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November 18, 2013

Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attn: CMS-1443-P
P.O. Box 8013
Baltimore, MD 21244-1850

Submitted via www.regulations.gov

Re: CMS-1443-P, Proposed Rule, Medicare Program; Prospective Payment System for Federally Qualified Health Centers

To Whom It May Concern:

The National Association of Community Health Centers, Inc. (NACHC) is pleased to provide the following comments on the above-referenced notice of proposed rulemaking ("the Proposed Rule"). 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.

Health centers have an ever-growing role as medical homes to Medicare beneficiaries. A 2010 report of the U.S. Government Accountability Office (GAO) noted a seventy-two percent increase in the Medicare beneficiary population in FQHCs between 2001 and 2008. U.S. GAO, *Medicare Payments to Federally Qualified Health Centers* (July 30, 2010), at 4-5.

Medicare beneficiaries are often intensive users of health center services, and research shows that many individuals newly qualifying for Medicare today are proactive in seeking health care. In addition, this population is likelier to experience comorbidities than other health center patient populations as a whole. Improving the Medicare payment methodology for FQHCs is critical, as Medicare beneficiaries, a group with particularly intensive health care needs, become a more prominent health center patient population. The Affordable Care Act ("ACA") accordingly provided for a new prospective payment system ("PPS"), modeled in some respects on the Medicaid payment system, for FQHCs.

NACHC applauds CMS for working with the Health Resources and Services Administration ("HRSA") toward implementing a payment methodology that is consistent with health centers' unique features, including their comprehensive model of care.

This effort is sorely needed. As CMS acknowledges in the preamble to the Proposed Rule, while the payment methodology presently in effect is nominally cost-based, the application of the Medicare

FQHC upper payment limits (UPLs) and provider productivity screens has resulted in payment that falls far short of the reasonable costs of care for the majority of health centers.

While we welcome the introduction of a new payment methodology and for the most part support CMS's specific proposals, there are some aspects of the Proposed Rule that could result in a continuation of the inequities and complexities of the current system, in contrast to the Proposed Rule's intent, if not clarified. A summary of our key comments is below.

NACHC applauds the use of a bundled PPS rate. NACHC applauds CMS's proposal to offer a bundled PPS rate, reflecting the national average costs of providing Medicare FQHC services as defined in the Social Security Act, with a geographic adjustment factor. We also appreciate CMS's proposal to provide an upward adjuster for new patient visits. NACHC agrees with CMS's reasoning that the encounter-based approach is consistent with the goal of encouraging more integrated provision of services, and that this methodology will function more effectively because of its similarity to the Medicaid bundled payment. NACHC appreciates CMS's commitment to this type of payment methodology, which promotes health centers' mission of providing comprehensive primary care services.

CMS should permit health centers to bill for multiple visits of different types on the same day. CMS sought comment on its proposal not to recognize multiple billable visits per day for services provided under the PPS. We urge CMS to withdraw this proposal and instead to apply, for services provided under the new FQHC PPS, the existing regulatory provisions on same-day visits. The existing rules allow health centers to bill for more than one visit on the same day when the patient suffers illness or injury requiring additional treatment after the first encounter, or when the patient has a medical visit and a mental health visit, diabetes self-management training (DSMT), or medical nutrition therapy (MNT) service in the same day. Given these services are often provided by multiple providers, in order to integrate these types of services into one visit, the costs associated with the single per diem rate would not adequately cover the costs of all providers. NACHC is concerned that the "per diem" aspect of the payment methodology (*i.e.,* the limit of one billable visit per day) will impede the current movement toward more integrated care for Medicare beneficiaries in health centers. In addition, the ability to schedule more than one visit on the same day is crucial to ensuring access to care for elderly and disabled patients, who may have transportation constraints or face other health care access barriers.

CMS does not have statutory authority to enforce the lesser-of-PPS-or-charges provision. NACHC's most serious concern about the Proposed Rule relates to Section 1833(a)(1)(Z) of the Social Security Act (the "lesser-of provision"), which requires Medicare payment for FQHC services provided under the PPS to equal "80 percent of the lesser of the actual charge or the amount determined under [the PPS provisions]." In NACHC's opinion, CMS does not have the legal authority to enforce this provision. By its terms, the lesser-of provision applies only to services "described in section 1832(a)(1)." Section 1832(a)(1), in turn, explicitly excludes FQHC services. We recommend that CMS at a minimum obtain a legal determination as to whether it is authorized under the statute to enforce this limitation.

In addition, the draft regulations do not define "charge" or explain how CMS plans to implement the limitation. CMS also appears to have overlooked the lesser-of provision in its regulatory impact analysis.

Since the PPS is a per-encounter payment, the negative impact of the lesser-of provision will be especially acute if CMS contemplates a comparison, for each visit, of the PPS rate to the charges

associated with specific HCPCS procedure codes that the health center billed for FQHC services on the day the visit occurred. That type of comparison would be "apples to oranges" – comparing costs of an aggregate bundle to charges associated with a specific visit or encounter. That approach would routinely result in underpayment of health centers.

If after considering the statutory language in Sections 1832(a)(1) and 1833(a)(1) of the Social Security Act, CMS concludes that it has statutory authority to enforce the lesser-of provision, NACHC recommends that CMS provide all interested parties with an opportunity to review and comment on any changes or additions may be made to the proposed rule. Additionally, CMS should implement the provision in a way that ensures parity between the bundled rate and charges compared. For example, the PPS rate could be compared with the health center's average charge per FQHC visit, as determined on an annual basis. For every service provided in a given year, the PPS rate would then be compared to the prior year's average charge per visit, as adjusted by the applicable inflation factor. That type of approach would mitigate the negative effects of the lesser-of provision by ensuring an "apples to apples" comparison of the PPS rate to charges, by using a bundled approach for both.

CMS should clarify that it will provide 100 percent payment for the preventive services for which coinsurance is waived. The preamble to the Proposed Rule states that health centers will be required to waive the application of coinsurance for a variety of preventive services included in the PPS rate. However, this requirement is not stated in the draft regulations on coinsurance. Further, the draft regulations do not provide that Medicare will pay 100 percent of the PPS rate for those services. We presume that CMS's intention was for Medicare to pay the health center 100 percent of the PPS where coinsurance is waived. Otherwise, health centers would receive only partial payment (80 percent) for preventive services that are essential to encouraging better health outcomes, such as annual wellness visits (AWV), the "welcome to Medicare" visit ("initial preventive physical examination," or IPPE), and medical nutrition services. We urge CMS to clarify this point in the final regulations.

