Whom It May Concern:

The National Association of Community Health Centers, Inc. (NACHC) is pleased to respond to the above-referenced Notice of Proposed Rulemaking (NPRM) concerning amendments to the Medicare regulations. NACHC is the national membership organization for federally qualified health centers (hereinafter interchangeably referred to as "health centers" or "FQHCs") throughout the country, and is a Section 501(c)(3) tax-exempt organization.

Our comments focus on the portions of the NPRM that address payment to FQHCs and rural health clinics ("RHCs").

NACHC welcomes the provisions in the NPRM omitting the present requirement that a physician be physically present in the FQHC at least once in every two-week period, and clarifying the scope of the definition of "physician" for purposes of FQHC and RHC services. NACHC also appreciates CMS's request for comment on means to provide additional flexibility for RHCs (and FQHCs) to provide care through telehealth and for homebound individuals in in-home settings.

In the Final Rule, CMS should include more measures encouraging the use of telemedicine and encouraging the provision of home health services in FQHCs. These services modalities are critical to ensure that FQHCs can provide patients (particularly those in remote areas) with adequate access to care. Telemedicine also increases efficiency in the delivery of primary care services and builds on the patient-centered medical home model of care that is prevalent in FQHCs.

I. Background on Health Centers

There are, at present, more than 1200 health centers with more than 8000 sites serving more than 20 million patients nationwide. Most of these health centers receive federal grants under Section 330 of the Public Health Service Act ("PHS Act"), 42 U.S.C. § 254b, from the Bureau of Primary Health Care ("BPHC"), within HRSA. Under this authority, health centers fall into four general categories: (1) those centers serving medically underserved areas, (2) those serving homeless populations within a

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particular community or geographic area, (3) those serving migrant or seasonal farmworker populations within similar community or geographic areas, and (4) those serving residents of public housing.

To qualify as a Section 330 grantee, a health center must be serving a designated medically underserved area or a medically underserved population. In addition, a health center's board of directors must be made up of at least fifty-one percent (51%) users of the health center and the health center must offer services to all persons in its area, regardless of one's ability to pay. BPHC's grants are intended to provide funds to assist health centers in covering the otherwise uncompensated costs of providing comprehensive preventive and primary care and enabling services (such as translation, transportation services, smoking cessation classes, etc.) to uninsured and underinsured indigent patients, as well as to maintain the health center's infrastructure. Patients from eligible communities, who are not indigent and are able to pay or who have insurance, whether public or private, are expected to pay for the services rendered.

Approximately 7.5 percent of FQHC patients are Medicare beneficiaries. FQHCs are providing a growing share of primary care services for Medicare beneficiaries. A 2010 report of the U.S. Government Accountability Office ("GAO") noted a seventy-two percent (72%) increase in the Medicare beneficiary population in FQHCs. U.S. GAO, *Medicare Payments to Federally Qualified Health Centers* (July 30, 2010), at 4-5.

II. Comments

A. FQHC Physician Responsibilities (42 C.F.R. § 491.8(b)(2))

CMS proposes to eliminate the requirement in the current regulations that as a condition for participation in Medicare, each FQHC ensure that each physician be present at the health center at least once in every two-week period to provide medical direction, medical care services, consultation and supervision of other clinical staff. 78 Fed. Reg. at 9229. NACHC supports this proposed change. As CMS noted in its preamble, FQHCs in remote areas may find it difficult to comply with the biweekly schedule requirement. In addition, physician assistants, nurse practitioners, and other midlevel providers in FQHCs often assume significant responsibilities for the delivery and supervision of patient care. In addition, increasingly, technology enables physicians to supervise the provision of some services remotely.

NACHC supports CMS's proposal to revise the biweekly presence requirement with a requirement that physicians periodically review the FQHC's patient records and medical orders and provide patient care services.

