November 16, 2010

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-2325-P
P.O. Box 8016
Baltimore, MD 21244-8016

RE: Medicaid Program; Review and Approval Process for Section 1115 Demonstrations

To Whom It May Concern:

The National Association of Community Health Centers, Inc. (NACHC) is pleased to respond to the request for comments from the Department of Health and Human Services (HHS), Center for Medicare and Medicaid Services(CMS) regarding CMS's proposed rule entitled "Review and Approval Process for Section 1115 Demonstrations" as published on September 17, 2010 (75 Fed Reg 56946 et seq). 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 non-profit organization.

At the outset, NACHC applauds CMS' proposed rule as we believe it reflects a major step forward in promoting critically important transparency in the review and approval of demonstration projects. We believe there is room for some improvement in CMS's proposal, however, and in that regard, NACHC has signed onto, supports, and incorporates the comments submitted by the Georgetown Center for Children and Families, the Center for Budget and Policy Priorities, and a broad list of national and state consumer and provider organizations.

However, in the past 16 years Section 1115 Demonstration projects have had substantial negative impact on FQHCs and their ability to serve their patients because frequently these projects have included waivers of the provisions in the Social Security Act (SSA) that establish services of an FQHC as a required Medicaid service and that require a statutorily proscribed PPS reimbursement methodology for FQHCs. In the remainder of this document, therefore , NACHC is limiting its comments primarily to the relevance and importance of Section 1115 waivers to FQHCs and the services they provide, and in turn, the need for specific protections for FQHC services and reimbursement in the Section 1115 proposal and approval process. Finally, NACHC suggests in this document what those protections might include.

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I. Background

To best explain and support the focus in our comments and suggestions, we believe the following background review is appropriate.

There are, at present, more than 1200 FQHCs with more than 7000 sites serving close to 20 million patients nationwide. Most of these FQHCs receive federal grants under Section 330 of the Public Health Service (PHS) Act (42 U.S.C. 254b) from the Bureau of Primary Health Care (BPHC), within the Health Resources and Services Administration (HRSA) of HHS. Under this authority, health centers fall into four general categories (1) those centers serving medically underserved areas, (2) those serving homeless populations within a 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 located in a designated medically underserved area or serve 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 35 percent of health center patients are Medicaid recipients, approximately 7.5 percent are Medicare beneficiaries, and approximately 40 percent are uninsured. NACHC estimates that the Medicaid expansions mandated in the ACA will result in health centers serving approximately 18.4 million Medicaid recipients by 2015.

Congressional support and funding for health center services and expansion, particularly with regard to serving Medicaid recipients, has been bi-partisan and unequivocal. Evidence of this support is as follows:

1. Recognizing the importance of health center services to Medicaid beneficiaries, Congress in the Omnibus Budget Reconciliation Act of 1989 made the services of a Federally Qualified Health Center (FQHC) a guaranteed Medicaid benefit offered to beneficiaries in every State Medicaid program. 42 USC 1396d(a)(2)(C) and 1396a(a)(10)(A). Most important, Congress recognized and acknowledged that Medicaid reimbursement to FQHCs must be sufficient to assure that health centers were paid their full reasonable costs for serving Medicaid patients (so that they would not have to use their Public Health Service Act grant funds to subsidize low Medicaid payments). In the accompanying Committee report, lawmakers wrote:

> The Subcommittee on Health and the Environment heard testimony that, on average, Medicaid payments to Federally-qualified health centers cover less than 70 percent of the costs incurred by the centers in serving Medicaid patients. The role of [the federal Health Centers program] is to deliver comprehensive primary care services to underserved populations or areas without regard to ability to pay. To the extent that the Medicaid program is not covering the cost of treating its own beneficiaries, it is compromising the ability of the centers to meet the primary care needs of those without any public or private coverage whatsoever. *U.S. Congress, House Rpt-- Committee Print 101-M, p.63 (1989).*

Congress further amended Medicaid payment methodology in 2000, to assure that health centers receive a payment that approximates their costs in serving their Medicaid patients. 42 USC 1396a(bb). This Medicaid FQHC Prospective Payment System (PPS) mandate is almost unique in the Medicaid statute, as Congress is inclined generally to allow states a great deal of leeway in establishing provider payment. However, as explained in the legislative history cited above, this FQHC payment requirement reflects Congressional recognition of the importance of FQHCs' provision of primary care and preventive services to the poor in this county.