CMS should not exclude outlier health centers and outlier visits from total allowable costs in computing the PPS rate. CMS explains in the preamble to the Proposed Rule that it has excluded from the costs used to set the national PPS rate both (1) the costs of specific FQHCs whose total costs per visit on the cost reports that CMS used as the basis of the PPS rate were more than three standard deviations from the geometric mean, and (2) the costs associated with individual visits on the claims data CMS used in developing the PPS rate that were more than three standard deviations from the mean. Using these methods, CMS reduced the proposed initial PPS rate significantly. The application of these limitations is in our opinion inconsistent with the statute, which requires that the aggregate amount of PPS rates be based on "100 percent of the estimated amount of reasonable costs," without the application of caps and screens. NACHC urges CMS, in computing the base PPS rate, to use the costs per visit without exclusion of outliers.

CMS should modify the geographical adjustment factors. To take into account regional variations in the costs of care, CMS proposes to use the Geographic Practice Cost Indices (GPCIs) currently used under the Physician Fee Schedule (PFS). In general, NACHC does not object to use of the GPCIs, but the factors influencing costs for urban versus rural providers are different for FQHCs than they are for physician practices. As one example, rural health centers face unique challenges in recruiting clinicians and often need to incorporate payment incentives to attract qualified candidates. The proposed geographical adjustment factors published in the Proposed Rule may result in underpayment to rural health centers and should be revised accordingly.

CMS should develop an FQHC-specific inflationary index. NACHC urges CMS to develop a specific inflation factor for the market basket of FQHC services, as required in the ACA amendments. As noted by the Government Accountability Office in a 2005 report, the Medicare Economic Index (MEI) falls short of the true rate of inflation affecting health center services because the MEI takes into account only physicians' service costs, not the broader range of costs affecting health center operations. NACHC will gladly work with CMS on the development of the FQHC-specific index.

CMS should take this opportunity to clarify other important aspects of FQHC Medicare billing. NACHC also urges CMS to use the present rulemaking as an opportunity to resolve several issues concerning Medicare FQHC billing that have plagued the Medicare FQHC reimbursement system for years. For example, the fact health centers currently work with multiple Medicare fiscal intermediaries has propagated confusion, as each fiscal intermediary issues different instructions concerning the FQHC benefit and associated billing requirements. Under the Medicare administrative contractor (MAC) system, NACHC encourages CMS to assign one MAC to work with all FQHCs. Greater clarity is also needed concerning the requirement that health centers bill Medicare for the technical components of FQHC services separately under Part B. CMS indicated in the preamble that it intends to issue program guidance on this topic, and we encourage CMS to do so.

I. Background

A. Health Centers' Obligations Under the Public Health Service Act

NACHC appreciates the discussion in the preamble to the Proposed Rule of the history and purposes of the health center program. The preamble conveys health centers' prevalence as a source of primary care in the U.S., their integral role in the nation's safety net care system, and the role of federal grants from the Bureau of Primary Health Care ("BPHC") under Section 330 of the Public Health Service Act ("PHS Act") in covering health centers' costs of care in serving the uninsured and underinsured.

NACHC nonetheless wishes to supplement the background discussion in the Proposed Rule by pointing out two aspects of health centers' obligations under Section 330 of the PHS Act that bear strongly on the implementation of the Medicare FQHC PPS methodology.

Payment from government programs. Health centers are required under Section 330 to collect full payment from every payor, including government programs. Under the PHS Act, as a condition of eligibility for an operating grant, a health center must show that it "has made or will make and will continue 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 title XVIII of the Social Security Act. . . ." PHS Act § 330(k)(3)(F), 42 U.S.C. § 254b(k)(3)(F) (emphasis added).

Schedule of charges. Relatedly, under Section 330 of the PHS Act, each health center must show that it "has prepared a schedule of fees of payments for the provision of its services consistent with locally prevailing rates or charges *and designed to cover its reasonable costs of operation* . . ." PHS Act § 330(k)(3)(G)(i) (emphasis added).

Both the above points demonstrate health centers' obligation to seek payments that cover costs from all payors, from government programs to individuals with the means to pay for care. Both spring from Congress' concern that Section 330 grant funds be used only as "last dollar" funding. As clarified by the legislative history, one of Congress' main goals in enacting Section 330 of the PHS Act was to ensure that each health center

> become[s] as self-sufficient as possible – collecting its cost for services other than grant funds to the greatest extent possible. These services may in some cases be

> reimbursable under Medicare or Medicaid for some of the people which the centers serve. Whenever this is the case, [the law] specifically requires that centers collect from Medicare or Medicaid and that no grant funds be awarded under the grant for such services. . . .

S. Rep. No. 94-29, at 5 (1975), *reprinted in* 1975 U.S.C.C.A.N. 469.

B. FQHC Payment Methodologies under Medicare and Medicaid

In both the Medicare and Medicaid programs, Congress has overhauled the payment methodology for health centers twice since the enactment of Section 330 of the PHS Act. For each program, the first payment reform—in 1989 for Medicaid, and in 1990 for Medicare—provided for cost-based payment. (As noted below, in the case of Medicare, the methodology did not end up serving its intended purpose due to the application of the UPLs and productivity screens.) The second major payment reform took effect in 2001 for the Medicaid program, and was enacted through the ACA of 2010 for Medicare. In each case, Congress described the new system as a "prospective payment system."

1. Medicaid

In 1989, Congress defined a set of "federally-qualified health center services" in Medicaid and enacted a new cost-based payment methodology for those services. Pub. L. No. 101-239, Omnibus Budget Reconciliation Act of 1989. As noted in the House Conference Report accompanying that legislation:

> 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.

H.R. Rep. No. 101-247, at 392, *reprinted in* 1989 U.S.C.C.A.N. 1906, 2118-2119.

Congress again amended the Medicaid payment methodology, effective January 2001, in the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA 2000"). The resulting methodology, a "prospective payment system," as described in the House Conference Report, provides for "per visit payments equal to 100% of [each health center's] average costs incurred during 1999 and 2000 adjusted to take into account any increase or decrease in the scope of services furnished." H.R. Conf. Rep. 106-1033, at 906 (Dec. 15, 2000).

After the first year of the PPS system (2001), per-visit payments to FQHCs were required to be "equal to amounts for the preceding fiscal year increased by the percentage increase in the Medicare Economic Index [MEI] applicable to primary care services for that fiscal year, and adjusted for any increase or decrease in the scope of Services furnished during the fiscal year." *Id.*; *see also* Social Security Act (SSA) § 1902(bb).

2. Medicare

Congress instituted a cost-based payment methodology for FQHCs in Medicare in 1990, in the Omnibus Budget Reconciliation Act of 1990.

