April 2, 2012

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–2345–P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: File Code CMS–2345–P: Medicaid Program; Covered Outpatient Drugs

To Whom It May Concern:

The National Association of Community Health Centers, Inc. ("NACHC") submits the following comments in response to a proposed rule that would revise requirements pertaining to Medicaid reimbursement for covered outpatient drugs, published by the Centers for Medicare and Medicaid Services ("CMS") on February 2, 2012 (the "Proposed Rule"). NACHC is the national membership organization for federally supported and federally recognized health centers throughout the country (hereinafter referred to as "FQHCs"), and is an Internal Revenue Code Section 501(c)(3) organization.

The Proposed Rule would implement provisions of the Patient Protection and Affordable Care Act of 2010, as amended by the Health Care and Education Reconciliation Act of 2010, (collectively known as the Affordable Care Act). In addition, the Proposed Rule addresses other issues related to Medicaid reimbursement for covered outpatient drugs and would, therefore, affect covered entities participating in the outpatient drug discount program established under Section 340B of the Public Health Service Act (hereinafter "340B Program").[1] All FQHCs qualify as "covered entities" as defined in Section 340B.[2] Accordingly, NACHC's comments on the Proposed Rule focus on issues that are of particular importance to FQHCs that participate, or intend to participate, in the 340B Program.

I. Background

A. Federally Qualified Health Centers

There are, at present, more than 1200 health centers, with over 8000 sites, serving over 20 million patients nationwide. Most of these FQHCs receive federal grants under Section 330 of the Public Health Service Act[3] from the Bureau of Primary Health Care ("BPHC"), within the Health Resources and Services Administration ("HRSA"). Under this authority, FQHCs fall into four general categories: (1)

[1] 42 U.S.C. §256b.
[2] *See* 42 U.S.C. §256b(a)(4)(A) incorporating the definition of FQHC found in Section §1905(l)(2)B) of the Social Security Act .
[3] 42 U.S.C. §254b.

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those 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*. FQHCs operated by local governmental units such as health departments), each health center is a charitable, nonprofit, tax-exempt Internal Revenue Code Section 501(c)(3) corporation formed under the laws of the state in which it operates.

To qualify as a Section 330 grantee, and, accordingly, to become an FQHC, a health center must be located in a designated medically underserved area or serve a medically underserved population. In addition, an FQHC'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. Health centers that do not actually receive Section 330 funds also qualify as FQHCs if they meet all of the requirements for a grant under Section 330. As noted, all FQHCs meet the definition of "covered entity" for purposes of the 340B Program.

Section 330 grants are intended to assist FQHCs in covering the otherwise uncompensated costs of providing comprehensive preventive and primary health care and enabling services to uninsured and underinsured indigent patients, as well as maintaining the health center's infrastructure. Moreover, all FQHCs enjoy certain benefits provided under Federal law, such as enhanced Medicaid and Medicare reimbursement, which are designed to cover the additional costs of serving the poor and otherwise vulnerable patients that FQHCs are intended to serve. However, 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.

B. FQHCs and the 340B Program

FQHCs are required to provide pharmaceutical services, as appropriate, for their particular situation.[4] FQHCs also are required by law to provide a discount to uninsured persons based on their ability to pay, and may not deny services solely on account of an individual's inability to pay.[5] Nationally, 37.8% of FQHC patients are uninsured and 38.8% are covered by Medicaid/CHIP. Only 13.9% have private insurance. Importantly, 80% of FQHC patients have incomes below 200% of the Federal Poverty Income Level ("FPL"), and 71.8% have incomes below 100% FPL.[6] If uninsured, those patients are entitled to a discount of the FQHC's charges, those with incomes below 100% FPL being entitled to a "full discount" or at most a "nominal fee."[7]

Prior to the inception of the 340B Program in 1992, relatively few FQHCs were able to operate a robust pharmaceutical program, due to the high cost of outpatient drugs and the limited resources available to serve uninsured and low income persons. With the cost savings afforded through the 340B Program, many FQHCs now are able to provide comprehensive pharmaceutical services.

