



November 16, 2010

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-6028-P
Mail Stop C4-26-05,
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: File Code CMS-6028-P: Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers.

To Whom It May Concern:

The National Association of Community Health Centers, Inc. ("NACHC") is pleased to respond to the above-cited solicitation from the Department of Health and Human Services ("DHHS") Centers for Medicare and Medicaid Services ("CMS") for comments on the Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions, and Compliance Plans for Providers and Suppliers (the "Proposed Rules").

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.

I. Background

There are, at present, more than 1200 FQHCs nationwide. Most of these FQHCs 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 Health Resources and Services Administration ("HRSA") of DHHS. 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. Except for a limited number of public health centers (i.e., health centers operated by local governmental units such as health departments), each health center is a charitable, nonprofit, tax-exempt IRC Section 501(c)(3) corporation formed under the laws of the particular State in which it operates. Although there

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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.

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 composed of at least fifty-one percent (51%) users of the health center, and the health center must offer services to all persons in its catchment area, regardless of their ability to pay or insurance status.

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 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 able to pay or who have insurance, whether public or private, are expected to pay for the services rendered. Approximately 35% of the patients served by health centers are Medicaid recipients, approximately 7.5% are Medicare beneficiaries, and approximately 40% are uninsured.

II. Comments on the Proposed Rule

A. Provider Screening Under Medicare, Medicaid, and CHIP

NACHC appreciates that CMS designated FQHCs as a limited categorical risk for screening purposes. One of the screening tools applicable to providers and suppliers in the limited risk category includes "[v]erification that a provider or supplier meets any applicable Federal regulations, or State requirements for the provider or supplier type prior to making an enrollment determination."¹ NACHC requests that CMS clarify in its final rule that, with regard to FQHC grantees and look-alikes, the verification contemplated as a screening tool consist of the HRSA certification of compliance with requirements to obtain FQHC status.

Furthermore, in light of all of the factors that resulted in FQHCs' being classified in the low risk category, including HRSA's oversight of FQHCs through the implementation of the health center program, NACHC agrees that the additional screening requirements applicable to those providers identified in the moderate and high categorical risk classifications should not be required of FQHCs. In particular, CMS has repeatedly stated that FQHCs are not subject to surveys² and continues to apply this policy here.

However, in the Proposed Rules, CMS solicits comment on "the applicability of geographical circumstances as a possible criterion for adjusting providers or suppliers from one risk level to

¹ 75 Fed. Reg. 58204, 58209 (Sept. 23, 2010).

² See, e.g., 57 Fed. Reg. 24961, 24964 (June 12, 1992) ("However, since the PHS already closely monitors and conducts periodic onsite reviews of grantees, we have not incorporated the certification procedure applicable to RHCs into the FQHC requirements. HCFA will not routinely conduct surveys of FQHCs."); 61 Fed. Reg. 14640, 14643 (Apr. 3, 1996) (We are not planning to conduct routine surveys of FQHCs...).

another.”³ The result of an increase in risk level for FQHCs to the moderate risk level would be the implementation of site surveys for FQHCs, a significant change on long-standing policy. NACHC recognizes the concentration of fraud, waste, and abuse in certain geographic areas, but does not agree with the application of higher scrutiny on FQHCs that might be located in such areas. For the many, well-documented reasons that FQHCs do not undergo regular surveys under current policy, NACHC recommends that CMS exclude FQHCs from any increase in risk level increases resulting from actions not related directly to FQHCs.

B. Application Fee—Medicare, Medicaid, and CHIP

NACHC recognizes the need for CMS to implement an application fee for enrollment in Medicare, Medicaid, and CHIP in order to cover the costs of the additional screening procedures mandated under the Patient Protection and Affordable Care Act (“PPACA”), and further described in the Proposed Rules. However, NACHC believes that FQHCs should be exempted from the application fee requirement for two reasons.

First, under the proposed rules, FQHCs would be responsible for paying for a disproportionate amount of CMS’ costs of the additional provider screening. Unlike other providers, FQHCs are not permitted to submit one Medicare enrollment application for all of their sites. Rather, 42 C.F.R. § 491.5 requires that each permanent unit of a FQHC entity be certified independently. Accordingly, where other multi-site providers would only be responsible for one application fee, FQHCs would be subject to multiple fees for the same number of sites. This requirement, coupled with the proposed rule placing FQHCs in the lowest categorical risk level for screening would result in FQHCs paying additional fees for the lowest level of additional screening while large multi-site providers in higher risk categories would be paying less for more intense screening.

Second, a significant portion of FQHCs’ budgets include Section 330 grant funds. To the extent that the application fee for enrollment in Medicare, Medicaid, and CHIP imposes additional costs on FQHCs, it is likely that such costs would be covered by such grant funds. The result of this requirement therefore would be transfer of HRSA funds to CMS via FQHCs’ budgets, where the primary intended use of such funds is to cover the otherwise uncompensated costs of providing comprehensive preventive and primary care and enabling services to uninsured and underinsured indigent patients.