2. In 1990, Congress, for reasons similar to its 1989 Medicaid enactment, legislated a similar payment methodology for FQHCs in the Medicare program. In the Affordable Care Act enacted last March, Congress amended this payment requirement, effective 2014, and provided that unreasonable payment caps and screens were not to be applied in any Medicare payment system that CMS may implement for FQHCs in 2014. Section 10501(i)(2) of ACA.

3. In the Deficit Reduction Act of 2005(DRA), Congress amended the Medicaid statute to allow states to opt to provide limited Medicaid services ("benchmark benefit packages" and "benchmark equivalent coverage") to certain groups of Medicaid eligible beneficiaries. 42 USC 1396w. Significantly, while that statutory amendment affords states some flexibility in Medicaid's long-standing service comparability requirements, Congress made it clear in that same section of the law that such leeway does **not** apply to the FQHC service and payment mandates. Specifically, the amended section states that a State may not make use of this option to offer limited Medicaid benefits to certain Medicaid eligible beneficiaries unless those beneficiaries have access to the services of an FQHC and payment for such FQHC services are made in accordance with the FQHC PPS payment requirements found in 42 USC 1396a(bb). 42 USC 1396w(b)(4)

4. Consistent with this on-going direction of Congress to safeguard health center services and payments, Congress in 2009—in reauthorizing and expanding the CHIP program—required that CMS reimburse FQHCs for services to CHIP beneficiaries no less than what the center

would receive for such services under 42 USC 1396a(bb), the Medicaid FQHC PPS payment system. 42 USC 1397gg(e)(1)(E).

5. In the American Recovery and Reinvestment Act of 2009 (ARRA), Pub L No 111-5, Congress appropriated $500 million in Section 330 grant funds for health center expansion (over and above their $2.1 billion annual appropriation) and provided an additional $1.5 billion for health center capital/infrastructure and HIT costs. In that same legislation, Congress also provided funding incentives in the Medicaid (and Medicare) program for providers who could demonstrate meaningful use of certified electronic health records (EHR) technology. Section 4201 of ARRA. Notably, in that legislation, FQHCs are the only non-hospital entity for which Congress established multiple provider eligibility and payments when such providers practice predominantly at FQHCs.

6. In the recently enacted Affordable Care Act (ACA), Congress' resolve that health centers play a critical role in the expansion of health care coverage and the furnishing of health care services in this country is underlined in several critical provisions of that new law. Two of the most significant provisions are found in Sections 1311 and 10104. In Section 1311, Congressional direction relating to the establishment of Exchanges provides that such Exchanges must require plans that are seeking to become qualified health plans to include in their networks "essential community providers", which the statute defines to include Section 340B covered entities. FQHCs are covered entities under Section 340B.

With regard to these same plans, Section 10104 of the ACA provides that "if any item or service covered by a qualified health plan is provided by a Federally-qualified health center as defined in [the Medicaid section of the] Social Security Act to an enrollee of the plan, the offeror of the plan **shall pay** to the center for the item or service an amount that is not less than the amount of payment that would have been paid to the center under Section 1902(bb) [42 USC 1396a(bb)] of such Act "(emphasis added).

The ACA makes clear, therefore, that in furnishing services to an individual who is covered by an Exchange-qualified health plan, health centers are to be paid by such plans no less than what they would have been paid under Medicaid law. This section brings payment to health centers by Exchange-certified Qualified Health Plans (QHP) in line with what they are currently paid (and will continue to be paid in 2014) under the Medicaid and CHIP programs.