Taking into account its obligations to poor, uninsured patients, it is very difficult for an FQHC with a significant Medicaid population to sustain a comprehensive pharmacy program unless it receives

[4] 42 U.S.C. §254b(b)(1)(A)(i)(V).
[5] 42 U.S.C. §254b(k)(3)(G)(iii).
[6] NACHC Fact Sheet #0811 (August, 2011) www.nachc.com/research
[7] 42 C.F.R. §51c.303(f).

adequate reimbursement from Medicaid. Although many FQHCs have the benefit of Section 330 funding to support the cost of services provided to low income uninsured patients, unless Medicaid pays its fair share of the costs, an FQHC is forced to use its Section 330 funds to cover the cost of providing drugs to Medicaid patients. This clearly is contrary to the intent of Federal law.[8] Obviously, the situation is worse for FQHCs that do not have a Section 330 grant in the first place. As FQHCs cannot discriminate based on a patient's ability to pay or insurance coverage, the only alternative may be for the FQHC to scale down or to entirely shut down its pharmacy program.

Accordingly, NACHC urges CMS to adopt in the final rule, issued pursuant to this Proposed Rule, policies that will encourage states to reimburse FQHCs and other 340B covered entities in a manner that promotes access to care and that mutually benefits the state and 340B covered entities. NACHC's comments and recommendations on specific provisions of the Proposed Rule follow.

II. Comments on the Proposed Rule

A. CMS should require, as a condition of approval of a state's Medicaid plan, documentation that 340B covered entities are reimbursed fairly for services to Medicaid beneficiaries. (Proposed §447.502 – Definitions; Proposed §447.518 – State Plan Requirements, Findings, and Assurances)

There are three components of the Proposed Rule that, if implemented, will determine whether 340B covered entities are fairly reimbursed for services to Medicaid beneficiaries.

1. Definition of Actual Acquisition Cost

CMS proposes to re-define the ingredient component of the reimbursement formula for pharmaceutical services as "actual acquisition cost" ("AAC") as opposed to the current "estimated acquisition cost." AAC would be defined as the state Medicaid agency's "determination of the pharmacy providers' actual prices paid to acquire drug products marketed or sold by specific manufacturers." In the commentary to the Proposed Rule, CMS states that "payment based on an average of the actual acquisition costs from a number of representative pharmacies would still fit within this definition" even though a state may not be able to determine the actual price of each individual drug.[9] However, CMS noted that paying 340B covered entities at cost, *i.e.* the 340B acquisition cost, would meet the proposed AAC requirements, and solicited comments on what other methodologies would meet the proposed AAC requirements.[10] As discussed more fully below, NACHC believes that there are a number of proven alternative methodologies that, if utilized, would benefit both the state and the covered entity

2. Definition of Professional Dispensing Fee

CMS did not propose substantive changes to the definition of the dispensing fee, the other component of the Medicaid reimbursement formula. However, CMS noted, correctly, that the reimbursement for the ingredient costs and reimbursement for the professional component are inextricably related. One cannot be changed without evaluating the consequences for the other. In that

[8] *See, e.g*. 42 U.S.C. §254b(k)(s)(F) and (G)(ii)(II) providing that FQHCs must charge Medicaid customary fees. *See also* §1902(bb) of the Social Security Act requiring cost-based Medicaid reimbursement for FQHCs.

[9] 77 *Fed.Reg*. 5321 (February 2, 2012).

[10] *Id* at 5350.

regard, CMS stated that a state should look at the unique circumstances of 340B covered entities to determine if a different professional dispensing fee is warranted.[11] In NACHC's view, the state dispensing fees paid to 340B covered entities generally are inadequate. CMS ought to use its authority under existing regulations, as well as the authority that it would have under the Proposed Rule to approve the reimbursement methodology in a state's Medicaid State Plan ("MSP"), to correct those deficiencies.

3. Medicaid State Plan Requirements

CMS proposes to require a state's MSP to comprehensively describe the state's payment methodology for drugs dispensed by a 340B covered entity (including contracted pharmacies). This is an extremely important feature of the Proposed Rule because it would, if properly implemented, not only require states to present a rationale for their reimbursement policies but also to provide a vehicle for Federal oversight and enforcement. NACHC supports the intent of proposed §447.518(a), requiring states to formalize their 340B reimbursement methodology as part of their CMS-approved State Plan, but with the following comments and recommendations:

(a). CMS should specifically recognize alternatives to 340B acquisition cost as satisfying the proposed AAC methodology.

As the Office of Inspector General (OIG) of the Department of Health and Human Services has pointed out, approximately 50 percent of states reimburse FQHCs (and other 340B covered entities) based on their actual acquisition cost of the drug (referred to hereinafter as "340B acquisition cost" as distinguished from the actual acquisition cost ("AAC") reimbursement methodology set out in the Proposed Rule), plus a state-established dispensing fee.[12] This situation occurs because, under Federal law, a 340B covered entity cannot seek reimbursement under Medicaid for a drug acquired at 340B prices when that drug is subject to a manufacturer rebate.[13] Accordingly, a state following this somewhat outdated approach forgoes its rebate but, effectively, recoups the value of the rebate from the 340B pricing available to the covered entity.[14]

It is understandable that a state would prefer this approach rather than seeking a rebate, as the 340B discount savings can be in excess of the rebate that the state would have received from the manufacturer. Further, taking the discount at the point of sale eliminates the state's administrative burden in chasing manufacturer rebates. There are, however, two problems with this method.