The amendments were analogous in many ways to the 1989 Medicaid amendments. Congress defined a "federally-qualified health center services" Medicare benefit and provided for payment based on costs "which are reasonable and related to the cost of furnishing [FQHC services] or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations." Social Security Act (SSA) § 1833(a)(3)(A). Implementing regulations issued in 1992 authorized HCFA to establish "screening

guidelines" and "payment limitations" as tests of reasonableness. HCFA, Final Rule, Medicare Program, 57 Fed. Reg. 24,961, 24,977 (June 12, 1992).

Health centers collected coinsurance not to exceed 20 percent of the health center's reasonable and customary charges. SSA § 1866(a)(2)(A). Payment to the health center from the fiscal intermediary (FI) under the system Congress enacted in 1990 equaled a health center's cost-based all-inclusive rate (AIR), less coinsurance; however, total payment from the FI could not exceed 80 percent of the health center's reasonable costs. SSA § 1833(a)(3)(A); *see also* 42 C.F.R. § 405.2462(b)(3) (providing that Medicare will pay "80 percent of the all-inclusive rate"). The 1992 implementing regulations provided for an annual reconciliation of payments to per-visit costs as reflected on the cost report. 57 Fed. Reg. at 24,977. Implementing regulations promulgated in 1996 defined a "visit" for purposes of Medicare FQHC payment as a face-to-face encounter with a core provider of FQHC services. HCFA, Final Rule, Medicare Program, 61 Fed. Reg. 14,640, 14,658 (Apr. 3, 1996).

Congress' goals in enacting the Medicare FQHC benefit in OBRA 1990 were similar to the goals behind the Medicaid amendments in OBRA 1989. Congress was concerned that the prior Medicare reimbursement system had resulted in underpayment of health centers, thus requiring health centers to use 330 grant funds to otherwise make up for losses from low Medicare payments. The prior system, under which "Medicare . . . [had paid] for services on the basis of the lesser of costs or charges, even when the charges have been adjusted under required PHS sliding fee scales for low-income patients," was replaced by a system in which health centers would receive an AIR, with total payments to be reconciled to costs annually, "without regard to the actual charge for the service."[1] H.R. Conf. Rep. No. 101-964, *reprinted in* 1990 U.S.C.C.A.N. 2374, at 2459.

Through five sets of amendments to the Medicare laws over the intervening years, Congress expanded the Medicare FQHC benefit. With limited exceptions, the added services are preventive services that do not result in a billable visit.

In the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, Congress added a provision for wraparound payments for services provided under Medicare Advantage (MA) plans, similar to the provision in effect in the Medicaid program.

Over time, flaws in the Medicare cost-based payment system, as carried out in the implementing regulations, became clear. Most importantly, as noted in a July 30, 2010 GAO report, the application of the UPLs and productivity screens resulted in total payments to health centers that fell far short of their reasonable costs. In 2007, for example, the application of the UPLs and screens collectively excluded $72.8 million, or 14.5% of the health centers' otherwise-allowable costs. United States GAO, *Medicare Payments to Federally Qualified Health Centers* (July 30, 2010), p.9.

C. The Medicare FQHC Prospective Payment System

In Patient Protection and Affordable Care Act (PPACA) § 10501(i), Pub. L. No. 111-148, Congress provided for the development and implementation of a new PPS for FQHCs in Medicare. While there is

[1] The implementing regulations issued in 1992 explained that CMS (then HCFA) was tasking Part A intermediaries, rather than Part B carriers, with processing FQHC payment, even though FQHC services is a Part B benefit, because carriers were accustomed to administering payments on a reasonable charge basis, and intermediaries to reimbursing providers on a reasonable cost basis. The regulations specified that the limitation of payments to reasonable charges did not apply to FQHC services. 57 Fed. Reg. 24,961, 24,975 (June 12, 1992) (amending 42 C.F.R. § 405.502).

no legislative history available, we agree with CMS's assessment in the preamble to the Proposed Rule as to the goal of the legislation: to ensure that "FQHCs are fairly reimbursed for the services they provide to Medicare patients in the least burdensome manner possible, so that they may continue to provide primary and preventive health services to the communities they serve." 78 Fed. Reg. at 58,391. In that regard, the purposes of the Medicaid PPS and Medicare PPS appear to be the same: to lighten administrative burdens while ensuring fair payment, and to encourage health centers to continue to provide cost-effective, comprehensive primary care services.

With respect to development of the PPS, the ACA required generally that the new prospective payment system have several key characteristics, including that the system "be established to take into account the type, intensity, and duration of services furnished by Federally qualified health centers." SSA § 1834(o)(1).

With respect to implementation of the PPS, the statute requires that health centers be paid according to the new PPS for cost reporting periods beginning on or after October 1, 2014, with payments structured as follows:

1. In the first year of implementation, the "estimated aggregate amount of prospective payment rates" must "equal to 100 percent of the estimated amount of reasonable costs . . . that would have occurred . . . if the system had not been implemented." For purposes of this analysis, the "aggregate amount" of PPS rates is determined prior to the application of the "lesser-of-PPS-or-charges" rule described in (4) below, and the "estimated amount of reasonable costs" is determined without application of the present UPLs or productivity screens, and prior to the application of the coinsurance provisions.
2. In the first year *after* the year of implementation of the system, the PPS rate will be increased by the percentage increase in the MEI.
3. In subsequent years, the PPS rate will be increased by the percentage increase in "a market basket of Federally qualified health center goods and services as promulgated through regulations," or if such an index is unavailable, by the MEI.

The ACA also revised the statutory provisions concerning MA wraparound payments, to ensure that for services provided under contract with an MA organization pursuant to the PPS methodology, the wraparound payment is based on the PPS rate. SSA § 1833(a)(3)(B)(i)(II).

II. Comments

NACHC supports and shares CMS's goal that the new PPS methodology "fairly reimburse [FQHCs] for the services they provide to Medicare patients in the least burdensome manner possible, so that they may continue to provide primary and preventive health services to the communities they serve." 78 Fed. Reg. at 58,391. NACHC also commends CMS for recognizing that a per-visit payment methodology is consistent with health centers' comprehensive model of care.

Nevertheless, in two major respects, NACHC believes that the provisions CMS has proposed will undermine the agency's own goals, and in particular, the goal to encourage "greater bundling of services." 78 Fed. Reg. at 58,391.

First, NACHC believes that CMS lacks statutory authority to enforce the "lesser-of" provision, as explained further below. Second, CMS's proposal not to recognize multiple encounters in a day under any circumstance (the "per diem" concept) undermines the goal of encouraging bundling of services. If health centers are not able to receive payment for encounters for different service types on the same day, it will also impair access to services for elderly and disabled Medicare beneficiaries. NACHC

appreciates CMS's openness to input on this point and recommends that CMS withdraw this portion of the Proposed Rule.