B. Physician Definition

CMS proposes to revise the definition of "physician" in 42 C.F.R. § 491.2 to conform to the definition in 42 C.F.R. § 405.2401. 78 Fed. Reg. at 9229. The revised § 491.2 would clarify that the term "physician," per Social Security Act § 1861(r), includes doctors of medicine and osteopathy, doctors of dental surgery and medicine, doctors of podiatric medicine, doctors of optometry, and chiropractors, with certain limitations listed in the statute. NACHC welcomes this proposal and agrees it would clarify the scope of this term.

We note that the definition of "physician" in 42 C.F.R. § 405.2401(b) specifically includes residents. (See subsection (3) of the definition.) We would recommend that to ensure consistency between the definitions in Part 405 and Part 491, CMS add residents to the definition of physician in 42 C.F.R. § 491.2.

C. Solicitation of Comment on Reducing Barriers to Services

CMS solicits comment on means for facilitating the provision of services in RHCs located in remote areas, by providing for greater flexibility to provide telemedicine and services that are not clinic-based such as home health and hospice. 78 Fed. Reg. 9229-9230. NACHC agrees with the need for such flexibility; however, this need is present in FQHCs just as much as RHCs. About 49% of FQHCs are identified as having a "rural" status.

The goal of reducing barriers to care imposed by geography, inadequate transportation, and clinician shortages is just as pressing in FQHCs as in RHCs. Moreover, this is not a uniquely rural problem. Many FQHCs in urban areas report that due to inadequate public transportation and provider shortages, patients have problems accessing the health center and telemedicine is critical to ensuring timely access to care.

Therefore, NACHC responds with the following proposed regulatory changes or revisions to Publication 15-1, the Medicare Benefit Policy Manual, to enhance telemedicine in Medicare FQHC services:

1. Telehealth Services

Telehealth or telemedicine – the use of medical information exchanged from one site to another via electronic communications to improve patients' health status[1] – plays an increasingly prominent role in health centers today. Consultations between patients and physicians or midlevel providers through audio and video telecommunications are a convenient and cost-effective way to provide certain services, such as counseling, pharmacologic management, and disease management. The importance of telehealth is growing as FQHCs serve an ever-increasing number of patients with chronic conditions and with co-occurring physical and behavioral health conditions.

The types of services that may be provided effectively and efficiently through telehealth are just as prominent in FQHCs, as in RHCs. For example, FQHCs are authorized under Medicare to provide medical nutrition therapy services and outpatient diabetes self-management training services – two services well-suited to telehealth.

As CMS notes, FQHCs and RHCs under current rules are not authorized to serve as the distant site for Medicare telehealth (*i.e.,* where a practitioner is furnishing telehealth services). CMS notes that telehealth is a distinct service under Medicare Part B and providing a separate telehealth payment to an FQHC/RHC could result in duplicate payment, if the telehealth service is also included in the FQHC's/RHC's cost report. NACHC agrees with this conclusion; however, in NACHC's view, it is not necessary to extend the discrete Medicare telehealth benefit at Social Security Act § 1834 to FQHCs and RHCs in order to allow greater flexibility for FQHCs/RHCs to use this technology. This is because unlike the Medicare payment methodologies for suppliers under Part B, the Medicare all-inclusive payment methodology for FQHCs is not focused solely on office visits and allows for reimbursement of health centers' telemedicine services.

To promote telehealth in FQHCs, CMS should (1) modify the definition of "visit" at 42 C.F.R. § 405.2463, and (2) revise the regulations defining "incident to" services (42 C.F.R. §§ 405.2413, 405.2415, and 405.2452) and the guidance on "incident to" services (CMS Publication 15-1, Medicare Benefit Policy Manual, Chapter 13, § 110), to clarify that Medicare covers telehealth consultations of FQHC physicians, midlevel providers and other clinical staff with patients.

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[1] American Telemedicine Association, *What is Telemedicine?* http://www.americantelemed.org/learn/what-is-telemedicine.

Specifically, NACHC proposes the following:

Definition of "visit." The definition of "visit" in the Medicare regulations currently requires a "face-to-face encounter." While this phrase is ambiguous, it could be interpreted to prohibit telehealth sessions from qualifying as a "visit." Nothing in the statute requires that a visit be defined so restrictively, and the requirement hinders FQHCs and RHCs from delivering primary care in a more effective and economical manner. We recommend that CMS omit this requirement, and also that it modify the restrictions on multiple visits in a single day in the Medicare regulations in order to provide that a telehealth visit may occur on the same day as an office visit.