First, the dispensing fee offered by the state often is inadequate to cover an FQHC's actual cost of dispensing drugs acquired under 340B pricing. FQHCs report that they cannot sustain a pharmaceutical program solely on the dispensing fees provided by states, sometime as low as $3.00 per prescription. As a result, FQHCs with a large Medicaid population may find that they cannot afford to

[11] *Id* at 5351.

[12] State Medicaid Policies and Oversight Activities Related to 340B Purchased Drugs, (Office of Inspector General, June 2011), OEI-05-09-00321.

[13] 42 U.S.C. §256b(a)(5).

[14] Initially, HRSA directed covered entities to bill state Medicaid agencies (with respect to fee-for-service reimbursement) at actual acquisition cost. 58 *Fed. Reg*. 13838 (May 7, 1993). In 2000, HRSA retracted this guidance and directed covered entities to follow state billing requirements. 65 *Fed. Reg*. 13983 (March 15, 2000).

provide a competent pharmaceutical program at all, thereby depriving vulnerable patients of this important service.

As an alternative, FQHCs may purchase outpatient drugs for Medicaid patients outside of the 340B Program. Under this so-called "carve out" method, FQHCs are reimbursed in the same manner as other pharmacies participating in the state's Medicaid program. While this typically allows the FQHC to obtain reasonable reimbursement for pharmacy services provided to its Medicaid patients, it also means that the state loses any financial benefit that it could have had if the FQHC had purchased under 340B.

The second problem is that a few states have (or, we understand are seriously considering similar policies) "doubled down" on their restrictive reimbursement of FQHCs and other 340B covered entitles by eliminating the "carve out" option while, at the same time, allowing 340B covered entities to recoup only their 340B acquisition cost and the state's minimal dispensing fee. In NACHC's view, such policies are shortsighted. As noted, such restrictive state policies may well force an FQHC to close down its pharmacy. Obviously, if an FQHC cannot afford to operate a pharmacy (or to use a contract pharmacy) patients suffer and the state loses the advantage of the 340B price as well.

Several states have recognized this and have implemented alternative reimbursement methodologies, sometimes referred to as "shared savings" arrangements. In short, the state Medicaid agency enters into an agreement with FQHCs (and other 340B covered entities) in which both parties share the benefit of the 340B program. Typically, the state provides the covered entity with an incentive not to carve out Medicaid from its 340B program. These arrangements have taken various forms: (1) enhanced dispensing fees; (2) modest mark ups of the ingredient cost; and (3) fees for both providing drug ingredients at 340B acquisition cost plus care management or disease management services for targeted, high-cost Medicaid populations. In each of these circumstances, both the state and the covered entity benefit from the discounts available under the 340B Program since, as noted, the 340B prices often are substantially below Medicaid net payments (including rebates) for covered outpatient drugs. In short, states can structure a 340B reimbursement program under which both the state and 340B providers can benefit. Accordingly, for State Plan purposes, CMS ought to recognize such arrangements as satisfying the proposed AAC reimbursement methodology. Indeed, CMS ought to encourage states to promote such arrangements.

(b) <u>The final regulations should specifically require states to document, as a condition of approval of their MSP, that their professional dispensing fee appropriately and fairly reimburses FQHCs (and other covered entities) for their costs in dispensing drugs to Medicaid beneficiaries, consistent with the requirements of current law</u>.

In the commentary to the Proposed Rule, CMS states that it does "not intend to mandate a specific formula or methodology which the States must use to determine their dispensing fee, However, as is consistent with current policy, States would still be required to substantiate how their dispensing fee reimbursement to pharmacy providers reasonably reflects the cost of dispensing a drug and will ensure access for these drugs to Medicaid beneficiaries."[15] With due respect to CMS, it is questionable whether current policy does, in fact, result in reasonable, cost based, reimbursement for 340B covered entities. Indeed, the Government Accountability Office found, in the states it surveyed,

[15] *Id* at 5350.

that the dispensing fee paid generally did not cover the actual costs of dispensing 340B drugs.[16] This certainly is consistent with complaints about dispensing fees that NACHC has heard from FQHCs.