NACHC's comments on these and other provisions of the Proposed Rule are below.

A. Lesser-of-PPS-or-Charges (42 C.F.R. §§ 405.2462(d); preamble Section II.E.2)

Provisions of the Proposed Rule:

Proposed 42 C.F.R. § 405.2462(d) states that for FQHC visits billed under the PPS, Medicare pays "80 percent of the lesser of the FQHC's charge or the PPS rate." This provision implements the statutory provision at Social Security Act § 1833(a)(1)(Z).

The text of the Proposed Rule does not explain the implementation of this provision. CMS also does not explain the "lesser-of" comparison in the preamble. Further, neither CMS's regulatory impact analysis nor the report of the contractor that supported development of the PPS rate, Arbor Research Collaborative for Health, appears to have considered the effect of the lesser-of provision on health center reimbursement under the Medicare PPS. Accordingly, we expect this is because the policy is not intended to apply to health centers.

Comment:

In NACHC's opinion, CMS lacks statutory authority to implement the lesser-of provision. Social Security Act § 1833(a)(1) by its terms applies only to services "described in section 1832(a)(1)." Section 1832(a)(1), in turn, explicitly excludes FQHC services. FQHC services instead are described at Section 1832(a)(2). On its face, then, Section 1833(a)(1)(Z) appears not to apply to FQHC services. CMS should at minimum obtain a legal determination concerning its authority to enforce the provision.

If CMS determines that it does have authority to enforce the lesser-of provision, we urge CMS to clarify its implementation in the final rule, and since any revisions will likely be significant, NACHC urges CMS to give interested parties an opportunity to comment on any changes. Given that this provision will likely have a significant impact on FQHC payment,[2] the Proposed Rule does not contain enough detail concerning CMS's proposed implementation of the provision. At a minimum, CMS should define the term "charge" in the final rule.

The lack of detail concerning the implementation of the lesser-of provision in the proposed rule is particularly concerning to NACHC for several reasons.

First, charges have not played a role in health centers' Medicare reimbursement methodology since 1990. Health centers therefore need logistical assistance and guidance in understanding how the "lesser-of-rate-or-charges" limitation will work.

Second, the details of implementation are critical, because one approach CMS might choose – a comparison, for each visit, of the PPS rate to the charges associated with specific HCPCS procedure codes that the health center billed for FQHC services on the day the visit occurred comparing the PPS rate to charges for specific services listed on patient claims – would result in health centers receiving a reimbursement rate that effectively falls short of the PPS. CMS has designed the FQHC payment methodology as a comprehensive payment per visit for the bundle of FQHC services, based on a national average of costs per FQHC encounter. Comparing this bundled payment to charges for specific claims

[2] The Proposed Rule states that the PPS methodology is estimated to increase health center reimbursement overall by 30 percent. The report of the technical contractor, Arbor Research Collaborative for Health, at Table 26, shows the calculation behind this statement; however, the analysis appears to rest on the faulty assumption that each health center will receive its PPS rate for all services provided.

(or groups of claims for services provided to a patient on the same day) would be an "apples to oranges" comparison.

Such an approach would routinely yield underpayment. Health centers would receive payment capped at their charges for any visit where the associated charges on the day of the visit are less than the PPS. For visits whose associated charges equal or exceed the PPS, payment would be limited to the PPS. Where a health care provider is reimbursed under an average rate for a bundle of services, the provider must receive *the bundled rate for all services*—not just those services whose associated charges equal or exceed the average cost for the bundle.[3] If payment is capped for all services whose associated charges fall short of the mean, then the payment is effectively "unbundled," and the average payment by encounter for each health center would fall short of the average rate in many cases. The administrative burden would also be significant for health centers, as they would have to essentially unbundle each of their already bundled visits to make this comparison of PPS versus actual charge. This seems contrary to CMS's intent in the proposed rule.

If CMS chose to implement the lesser-of provision that way, it would make it difficult for health centers to meet their obligations under Section 330 of the PHS Act. Section 330 requires health centers to collect adequate payment (*i.e.,* payment sufficient to cover costs) from government programs, including Medicare. As detailed above, Congress enacted the Medicare FQHC provisions in OBRA 1990, which provided for cost-based payment to health centers, in part to ensure that the Medicare payment methodology harmonized with Section 330 requirements. The bundled PPS rate satisfies this requirement in a general manner because it provides for a per-encounter payment that is a proxy for the health center's actual cost per encounter.

But with a "lesser-of-rate-or-charge" limitation implemented on the basis of individual charges, the effective reimbursement falls short of that cost-related rate. Health centers will be underpaid for their Medicare visits and will be forced to subsidize the inadequate Medicare payments with amounts from their Section 330 grants – grants that are intended to cover the costs of serving the uninsured and underinsured.

As to implementation approaches that CMS should consider in revising the Proposed Rule, NACHC recommends the following.

We believe that CMS should exercise the flexibility they are given due to the statutory deficiency which does not bestow the authority to implement this provision. At a minimum CMS should obtain a legal determination whether it has authority to implement this provision. If CMS does not share

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[3] The statutory deficiency noted above bears out this critical distinction. The components of Medicare Part B for which payment is addressed by Social Security Act § 1833(a)(1) (*i.e.,* those referenced in Section 1832(a)(1)) are those paid for on a fee basis for each procedure, item, or service. For such a payment methodology, a "lesser-of-rate-or-charge" limit makes sense, and such a limit applies to most services referenced in Section 1833(a)(1). The Part B services that are excluded from 1833(a)(1) and addressed in other portions of 1833(a), including FQHC services, are those that are paid for on a different basis. For any service reimbursed on a basis other than a fee-schedule—for example, a bundled or cost basis—a "lesser-of-rate-or-charges" rule implemented on an individualized basis would result in underpayment. The statutory structure thus suggests that a "lesser-of" rule should not apply to FQHC services paid for under a bundled rate. The regulations implementing Social Security Act § 1833, located at 42 C.F.R. Part 405, Subpart E, reinforce this. The regulations provide that in general under Part B, Medicare pays no more than the "reasonable charge" for the service. 42 C.F.R. § 405.501(a). Certain categories of services that are reimbursed on the basis of "reasonable cost," including FQHC services, are excepted from this general rule. *Id.* § 405.501(b). CMS did not propose to amend those regulations as part of this Proposed Rule.