At 42 C.F.R. § 405.2463(a), we propose that CMS add, after each occurrence of the phrase "face-to-face encounter," the phrase "or encounter through audio and/or visual telecommunications." That phrase would be added as a qualifier to the face-to-face requirement with respect to visits in general (subsection (a)(1)), medical visits ((a)(2)), and "other health visits" ((a)(3)).

In addition, in subsection (b) of the same regulation, we suggest that CMS delete the phrase "and at a single location" in paragraph (b)(1), and add the following after paragraph (b)(2):

"(3) The patient has a face-to-face visit and encounter(s) through audio and/or visual telecommunications.

(4) The patient has face-to-face visits at different locations."

The revisions to subsection (a) would ensure that a telehealth visit is considered a visit. The revisions to subsection (b) would ensure that, for purposes of the restrictions on multiple visits in a single day, a telehealth visit is considered to be a visit at a distinct FQHC location. The latter change makes sense as a policy matter, because if a consultation by audio or videoconferencing meets the clinician requirements in the regulation for a "visit" -- *i.e.,* it is provided by a physician, midlevel, clinical psychologist, clinical social worker, medical nutrition services provider, or provider of outpatient diabetes self-management training services – then most likely the telehealth consultation would not be merely a communication incident to a face-to-face visit that occurred earlier in the day, but instead would comprise a separate service.

Definition of "incident to" services. Some telehealth communications – for example, a check-in consultation with a case manager who is not a clinician authorized to provide the core FQHC services (per 42 C.F.R. § 405.2446) that is a follow-up to a physician visit – would properly be considered "incident to" services, rather than visits. Such communications for the purposes of case management and care coordination would fall within the concept of "incident to" services as "[a]ssistance by auxiliary personnel such as a nurse, medical assistant, or anyone acting under the supervision of a physician." Medicare Benefit Policy Manual, Ch. 13, § 110. In other respects, as well, CMS's present guidance on "incident to" services would encompass routine, ongoing care coordination or case management telecommunications by a clinical staff member. For example, the Manual provides that "more than one incident to service or supply can be provided as a result of a single physician visit," and that "incident to services provided on a different day as the billable visit may be included in the charges for the visit if furnished in a medically appropriate timeframe." *Id.* §§ 110.1, 110.3. So for example, if an FQHC physician prescribed a new medication, and a clinical staff member scheduled check-in sessions with the FQHC patient via videoconferencing to answer questions concerning the new treatment protocol, those sessions could be considered "incident to" services even if they occurred on a later day.

At the same time, however, both the regulations on "incident to" services and provisions in the Benefit Policy Manual restrict the concept in ways that are not amenable to telehealth -- and as noted below, are also not amenable to in-home services. For example, "incident to" services are limited to services typically provided in a physician's office. 42 C.F.R. §§ 405.2413(a)(1), 405.2415(a)(1), and 405.2452(a)(1). In addition, under the regulations, an "incident to" service must be provided "under the

direct, personal supervision" of the clinician. *Id.* at §§ 405.2413(a)(4), 405.2415(a)(4), 405.2452(a)(4). The Medicare Benefit Policy Manual glosses the supervision requirement as meaning that "the physician must be in the RHC or FQHC and immediately available to provide assistance and direction." Medicare Benefit Policy Manual, Ch. 13, § 110.1. The Manual states that an "incident to" service may occur in locations other than the FQHC/RHC, such as when a nurse goes with the physician on a house call and administers an injection; however, the Manual does not explicitly address "incident to" services provided through telecommunications, or how the supervision requirements would apply to such services.

NACHC suggests that CMS revise the regulations concerning "incident to" services, at 42 C.F.R. §§ 405.2413, 405.2415, and 405.2452, as follows:

CMS should add in paragraph (a)(1) of each regulation (42 C.F.R. §§ 405.2413, 405.2415, and 405.2452), after "commonly furnished in a physician's office," the phrase "or other appropriate service site, or through audio or visual telecommunications."