Covered entities typically receive the "standard" state-established dispensing fee, except in states that have agreed to pay an enhanced dispensing fee. It may well be that state dispensing fees generally are inadequate for all providers. It is noteworthy that CMS believes that the change from reimbursement based on estimated acquisition cost to AAC (as defined in the Proposed Rule) will save states and the Federal government money "because of the highly inflated prices that the Medicaid programs currently are reimbursing providers"[17] If current reimbursement for ingredients is, in fact, so inflated, that may well make up for deficiencies in the state's dispensing fee for some pharmacies. Of course, covered entities that are reimbursed only for the actual 340B acquisition cost do not have that advantage, and depend on the dispensing fee to cover the cost of pharmacy operations.

Moreover, current law does, in fact, establish a methodology for determining the dispensing fee. Section 447.502, setting out the elements of a "dispensing fee" (and which would remain intact under the Proposed Rule), states that the fee "[i]ncludes only pharmacy costs associated with ensuring that possession of the appropriate covered outpatient drug is transferred to a Medicaid beneficiary." The regulation further provides that these costs include, *but are not limited to,* a variety of enumerated items, ranging from overhead to packaging and delivery. (Emphasis added).

In short, the law already provides a framework for establishing a reasonable dispensing fee for all Medicaid pharmacy providers. States should be required to document as part of their MSP how their dispensing fee adequately and appropriately takes into account *all* of the cost elements, without limitation, set out in Section 447.502. States also should be required to take into account any additional costs that FQHCs and other 340B covered entities incur in providing services to their Medicaid patients (*e.g*. patient counseling). Finally, and most importantly, CMS should not view these regulations as a limit on state Medicaid spending but rather as the critical element for ensuring access to Medicaid services, as required by §1902(a)(30) of the Social Security Act.

(c) <u>The final regulation should require states to implement a payment methodology, incorporated in the SMP, under which FQHCs (and other covered entities) can use a contract pharmacy to dispense 340B drugs to Medicaid patients</u>.

Although proposed §447.518(a)(1) requires a state to describe its methodology for reimbursing a covered entity when 340B drugs are dispensed by a contract pharmacy, it does not require a state actually to have such a methodology. Currently, HRSA guidance prohibits use of a contract pharmacy unless the pharmacy (presumably in cooperation with the covered entity) has a method in place to prevent a manufacturer from paying a rebate on a 340B drug, the so called "duplicate discount." In NACHC's experience, states have not been eager to entertain proposals from FQHCs to implement such methods.

Most FQHCs (as well as many other 340B covered entities) do not have in-house pharmacies. Contract pharmacy arrangements thus promote access to pharmacy services. While it is true that a Medicaid beneficiary may have a prescription filled at any Medicaid-participating pharmacy, contract

[16] Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement, GAO-11-836, p. 14-15 (September, 2011).

[17] 77 *Fed. Reg* at 5358 (February 2, 2012)

pharmacy arrangements enhance patient care because the close relationship between an FQHC and its contract pharmacy makes medication management and related patient services easier and more effective. Accordingly, CMS ought to require states to establish methods for preventing duplicate discounts in contract pharmacy arrangements as a matter of patient care.

(d) The final regulation should establish a specific deadline for states to amend their state plan to incorporate the features required under the regulation.

Proposed §447.518(a) would require states to include certain features, as discussed above, in their MSP, but does not provide for any deadline for a state to come into compliance. Subsections (b), (c), and (d) set out requirements when states propose amendments to their MSP but proposals to amend the MSP are, naturally, at the discretion of the states. Accordingly, as drafted, the important provisions required by subsection (a) might never be addressed unless and until a state sought to amend its MSP. This indeed would be an anomalous result and would vitiate the purpose of §447.518(a). It should be corrected in the final regulation.

B. CMS should prohibit states from implementing procedures for collecting rebates on drugs dispensed through Medicaid MCOs that unreasonably burden 340B covered entities. (Proposed §447.509(b) – Rebates for drugs dispensed through Medicaid managed care organizations (MCOs); Proposed §447.509(c) – State that has participating Medicaid Managed Care Organization (MCO)); Proposed §447.511(c) – State that has participating Medicaid Managed Care Organizations)

As required by the Affordable Care Act, proposed §447.509(b) provides that manufacturers participating in the Medicaid drug rebate program must pay rebates on covered outpatient drugs dispensed to individuals enrolled in Medicaid MCOs if the MCO is contractually required to provide such drugs, except that a manufacturer is not required to pay a rebate if the drug is discounted under Section 340B. This provision allows states to enjoy the benefit of a rebate on MCO-covered drugs, protects manufacturers from a duplicate discount on drugs dispensed by contracting 340B covered entities, and allows covered entities to use 340B pricing to their advantage in negotiating reimbursement with MCOs. In short, under the Proposed Rule, covered entities would be in the same position *vis-a-vis* MCOs as they were before enactment of the Affordable Care Act, exactly as the statute intended.