NACHC's view of their lack of statutory authority to implement this provision, then we suggest the following,

First, we note that if CMS makes significant revisions to the payment methodology or to its treatment of the "lesser-of" issue, CMS would have a responsibility to give the public a chance to comment on the new proposals before they could be finalized.[4]

Second, CMS should grant a moratorium of two to three years on implementation of this statutory provision. This would allow time for health centers, whose Medicare reimbursement has not been based on a charge structure since 1990, to adapt their capabilities to the new system. This transition time is particularly necessary because of the sometimes-contradictory guidance that health centers have received in the past concerning Medicare FQHC billing (and in particular, which "technical components" are excluded from the all-inclusive rate).

Finally, NACHC recommends that CMS implement the lesser-of provision in a way that ensures parity between the rate(s) and charges compared. For example, the bundled, per-encounter PPS rate could be compared with the health center's average charge per FQHC visit.[5] In order to avoid the need for a retrospective comparison, CMS could compare the PPS rate with the health center's average charge per visit in the prior year, trended forward by the MEI (or the FQHC-specific inflation index). Payment for every FQHC visit in a given year would therefore be at the same level – the lesser of 80 percent of the "average charge" that year, or the PPS rate.

Alternatively, CMS could conduct the "lesser-of-PPS-or-charges" comparison as an annual reconciliation of aggregate PPS rates paid to total allowable costs. As noted above, per Section 330 of the PHS Act, a health center's schedule of charges must be "consistent with locally prevailing rates or charges and designed to cover its reasonable costs of operation." PHS Act § 330(k)(3)(G)(i). The cost report is therefore a reasonable proxy for total "actual charges" during a cost reporting year. Under this proposed approach, the sum of all PPS payments to the health center during the cost reporting year would be compared with the health center's total allowable costs on its Medicare cost report.

B. Limit of One Billable Visit Per Day (42 C.F.R. §§ 405.2462(c), 405.2463(b)(2), 405.2464(b)(2); preamble Section II.B.1)

Provisions of the Proposed Rule:

Under the Medicare regulations governing the present (cost-based) payment system, health centers may bill for more than one visit on the same day when either (1) the patient suffers illness or injury requiring additional treatment after the first encounter, or (2) the patient has a medical visit and a mental health visit. 42 C.F.R. § 405.2463(b). In addition, health centers may bill for diabetes self-management training (DSMT) services and medical nutrition therapy (MNT) services as a separate visit even when on the same day as a medical visit. (CMS also proposes in the Proposed Rule to allow same-day billing for a medical or mental health visit and an IPPE visit for health centers that are still billing under the cost-based rate. 78 Fed. Reg. at 58,411.)

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[4]. "Given the strictures of notice-and-comment rulemaking, an agency's proposed rule and its final rule may differ only insofar the latter is a 'logical outgrowth' of the former." *Environmental Integrity Proj. v. EPA,* 425 F.3d 992, 996 (D.C. Cir. 2005) (internal citations omitted). Where an agency intends to publish a final rule that is "surprisingly distant" from the proposal, it must provide for a new comment period. *Id.*

[5] As noted in the preamble to the Proposed Rule, CMS computed an average charge per visit for health centers' 2011 FQHC visits as part of its development of the rule. 78 Fed. Reg. at 58,393. The "average charge" concept is familiar in Medicare.

CMS proposes not to observe these exceptions for services that are provided under the new PPS. Proposed 42 C.F.R. § 405.2462(c) states that FQHCs are to be paid a "single, per diem rate" based on the PPS, and proposed 42 C.F.R. § 405.2464(b) states that the rules allowing same-day visits set forth earlier in the regulations (at Section 405.2463) do not apply under the PPS.

In explaining this decision, CMS stated that based on its review of FQHC claims with dates of service between January 1, 2011 and June 30, 2012, "it is uncommon for FQHCs to bill more than one visit per day for the same beneficiary (less than .5 percent of visits)," despite the fact that same-day visits are permitted under the current system. CMS concluded that billing multiple visits on the same day "is a rare event," and "eliminating the ability to do so would not significantly impact either the FQHC payment or a beneficiary's access to care." 78 Fed. Reg. at 58,394. CMS also noted that eliminating the ability to bill for multiple visits on the same day would simplify billing requirements. On these grounds, CMS concluded that "the level of effort required to develop an adjustment or separate rate for each of these services when furnished on the same day as a medical visit would not be justified." 78 Fed. Reg. at 58,394. CMS also concluded that refusal to recognize same-day visits would be "consistent with an all-inclusive methodology."

CMS sought comment on this aspect of the Proposed Rule.

Comment:

NACHC appreciates CMS's request for feedback from commenters on this aspect of the Proposed Rule. We urge CMS to withdraw these provisions and instead, to apply to the PPS methodology the same rules currently used for same-day visits provided under the cost payment methodology.

NACHC feels that CMS's proposed approach is a counterproductive policy decision, because it discourages a positive trend in health centers toward integrated models of care, utilizing multiple providers in a patient's single trip to the health center.[6] This trend is gaining momentum with each passing month, and the claims data that CMS reviewed from 2011 and 2012 may not have accurately reflected the number of same day visits a patient actually receives. As of 2008, HRSA found that two thirds of health centers provide on-site mental health services and one-third provide on-site substance abuse treatment services. Today, those percentages have risen to almost 70% and 40% respectively. *See* http://www.hrsa.gov/publichealth/guidelines/BehavioralHealth/index.html. According to the 2012 Uniform Data System (UDS), the number of health center patients receiving behavioral health services nationwide increased by 21.4 percent from 2010 to 2012.

[6] The claims data that CMS has relied on to reach the conclusion that same-day billing is very rare may not be accurate. First, the exclusive use of 2011 and 2012 claims data limits the utility of the data, because in 2011 many health centers did not have enough advance notice or technical support to follow the coding requirements fully from the outset. The requirement for health centers to report procedure codes on claims, which took effect on January 1, 2011, was finalized on November 29, 2010, leaving the health centers with only one month of transition time before it took effect. *See* Final Rule, Medicare Program, 75 Fed. Reg. 73, 169, 73,613 (Nov. 29, 2010) (adding new 42 C.F.R. § 405.2470). In addition, CMS's own National Correct Coding Initiative (NCCI) may play a role in the low rate of billing same-day visits. We understand that under NCCI, CMS limits same-day billing for certain paired codes of services and practitioner types. One expert that reviewed the issue, while acknowledging that the restrictions were designed to prevent inappropriate billing, expressed concern that these rules might be limiting health centers' ability to bill for properly-provided same-day visits. *See* Truven Health Analytics, *Financing of Behavioral Health Services within Federally Qualified Health Centers* (July 23, 2013), p. 18.