7. Finally, in the ACA, Congress established a Community Health Center Trust Fund that provides $9.5 billion for health center capacity and service expansion operations over a five year period beginning in 2011 and an additional $1.5 billion for health center capital projects—and these funds will be available to health centers over and above their annual appropriations. In effect, Congress has signaled and funded health centers to be at the forefront of the expansion and provision of primary care to the many previously uninsured

individuals and families who will be covered in 2014 through ACA's Medicaid expansion and Exchange and Qualified Health Plan mandates.

II. FQHCs and Section 1115 Waivers

We have itemized health center-specific legislative enactments over the past 20 years to underline Congress'consistent and repeated support of health centers and their delivery of primary and preventive care services[1]. We have also provided this legislative recitation, because it reflects repeated determinations by Congress that a critical element in safeguarding the viability and furthering the expansion of health centers are the provisions in the Medicaid statute that establish FQHC services as a required service and that require that health centers be reimbursed for these services pursuant to the FQHC PPS provisions found at 42 USC 1396a(bb). It is from this vantage point, therefore, that NACHC requests CMS consider our comments and proposed additions to its Section 1115 transparency rules. All too often these FQHC service and reimbursement mandates have been frustrated and undercut by frequent and successful state requests to have these requirements waived as an element of a state's proposed Section 1115 demonstration project.

State requests for waiving FQHC service and/or reimbursement mandates appeared in State Section 1115 waiver applications and were approved by CMS, as early as 1994. States such as Tennessee, Hawaii, Oregon, Oklahoma, New York, Kentucky, Maryland, and others received waivers of the FQHC mandates as part of the broad state-wide mandatory managed care demonstration programs approved by CMS. Often these waiver applications did not address in any detail the reasons why the FQHC service or payment had to be waived (other than helping to establish budget neutrality), and rarely (if ever) did they analyze the impact of such a waiver on the viability of the FQHCs. However, invariably it was the FQHCs in these same states that continued to serve the Medicaid managed care patients long after other providers ceased accepting any new Medicaid patients and many of the managed care organizations dropped out of the waiver demonstration. The financial impact on health centers in these states was substantial, causing many of them to cut back on the services they could offer, the number of patients they could serve, the hours they could be open, etc.

More recently, states such as Utah and Michigan have sought and received waivers of the FQHC service and payment protections as part of a Section 1115 demonstration project that would expand Medicaid coverage to individuals, such as single adults, who would not be eligible for Medicaid but for the waiver proposal. These waiver proposals will likely increase as more states seek to bring those who will be eligible (under the ACA) into their Medicaid programs, prior to the requirement beginning in 2014. NACHC, of course, supports the expansion of Medicaid coverage in these demonstration programs.

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[1] In addition to ensuring their ability to continue caring for uninsured persons, another basis for this consistent Congressional support has been the recognition by Congress, by Administrations (both Democrat and Republican), in various academic studies, etc., that health centers provide critical cost-effective and cost-efficient primary and preventive health care and enabling services to a relatively high-risk vulnerable population and that they offer a health care home model that should be a central and necessary component in any legislative effort and subsequent public policy seeking to expand coverage to the uninsured and under-insured in this country.

Indeed, many of the individual s who will be brought into Medicaid under these demonstration waiver proposals are currently being served by health centers, and will likely continue to be served by them as newly eligible Medicaid recipients. We oppose, however, such waivers being the basis for paying health centers substantially less than a PPS rate consistently supported by Congress as a key element in assuring health center sustainability.