In order to effectuate the MCO rebate requirement, proposed §447.509(b)(3) requires applicable MCOs to report data regarding outpatient drugs dispensed to Medicaid beneficiaries within 30 days of the end of each quarter. This data is then used to compile invoices to manufacturers as specified in proposed 447.511(a) and for reports to CMS as provided in proposed §447.511(b) and (c), the latter relating specifically to MCO enrollees. Significantly, the Proposed Rule provides no direction to either MCOs or to states as to how drugs acquired under Section 340B (for which the state may not claim a rebate) should be identified so as to prevent the manufacturer from being subject to a duplicate discount.

The obligation for a manufacturer to pay and for the state to collect rebates on drugs dispensed by MCOs (other than 340B drugs) was effective March 23, 2010, with the enactment of the Affordable Care Act. Absent Federal guidance on how to meet their rebate responsibility, states have taken measures that are troubling and, potentially, could undermine the value of the 340B Program for covered entities.

As an example, New York requires 340B covered entities contracting with MCOs to identify 340B transactions at the point of sale, *i.e.* when the claim is submitted to the MCO. Although this may seem like a straight forward requirement, it is not. This is particularly problematic in a contract pharmacy environment where multiple claims to various payers are being processed. Simply put, the software systems that have been developed to prevent diversion of 340B drugs and duplicate discounts, and that have been proven effective over time, do not readily accommodate this requirement. That is not to say that 340B claims cannot be accurately identified, only that they cannot be identified in the particular way that the state demands without subjecting covered entities to significant and costly administrative burdens. Indeed, this burden is such that some New York FQHCs have begun to exclude Medicaid MCO prescriptions from their 340B program. NACHC believes that other states may be contemplating this approach, or are simply forcing a "carve out" of 340B drugs from MCOs so that all MCO claims would be eligible for a rebate.

In short, CMS should, by regulation, establish mechanisms that a state can use to separate 340B claims from other MCO claims. A state-based exclusion file for MCOs, similar to the exclusion file that HRSA maintains for fee-for-service claims, is but one example. There are others. NACHC understands that FQHCs (along with other covered entities) share responsibility for 340B compliance. However, it is unreasonable to expect covered entities to bear the entire burden.

B. CMS should revise proposed section 447.505(c) in the final rule so that all manufacturer sales to a 340B covered entity will be excluded from the best price determination. (Proposed §447.505 – Determination of best price).

Currently, §447.505(d) provides that "[a]ny prices on or after October 1, 1992 charged to . . . a covered entity described in section 1927(a)(5)(B) of the [Social Security] Act…" are excluded from the manufacturer's best price. Under the Proposed Rule, §447.505(c)(2)(i), only "[p]rices *charged under the 340B drug pricing program* to a covered entity described in section 1927(a)(5)(B) of the [Social Security] Act" would be excluded. (Emphasis added). This would be a significant and legally unsupportable narrowing of the best price exclusion.

According to CMS, the proposed revision is intended to make the regulation consistent with the definition of "best price" found in section 1927(c) (1)(C) of the Social Security Act ("the Act"). Section 1927(c) (1) (C) (i)(I) excludes, without any qualification whatsoever, "*any prices* charged on or after October 1, 1992, to . . . a covered entity described in subsection (a)(5)(B) [of the Act]." (Emphasis added). Section 1927(a)(5)(B), in turn, defines "covered entity" as any entity described in Section 340B of the Public Health Service Act. In short, the statutory predicate for both the current and proposed regulation is exactly the same. There is nothing in the statute that authorizes CMS to narrow the best price exclusion as it proposes to do.

Further, even if CMS had such authority, it would be bad policy to limit the best price exclusion as proposed. FQHCs (and other covered entities) are, by definition, safety net health care providers. The resources available to serve their patients are limited. If a drug manufacturer is willing to sell drugs to an FQHC at a price that is lower than the 340B ceiling price (but higher than the nominal price as defined in §447.508) it should be encouraged to do so without concern that it will be setting a new "best price" for the product.

Thank you for the opportunity to comment on this proposed rule. 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.

Sincerely,

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