Health centers are well-situated to serve as health homes that address behavioral health needs. Some health centers have created a team-based primary health-behavioral health approach, in which a behavioral health consultant is part of the primary care treatment team. Health centers that have implemented this model also try to increase efficiency in the treatment of patients with chronic medical and behavioral health conditions by coordinating same-day office visits with the primary care provider and the behavioral health clinician. These approaches have significant benefits for Medicare beneficiaries. Among dual eligible (Medicare-Medicaid) beneficiaries, 40% suffer from both a physical and mental or cognitive disease or condition; this figure stands at 17% for Medicare beneficiaries as a whole. Kaiser Comm'n on Medicaid and the Uninsured, *Chronic Disease and Comorbidity Among Dual Eligibles*, p. 1 (July 2010).

CMS should seek through policy to encourage, not discourage, this trend toward integration. Even if the practice of same-day billing of primary care and behavioral health services is rare on a national basis, it is very common in a growing number of health centers that will be disproportionately harmed by this decision.

CMS's proposal would encourage "unbundling" of medical and behavioral health services, which would have a particularly negative effect on access to care for Medicare beneficiaries. For instance, transportation barriers are often a significant issue for elderly and disabled patients of health centers. It is important for health centers to be able to offer these patients the convenience of scheduling visits with multiple clinicians in the same day.

For these reasons, we encourage CMS, at a minimum, to maintain, for purposes of services provided under the PPS, health centers' present capacity to bill for same-day visits.

C. Payment and Coinsurance for Preventive Services (42 C.F.R. § 405.2410; preamble sections II.B.2, II.E.4)

Provisions of the Proposed Rule:

Under the existing regulations, a beneficiary's coinsurance for FQHC services "may not exceed 20 percent of a reasonable amount customarily charged by the center for that particular item or service."[7] 42 C.F.R. § 405.2410(b)(2)(ii). CMS proposes to amend the regulation to provide that coinsurance shall be equal to 20 percent of the lesser of the FQHC's charge of the PPS rate. 78 Fed. Reg. at 58,397 and 58,408.

CMS acknowledges that this revision is not motivated by any statutory amendment but states that the revision "is consistent with the statutory change to the FQHC Medicare payment and is consistent with statutory language . . . that addresses coinsurance amounts and Medicare cost

[7] The statutory authority for FQHC coinsurance under Medicare is Social Security Act § 1866(a)(2)(A), which provides that for services under Part B, a provider of services may charge a coinsurance "an amount equal to 20 per centum of the reasonable charges for such items or services (not in excess of 20 per centum of the amount customarily charge for such items or services by the provider)." CMS notes in the preamble that because coinsurance is based on charges under the existing cost-based system, while payment always equals 80 percent of the AIR, total payment to the health center may exceed the AIR. CMS states that claims data from 2011-2012 suggest that beneficiary coinsurance based on charges was approximately 18 percent higher than coinsurance based on AIR. The fact that total payment to the health center exceeded the AIR by virtue of the level of coinsurance does not mean the payment to the health center exceeded its reasonable costs. As noted above, because of the application of the upper payment limits, more than 70 percent of health centers received payments below their reasonable costs of providing services.

principles." 78 Fed. Reg. at 58,397. CMS states that the goal of the revision is to ensure that "total payment to the FQHC, including both Medicare and beneficiary liability, would not exceed the FQHC's charge or the PPS rate."

With respect to preventive services, CMS states in the preamble to the Proposed Rule: "Effective January 1, 2011, Medicare waives beneficiary coinsurance for eligible preventive services furnished by a FQHC." 78 Fed. Reg. at 58,397. However, the regulation on coinsurance, as revised in the Proposed rule (see draft 42 C.F.R. § 405.2410) does not state this requirement. The regulation on payment (42 C.F.R. § 405.2462), similarly, does not clarify that Medicare's payment to the health center will be at a higher level (100 percent, rather than 80 percent) for those services or service components for which coinsurance is waived.

Comment:

NACHC recommends that CMS amend the regulation on payment (42 C.F.R. § 405.2462) to state that Medicare will pay the health center 100 percent of the relevant rate—*i.e.,* the lesser of PPS or charges (if CMS determines that it has statutory authority to implement that limitation)—for any service or service component for which CMS proposes to require health centers to waive the application of coinsurance. We also recommend that CMS include the required waiver of coinsurance for preventive services in the coinsurance regulation (42 C.F.R. § 405.2410).

Finally, we recommend that when CMS evaluates whether it has statutory authority to impose the "lesser-of" provision and considers alternative mechanisms for implementing that provision, CMS make corresponding revisions to the coinsurance regulation.

1. Medicare's Payment for Preventive Services (42 C.F.R. § 405.2462(d))

NACHC recommends that CMS clarify the regulation to ensure that Medicare's payment to health centers for FQHC visits consisting of or containing preventive services is 100 percent.

In the Affordable Care Act, Congress required that several preventive services be paid by Medicare at one hundred percent of the relevant payment rate, thus eliminating the need for the provider or supplier to collect beneficiary coinsurance. Importantly, Congress did not separately amend the statute to prohibit the imposition of coinsurance.

Under existing law at the time the ACA was enacted, coinsurance had already been waived in that manner--*i.e.,* Medicare made payment at 100 percent--for clinical laboratory tests. *See* Social Security Act § 1833(a)(1)(D). In the ACA, Congress extended this waiver of coinsurance mechanism to encourage other preventive services, providing for payment by Medicare at 100 percent of the relevant payment methodology for medical nutrition therapy services; for certain "additional preventive services" (including services listed at SSA § 1861(ww)(2)), so long as they are reasonable, appropriate to the patient, and recommended with a grade of A or B by the United States Preventive Services Task Force; and for the IPPE and AWV. *See* PPACA §§ 4103, 4104(b), 10406 (adding or amending SSA §§ 1833(a)(1)(T), (W), (X), (Y)). As CMS noted in a 2010 rulemaking, by virtue of those ACA amendments augmenting payment, Congress impliedly "waived any coinsurance that would otherwise be applicable" for those services. *See* CMS, Final Rule, Medicare Physician Fee Schedule (PFS), 75 Fed. Reg. 73,414 (Nov. 29, 2010).

These developments affected health centers, because all of the services for which Congress implemented the waiver of coinsurance are provided as part of the FQHC benefit. In the ACA, Congress amended the scope of FQHC services to clarify that the same preventive services listed above are part of "federally qualified health center services." Specifically, Congress amended the definition of FQHC services to include "preventive services (as defined in section 1861(ddd)(3)." *See* PPACA § 10501(i)(2)(A)

(amending Social Security Act § 1861(aa)(3)(A)). That clause, in turn, designates the screening and preventive services described in Social Security Act § 1861(ww)(2)[8], as well as the IPPE and AWV.