Particularly important, the process through which waiver of FQHC services and payment are sought and approved in the Section 1115 demonstration process have often failed to reach even a modicum of transparency. In some instances, an FQHC waiver was not included in the state's initial 1115 waiver request, but showed up as a Special Term and Condition (STC) when CMS approved the project. In some cases the approved waiver or STC would allow MCOs in a state to not contract with FQHCs if they could demonstrate that the services offered by an FQHC are being met by other enrolled providers, However, the waiver does not spell out what the plan must do to demonstrate they have met this standard (for example, are these non-FQHC providers accepting new Medicaid patients, are they offering the broad services a patient can get at an FQHC, is the plan's non-FQHC provider culturally competent in treating the patient, etc.) .

III. NACHC's Proposal for Transparency When a State Seeks a Waiver of FQHC Service and Payment Requirements as an Element of Its Section 1115 Demonstration Project

As stated at the Introduction section of our comments, NACHC endorses and supports the comments regarding this proposed rule submitted by the Georgetown Center for Children and Families, the Center for Budget and Policy Priorities, and a broad list of national and state consumer and provider organizations. We believe the adoption of the proposed rule along with the revisions suggested in those comments will go a long way to assure that a proposed waiver of FQHC services and reimbursement in a Section 1115 waiver application will be dealt with on both state and federal levels through a substantially improved waiver transparency process. However, given Congress' repeated endorsement of the FQHC protections and the repeated examples of Section 1115 waiver usurpation of these protections, NACHC requests additional safeguards in the Section 1115 waiver process. Specifically, we request that the following changes/additions be added to the final rule and that the final rule be drafted such that these new provisions would be applicable in the event that an initial Section 1115 proposal or an extension of a current 1115 demonstration would seek to waive FQHC service or reimbursement requirements:

> **Section 431.408—**In the public notice required in 431.408, the state would be required to identify FQHC-specific waiver requests, the rationale, purpose and justification for these specific proposals, and the anticipated financial and services impact of such waivers on health centers and their patients. Such public notice would also have to be sent directly (electronically and by mail) to each FQHC in the state as well as to the state Primary Care Association. In the public hearings required in this rule, the State Primary Care Association and at least two FQHCs (one urban and one rural) would have to be accorded reasonable and adequate time to speak.

Section 431.412—The state application would have to describe the specific FQHC-related waivers being sought; the rationale and justification for such waivers; if and why such waivers are necessary for the project to achieve its goals and how the demonstration would be adversely affected if the FQHC-related waiver were not approved; the financial impact on the FQHCs and their ability to provide services to their patients if the FQHC-specific waivers were approved; and the written responses and testimony provided by FQHCs and other interested parties during the state public notice process.

Section 431.416—CMS's electronic mailing to " interested parties" as provided in 431.416(b)(2) would include the Primary Care Association of the state which is seeking to waive the FQHC protections; as an exception to the general rule under proposed rule 431.416(d), CMS would provide written responses to public comments relating to waiver of the FQHC service and payment protections; in the event that CMS approves such FQHC waiver requests, an explanation as to the considerations and conclusions reached by CMS that resulted in the agency granting such waivers and particularly the conclusions reached by CMS as to the impact such waivers would have on the viability of the FQHCs and their continuing capacity to serve it patients.

NACHC understands that the above additions to the proposed transparency rules would provide an additional administrative burden on both the states and CMS in implementing and considering such projects. However, we believe that Congress' continued and repeated legislative support of these service and payment protections for FQHCs in Medicaid and in other programs, necessitates CMS operating under the presumption that waiving these protections is contrary to Congressional mandate and intent and therefore CMS must apply a higher standard of review and scrutiny in reviewing these proposals. Too often in the past, such a standard was missing and health centers and their Medicaid and uninsured patients suffered as a result.

NACHC appreciates the opportunity to comment on these proposed rules. We request that CMS give serious consideration to the concerns we have raised and to our proposals regarding the need for a high degree of scrutiny and justification before any waiver of FQHC service and payment requirements would be approved in a Section 1115 demonstration waiver application.

If CMS has any questions or wishes to follow-up with further communication on these comments, please contact me at 202-296-0158 or by email at rschwartz@nachc.org.

Respectfully Submitted,

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