In (a)(4) of each of 42 C.F.R. §§ 405.2413, 405.2415, and 405.2452, CMS should replace the phrase "furnished under the direct, personal supervision," with the phrase "furnished under the supervision" (*i.e.,* remove the "direct, personal" requirement).

CMS should amend the Medicare Benefit Policy Manual, Ch. 13, § 110.1, to make clear that an "incident to" service may be provided through telecommunications, and that the standard for physician (or other core provider) "supervision" of "incident to" services may be met so long as the staff member carrying out the service is following a plan of care developed by the physician.

In making the above recommendations, NACHC emphasizes that we believe the recommendations related to the "visit" definition are more important than those related to "incident to" services. Many services that clearly (aside from the telecommunications format) comprise FQHC "encounters" -- ranging from psychologist consultations, to physician medication management sessions, to medical nutrition and diabetes self-management sessions -- may be effectively provided via telehealth. Establishing the costs of such services provided via telehealth as "incident to" services would be inconsistent with the reality that a clinician authorized to perform FQHC services is administering the service.

In addition, in most instances, under the current reimbursement system, changes to the "incident to" definition to expand that concept would not result in any additional reimbursement for FQHCs. The GAO's 2010 report found that as of 2007, about seventy-two percent of FQHCs had Medicare costs per visit that exceeded the relevant upper payment limit (rural or urban). U.S. GAO, *Medicare Payments to Federally Qualified Health Centers* (July 30, 2010), at 7. For any FQHC with costs exceeding the relevant cap, the ability to include more telehealth activities as "incident to" services would not result in any additional benefit.

2. **Hospice Services and Home Health Services**

CMS also seeks input on means for encouraging RHCs to provide a greater volume of home health services, and to permit RHCs to provide hospice services.

NACHC would like to emphasize that FQHCs, to just as great a degree as RHCs, are called upon to provide in-home care for their patients, and the need for this service is particularly acute in FQHCs located in rural areas. Therefore, as we did with telehealth above, NACHC is providing here suggestions for encouraging the provision of these services in FQHCs. These revisions are intended to make it easier for a Medicare beneficiary who is a primary care patient of the FQHC, and resides in an area without ready access to home health and/or hospice services, to continue to receive services from the health center when he or she is homebound or terminally ill.

Under current law, FQHCs that are located in areas where there is a shortage of home health agencies are authorized to provide "visiting nurse" care to homebound individuals (*see* Social Security Act §§ 1861(aa)(1)(C), 1861(aa)(3)). However, FQHCs are not authorized to serve as attending physicians for purposes of the hospice benefit under Part A. As we noted in the area of telehealth, the inability to be reimbursed for hospice services per se does not necessarily preclude FQHCs from providing in-home care for terminally ill patients (or other homebound patients), since the FQHC all-inclusive payment methodology contemplates a more comprehensive model of care than the model under which physicians are paid under Medicare Part B. The Medicare regulations and Benefit Policy Manual do not preclude a "visit" from being administered in a home.

NACHC recommends the following revisions to the Benefit Policy Manual and/or regulations to reduce the barriers under the present law to FQHCs providing in-home services:

Restrictions on Visiting Nurse Services in Benefit Policy Manual. NACHC recommends that CMS re-evaluate and revise the provisions of the Benefit Policy Manual on Visiting Nurse Services (Chapter 13, §§ 180.1-180.5). The Manual unduly narrows the range of home health care that FQHCs/RHCs may provide.