Since the ACA effected a waiver of coinsurance only by increasing Medicare's payment from 80 percent to 100 percent, there would be no statutory authority for CMS to require health centers to waive coinsurance for preventive services included in the FQHC PPS rate unless Medicare correspondingly pays 100 percent of the PPS rate (or the lesser of PPS or charges, if CMS determines it has statutory authority to implement that limitation) for the relevant preventive service.

We do not believe this reading is controversial, because CMS agreed with it in the preamble to its 2010 regulation on the Physician Fee Schedule. There, CMS considered how best to harmonize the amendments to subparagraphs (T), (W), (X), and (Y) of Section 1833(a)(1) with the ACA amendments relating to payment for FQHC services, and concluded: "We believe we can give both section 1833(a)(1)(Y) and (Z) of the Act, and the definition of FQHC services (revised to include the broader scope of preventive services) their best effect *by providing Medicare payment at 100 percent* for preventive services as defined at section 1861(ddd)(3) of the Act." 75 Fed. Reg. at 73,417 (emphasis added).

Congress' goal in enacting PPACA §§ 4103 and 10406 was to encourage the provision of preventive services, and a payment methodology that deprives health centers of full payment would have the reverse effect. For CMS to require FQHCs to waive coinsurance but to provide payment only at 80 percent of the lesser of PPS or charges would mean that health centers are forced to forgo one-fifth of the required payment for critical services such as the annual wellness visit, welcome to Medicare visit, and medical nutrition therapy. For health centers to willingly accept such a payment reduction would violate their obligations under Section 330 of the PHS Act.[9]

While we feel confident that providing for total payment that falls short of the applicable rate was not CMS's intention, CMS should revise the regulation to make that clear. In order to ensure that the health center receives total payment at the lesser of PPS or charges, CMS should revise the payment regulation, 42 C.F.R. § 405.2462(d), to provide that where a health center provides preventive services that fall within the waiver of coinsurance as a discrete health center visit (*e.g.,* the AWV, IPPE, and medical nutrition therapy services), *or* where the health center provides preventive services / procedures that are a component of a health center visit that is paid for under the PPS rate, Medicare's

[8] The services listed in Social Security Act § 1861(ww)(2) include laboratory tests. CMS states in the preamble to the Proposed Rule that for the preventive services (screenings, *etc*.) that can be split into technical and professional components, "we have instructed FQHCs to bill the professional component as part of the AIR, and separately bill the Part B MAC under different identification for the technical portion of the service on a Part B practitioner claim." 78 Fed. Reg. at 58,394. However, at noted below, CMS's guidance on this point has not been clear.

[9] Because they provide discounts to patients with household income below 200 percent of the federal poverty level, health centers enjoy a safe harbor under the Anti-Kickback Statute under which they may "reduce or waive the coinsurance or deductible amounts for items or service for which payment may be made in whole or in part under part B of Medicare" if the coinsurance or deductible amounts are owed by an individual who qualifies for subsidized services because of his/her income. 42 C.F.R. § 1001.952(k)(2). The amounts that health centers waive under this authority are considered allowable costs under the health center's Section 330 grant. We wish to emphasize that no authority would exist to charge to the Section 330 grant coinsurance amounts waived in their entirety based not on the patient's ability to pay, but instead on a directive from CMS not to collect coinsurance.

payment for the visit would be equal to 100 percent of the PPS (or, if CMS concludes it has statutory authority to enforce such a limitation, 100 percent of the lesser of PPS or charges).

As we explain further below, the latter aspect of NACHC's suggestion – the proposal that the full visit be paid for by Medicare at 100 percent where a component (not the entire visit) is a preventive service with coinsurance waived – is intended to increase the administrative simplicity of the coinsurance waiver process. We believe that CMS's proposed method for health centers to calculate a partial coinsurance waiver for a visit that includes both preventive and non-preventive components is overly burdensome.

If CMS chooses to implement its proposed system under which a health center would partially waive coinsurance for a visit with preventive and non-preventive components, with the amount of the coinsurance waiver calculated based on relative values under the PFS, NACHC proposes that Medicare's payment for a visit including preventive and non-preventive components would be equal to the PPS rate (or the lesser of PPS or charges, if CMS concludes it has authority to impose such a limitation), less coinsurance collected. The goal would be to ensure that total payment equals the PPS rate.

2. Coinsurance (42 C.F.R. § 405.2410)

NACHC recommends that if CMS makes changes to the payment regulation (42 C.F.R. § 405.2462(d)) concerning the "lesser-of" provision, CMS should make corresponding revisions to the coinsurance regulation. In addition, we urge CMS both to specify rules regarding waiver of coinsurance for preventive services in the coinsurance regulation, and to withdraw its proposal for a complex process for health centers to compute partial coinsurance for FQHC visits that include some preventive and some non-preventive services.

a) Proposed Changes to the Coinsurance Requirement

The coinsurance provisions of the regulations are closely linked to the payment provisions, in that Congress' intent was for the sum of Medicare's payment and coinsurance to equal 100 percent of the applicable rate. Therefore, if CMS concludes that it has statutory authority to enforce Section 1833(a)(1)(Z) (the "lesser-of" provision),we urge CMS to revise the coinsurance regulation in keeping with its revision of the payment regulation to take this issue into account.

We suggested above that if it does enforce the provision, CMS should implement the lesser-of provision by comparing, on a per-visit basis, the health center's average charge per FQHC visit with the PPS rate. If CMS pursues that route, then we recommend that coinsurance should be set in an analogous fashion. On an annual basis, coinsurance for each FQHC visit would be established at the lesser of 20 percent of the FQHC's average charge, or 20 percent of the PPS rate.

NACHC also suggested above that CMS consider implementing the lesser-of provision by conducting an annual reconciliation to determine whether aggregate PPS payments exceeded or fell short of allowable costs (as a proxy for actual charges). If CMS chooses that approach, then coinsurance should be set at 20 percent of the PPS rate.