For the reasons above, imposing application fees on FQHCs essentially results in a circular transfer of funds across DHHS agencies through FQHCs with the only real result being inefficiency. Accordingly, CMS should exempt FQHCs from the application fee requirement.

³ 75 Fed. Reg. at 58212.

C. Temporary Moratoria on Enrollment of Medicare Providers and Suppliers, Medicaid and CHIP Providers

NACHC recognizes the concentration of fraud, waste, and abuse in certain geographic areas, but does not agree with the application of enrollment moratoria on FQHCs that might be located in such areas. FQHCs are required by law to contract with States in which they provide services to participate as providers reimbursed under the States' Medicaid and CHIP programs, and to "make every reasonable effort to collect appropriate reimbursement for its costs in providing health services to persons who are entitled to insurance benefits" under Medicare, Medicaid, and other public assistance programs.⁴ Imposing a moratorium on FQHC enrollment in Medicare, Medicaid or CHIP would interfere with FQHCs' ability to meet these obligations under Section 330.

Moreover, under Section 330, its implementing regulations and HRSA policy, FQHCs are required to serve all residents of their catchment area, regardless of the patients' ability to pay or whether they are reimbursed for providing such services, and may use their Section 330 grant funds to cover the otherwise uncompensated costs of providing such services. Should a moratorium be imposed where a FQHC was seeking to enroll, the FQHC would be required under Section 330 to continue treating beneficiaries of the Federal health care program under enrollment moratorium without compensation. This would result in the FQHC using its Section 330 grant funds to cover services that should otherwise have been reimbursed by Medicare, Medicaid or CHIP. Health centers operate on a razor thin financial margin and recipients of these three programs comprise a sizable portion of the health center's patient population. Loss of reimbursement from these programs could substantially impact the viability of many health centers as they struggle to continue to serve their patients.

D. Suspension of Payments

NACHC believes that FQHCs should be exempted from the potential application of the suspension of payments. As stated in Section B, above, reimbursement to FQHCs under Medicare, Medicaid, and CHIP is premised on a reimbursement of the FQHCs' reasonable costs. In particular, under the Medicare cost-based reimbursement methodology, FQHCs are subject to an annual reconciliation process, under which any surplus payments received by the FQHC in excess of reasonable Medicare costs are returned to the CMS contractor.

Similarly, PPS payment under Medicaid and CHIP are intended to be a proxy for cost-based reimbursement and some States provide for an annual reconciliation process, similar to that employed by Medicare. Accordingly, an across-the-board mandate for all States' Medicaid programs to suspend payments is overly broad to the extent it captures any payments that would be subject to annual reconciliation.

⁴ Section 330(k)(3)(E) (42 U.S.C. § 254b(k)(3)(E)).

Furthermore, in the proposed good cause exceptions to the suspension of payment requirement, CMS already recognizes the need for CMS or the Medicare contractor not to suspend payments where “[i]t is determined that beneficiary access to items or services would be so jeopardized by a payment suspension in whole or part as to cause a danger to life or health”⁵ and for States not to suspend payments where

- (4) Recipient access to items or services would be jeopardized by a payment suspension because of either of the following:
 - (i) An individual or entity is the sole community physician or the sole source of essential specialized services in a community.
 - (ii) The individual or entity serves a large number of recipients within a HRSA-designated medically underserved area.⁶

Because FQHCs by definition serve large numbers of recipients within HRSA-designated medically underserved areas and often are primary access points to needed health care services for underserved communities, CMS, the Medicare contractor, or the State hopefully would find good reason not to suspend payments should a credible allegation of fraud be alleged against a FQHC. However, for the reasons set forth above, NACHC believes that providing this discretion to suspend payments is unnecessary and, therefore, that FQHCs should be exempted from the potential application of the suspension of payments.

In addition, NACHC requests clarification regarding the implementation of a suspension of payments in an institutional setting. Specifically, CMS should clarify the effect on payments to an institutional provider when credible allegations of fraud are alleged against one or more individual providers employed or contracted by the institutional provider. NACHC does not believe that suspension of all payments to the institutional provider is appropriate in such a scenario.

E. Proposed Approach and Solicitation of Comments for Sections 6102 and 6401(a) of the ACA—Ethics and Compliance Program

As a general matter relating to the requirement that providers and suppliers establish compliance programs as a condition of enrollment in the Medicare, Medicaid and CHIP programs, NACHC requests clarification regarding the distinction between a condition of enrollment, which is a new term not otherwise employed in the context of Medicare enrollment, and a condition of participation.

⁵ Proposed 42 C.F.R. § 405.371(b)(1).

⁶ Proposed 42 C.F.R. § 455.23(e)(4); *see also* proposed 42 C.F.R. § 45523(f)(1).