The Medicare regulations provide that Visiting Nurse Services are covered in an FQHC/RHC if the (1) the FQHC/RHC is located in an area that HHS has determined to have a shortage of home health agencies; (2) the services are rendered to a homebound individual; (3) the services are furnished by a registered nurse (RN), licensed practical nurse (LPN), or licensed vocational nurse (LVN) employed by or contracted to the FQHC/RHC; and (4) the services are furnished under a written plan of care regularly reviewed by the supervising clinician. 42 C.F.R. § 405.2446(b)(7); *id.* § 405.2416(a). The scope of services covered under the regulation is broad, including both "skilled" nursing services ("services that must be performed by a registered nurse, licensed practical nurse, or licensed vocational nurse if the safety of the patient is to be assured and the medically desired results achieved"), and personal care services, "to the extent covered under Medicare as home health services" (including "helping the patient to bathe, to get in and out of bed, to exercise and to take medications"). *Id.* § 405.2416(b). The Benefit Policy Manual, at Chapter 13, § 40, makes clear that a visit between a RN, LPN, or LVN and a home-bound patient may be considered a "visit." In general (*i.e.,* in the non-FQHC context), Medicare covers personal care services as part of its home health benefit. *See* Benefit Policy Manual Chapter 7, § 50.2.

However, the Benefit Policy Manual chapter on FQHC services defines the scope of covered visiting nurse services in FQHCs more narrowly than the regulations, so that effectively only skilled nursing services are included, and personal care services excluded. Chapter 13, § 180.1. This omission limits FQHCs and RHCs significantly in their ability to treat homebound patients, and we encourage CMS to broaden the terms of the Manual to cover the full scope of services listed in the regulation.

Definition of "Incident to" Services. Some services provided by FQHC clinical staff to patients in their homes would not constitute encounters. For example, if a nurse or aide visits a patient's home not on a routine basis pursuant to a plan of care under the Visiting Nurse Service benefit but instead as a follow-up to an office visit (to provide supplies, administer injections, *etc*.), the visit would constitute an "incident to" service, not a visit. The Benefit Policy Manual contains restrictions on "incident to" services in home settings that are not required by the statute or regulations. In addition, the Medicare regulations on "incident to" services contain unwarranted restrictions that we recommend be removed. Our suggestions in this area overlap to some extent with the suggestions summarized in Section C.1 above for telehealth.

First, as noted above, "incident to" services should not be limited to services "typically provided in a physician's office," given that FQHC services may be administered in more diverse settings. *See* 42

C.F.R. §§ 405.2413(a)(1), 405.2415(a)(1), and 405.2452(a)(1). Therefore, as noted above, we recommend that CMS add in paragraph (a)(1) each regulation, after "commonly furnished in a physician's office," the phrase "or other appropriate service site, or through audio or visual telecommunications." The addition makes clear that an "incident to" service may occur via telehealth or in the course of an in-home visit.

Second, as we also noted above, the supervision requirements for "incident to" services are unduly restrictive. We propose that in subsection (a)(4) of each of 42 C.F.R. §§ 405.2413, 405.2415, and 405.2452, the phrase "furnished under the direct, personal supervision," be replaced by the phrase "furnished under the supervision." In addition, CMS should amend the Medicare Benefit Policy Manual, Ch. 13, § 110.2, to make clear that "incident to" services may be provided in the context of in-home visits. We recommend that CMS remove the provision in the Manual indicating that a physician must be physically present or nearby in order for the supervision requirement to be met, and that supervision is insufficient if a nurse or other clinical staff member makes an in-home visit and the physician is accessible only by telephone. Instead, the standard for physician (or other core provider) supervision required for "incident to" services should be that the staff member providing the service be acting pursuant to a plan of care developed by the physician.

As noted above in the case of telehealth, we wish to point out that while an expansion of the definition of services "incident to" FQHC services in principle would encourage FQHCs to provide more services via telehealth and in in-home settings, the reality is that most FQHCs' reasonable costs exceed the applicable cost cap, and therefore, the ability to consider more activities as "incident to" services would not result in any additional benefit for most health centers under the current reimbursement system. Thus, the revisions we propose to the definition of "visit" and to the definition of the Visiting Nurse Services benefit are particularly important.

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Thank you for the opportunity to comment on this NPRM. Please do not hesitate to contact me by telephone at (202) 296-0158 or by e-mail at rschwartz@nachc.org if you require any clarification on the comments presented above.

Sincerely,

Roger Schwartz
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