Use of the Seven ⁷Elements of an Effective Compliance and Ethics Program as Described in Chapter 8 of the U.S. Federal Sentencing Guidelines Manual

NACHC agrees with CMS' statement that the seven elements described in the U.S. Federal Sentencing Guidelines "instill a commitment to prevent, detect and correct inappropriate behavior and ensure compliance with all applicable laws, regulations and requirements."⁸ Accordingly, NACHC supports the continued use of the seven elements as the "core elements" of the compliance programs that will be required as a condition of enrollment in Medicare, Medicaid and CHIP.

The existence of and experience with State or other compliance requirements for various providers and suppliers and foreseeable conflicts or duplication from multiple requirements

FQHCs are subject to multiple audits that duplicate internal auditing efforts. Specifically, FQHCs that expend \$500,000 annually in Federal grant funds are required to obtain an audit that meets the requirements of Office of Management and Budget ("OMB") Circular A-133. OMB Circular A-133 was issued pursuant to the Single Audit Act of 1984, P.L. 98-502, and the Single Audit Act Amendments of 1996, P.L. 104-156.

Among the elements reviewed by the annual A-133 audit are FQHCs' compliance with requirements under Section 330 and its implementing regulations and the FQHCs' use of "program income." This review is intended to ensure that health centers are making efforts to collect "appropriate reimbursement" for their costs under Medicare and Medicaid.⁹ Accordingly, FQHCs should be able to rely on their A-133 audits to comply with Medicare and Medicaid billing requirements, as well as with other applicable laws and regulations.

Additionally, HRSA conducts regular on-site reviews of FQHCs' operations, assessing the FQHCs' compliance with 19 different elements of FQHC requirements, including health center program requirements, management and finance requirements, which include billing and collections, and governance requirements

For this reason, FQHCs undergoing annual A-133 audits and regular HRSA site visits should not be required to implement additional auditing functions, as efforts in this area would be duplicative of the audits already conducted.

⁷ OMB Circular A-133

⁸ 75 Fed. Reg. at 58828.

⁹ OMB Circular A-133 Compliance Supplement.

The criteria we should consider when determining whether, and if so, how to divide providers and suppliers into groupings that would be subject to similar compliance requirements including whether individuals should have different compliance obligations from corporations

In issuing compliance program guidances, the DHHS Office of Inspector General (“OIG”), differentiated among different types of providers and suppliers. NACHC commends the OIG for identifying and addressing the differences that can be found in the operations of different types of providers and suppliers and encourages CMS to issue core elements specific to different types of providers and suppliers. NACHC urges CMS, in issuing the core elements of compliance programs, to group FQHCs only with other provider and supplier types that face similar operational challenges to those faced by FQHCs.

FQHCs can vary greatly in size, from centers employing just a handful of staff to those that employ hundreds of providers and administrators. For this reason, a single set of strict guidelines applicable to all FQHCs would be inappropriate for many FQHCs. Because of the flexibility allowed by the OIG’s Compliance Program for Individual and Small Group Physician Practices (“Physician Guidance”) in implementing compliance programs that are scalable to the size of the provider’s operation, FQHCs primarily have looked to this guidance as the most appropriate source of applicable compliance program guidance.

NACHC urges CMS in its future proposed rules to implement core element requirements for FQHCs that, like the Physician Guidance, recognize the limitations of FQHCs in implementing compliance programs that result from the FQHCs’ limited size and resources, and that provide some flexibility for implementation.

A reasonable timeline for establishment of a required compliance program for various types and sizes of providers and suppliers, assuming the compliance program core elements were based on the aforementioned U.S. Federal Sentencing Guidelines’ seven elements of an effective compliance and ethics program, considering business model and industry sector or particular provider or supplier category

As stated above, FQHCs vary greatly in size. They also may vary greatly in terms of the complexity of their operations, including the scopes of services they may provide. Accordingly, implementing a compliance program may require more time and resources for certain FQHCs than for others. Accordingly, NACHC recommends that CMS adopt a timeline for implementation that allows for full implementation over a period of 18 months.

If CMS proposes core elements for compliance programs that provide FQHCs with flexibility in implementing the compliance programs that will be required as conditions of enrollment in Medicare, Medicaid, and CHIP, as recommended above, NACHC believes that FQHCs will be able to fully implement programs scaled to their operations within such a timeline.

III. Conclusion

Thank you for the opportunity to comment on the proposed rules: Medicare, Medicaid, and Children's Health Insurance Programs; Additional Screening Requirements, Application Fees, Temporary Enrollment Moratoria, Payment Suspensions and Compliance Plans for Providers and Suppliers. NACHC appreciates your consideration and favorable action on these comments.

Please do not hesitate to contact me by telephone at (202) 296-0158 or by e-mail at rschwartz@nachc.org if you have any questions or comments or if you require any clarification on the comments presented herein.

Respectfully Submitted,

A handwritten signature in black ink, appearing to read "Roger Schwartz". The signature is written in a cursive style with a large initial "R" and "S".

Roger Schwartz, Esq.
Associate Vice President and Legal Counsel