One incidental benefit of each of the proposals suggested above is that they are administratively more straightforward than a requirement that coinsurance equal the lesser of 20 percent of the PPS or the actual charge. Coinsurance is a significant administrative responsibility for health centers. NACHC is concerned that a model involving a comparison of the PPS rate with charges at the point of service would be administratively complex and unnecessarily burdensome.

b) Waiver of Coinsurance for Preventive Services

CMS describes its proposed requirements concerning the waiver of coinsurance only in the preamble to the Proposed Rule – not in the text of the regulations. NACHC recommends that CMS

amend the regulation to specify the rules concerning waiver of coinsurance. CMS should also clarify (for example, by adding this information to the Claims Processing Manual) the list of services to which the waiver requirement applies.[10]

CMS proposes in this section of the rulemaking a complex procedure for determining the amount of coinsurance where an FQHC visit billed under the PPS includes some preventive service components for which coinsurance should be waived, and some other components for which the health center is obligated to collect coinsurance. *See* preamble Section II.E.4, 78 Fed. Reg. at 58,397. CMS proposes that for such visits, payments under the PFS will be used to determine the proportional amount of coinsurance that should be waived, as a portion of the PPS encounter rate.

NACHC is concerned that it would be unduly burdensome on an operational level for the health center to conduct, at the point of service, the complex calculations described in the preamble. NACHC recommends that CMS instead require a complete waiver of coinsurance for any FQHC visit that includes a preventive service (as either a billable visit or an ancillary component). Medicare's payment, in turn, would equal 100 percent of the lesser of the PPS rate or charges for the visit for the entire visit for any visit with preventive service components. That solution would be would be more straightforward to administer, and more consistent with Congress' intent in the ACA to eliminate barriers to the provision of preventive services.

D. Development of Initial PPS Rate (42 C.F.R. § 405.2464; preamble Sections II.A.1, II.A.4, II.D)

Provisions of the Proposed Rule:

The Proposed Rule states, at 42 C.F.R. § 405.2464(b), that CMS proposes to calculate an encounter-based rate "by dividing total FQHC costs by total FQHC encounters to establish an average cost per encounter."

Elaborating on this process in the preamble, CMS explains that it has developed the PPS rate as a single bundled rate, equal to the sum of all health centers' allowable costs as reflected in a cost report covering some portion of 2011 and/or 2012, divided by the total number of health center visits as reflected on claims data collected in the same period. 78 Fed. Reg. at 58,392.

However, CMS proposes to exclude some health center data in determining "total costs." Specifically, CMS proposes to exclude from the costs used to set the national PPS rate both (1) the costs of specific FQHCs whose total costs per visit were more than three standard deviations from the geometric mean, and (2) the costs associated with individual visits (as reflected on claims data CMS used in developing the PPS rate) that were more than three standard deviations from the mean. 78 Fed. Reg. at 58,392 and 58,393.

CMS did not explain how the first set of exclusions (the exclusion of health centers with outlier costs) affected the base rate it developed ($150.42, before the adjustment of the rate for MEI). The second set (exclusion of visits) caused a reduction of approximately $4 in the mean cost per visit (the base rate would have been $154.89 without the exclusion of the outlier encounters). *See* 78 Fed. Reg. at 58,395.

[10] The services subject to waiver were listed in the 2010 rulemaking at 75 Fed. Reg. 73,420-73,430, but as the determination of whether coinsurance is waived for a given preventive services depends on whether the service has received a USPSTF rating or A or B, we understand that the list of services may change from time to time.

Comment:

NACHC urges CMS to reconsider this aspect of the analysis that yielded the base PPS rate.

CMS states that it omitted outlier health centers' costs and outlier encounters from the calculation pursuant to its authority under Section 1834(o)(1)(A) to "include adjustments" in the PPS system. 78 Fed. Reg. at 58,392-58,383. However, the statute commands the Secretary to implement a system in which the aggregate amount of PPS rates is equal to "100 percent of the estimated amount of reasonable costs (determined without the application of a per visit payment limit or productivity screen and prior to the application of [the coinsurance provisions])." SSA § 1834(o)(2)(B). To exclude the costs of certain health centers, and the costs of specific visits, simply because those costs exceed the mean by a specific amount, is a "per visit payment limit," and CMS's omission of those data from the calculation violates a specific command in the statute.

The requirement to include all reasonable costs in the computation of aggregate PPS rates is different from the statutory authority to "include adjustments" in two critical ways, and we believe that these distinctions make clear that CMS does not have the authority to exclude outlier data as proposed.

First, the requirement to include all reasonable costs in the computation of rates is more specific than the adjustment authority, speaking to the precise type of limitation that CMS has proposed to impose. It is located in the subparagraph of the statute (section 1834(o)(2)(B)) addressing requirements for PPS payments in the first year, whereas the adjustment authority is located in the subparagraph generally addressing development of the system (section 1834(o)(1)(A)).

Just as importantly, the "100 percent of reasonable costs" provision is mandatory, whereas the adjustment authority is permissive.

Canons of statutory construction provide that where two provisions of a statute are in tension, the statute should be interpreted so as to give effect to both. If the adjustment authority is interpreted to allow CMS to base the PPS rate(s) on an amount less than 100 percent of reasonable costs, then that broad interpretation of a permissive provision of the statute renders a mandatory provision (the 100 percent of reasonable costs requirement) meaningless.[11] Instead, the interpretation that would give effect to both provisions is one under which the adjustment authority cannot be exercised in conflict with the requirement concerning the aggregate amount of initial payment rates.

As to why some visits are associated with particularly high costs (as reflected through application of the cost-to-charge ratio), NACHC received comments from our field indicating that when health centers administer drugs and biologicals as part of an FQHC visit, the associated charges are often high due to the elevated cost of the drugs. (*See* SSA §§ 1861(aa)(3)(A), 1861(aa)(1), 1861(s)(2)(A) (including in FQHC services definition "drugs and biologicals which are not usually self-administered by the patient").) Unlike the costs of vaccines and technical components of preventive services, the costs of health center-administered drugs and biologicals have been incorporated into the all-inclusive rate and presumably will be incorporated in the PPS. By excluding "outlier visits" from the PPS rate, CMS implies that these visits involve excessive or wasteful services, when in fact, health centers cannot control the costs of certain high-intensity visits.

[11] Nor could CMS exclude the outliers under the justification that that measure is necessary to determine the costs' "reasonableness." By virtue of their inclusion in a cost report that was prepared according to the principles set forth in in 42 C.F.R. Part 413, Subpart A, the costs that CMS proposes to exclude were "reasonable."

E. Adjustments to Payment Rate (42 C.F.R. § 405.2462(c); preamble Sections II.C.1-4)

Provisions of the Proposed Rule:

Proposed 42 C.F.R. §§ 405.2462 and 405.2464 describe two types of adjustments that CMS proposes to make to the base PPS rate.

First, CMS proposes to adjust the rate for geographic differences in cost based on the GPCIs. The proposed adjustments by locality name are listed at pages 58,413-58,414 of the Proposed Rule.

Second, CMS proposes to adjust the rate for

> the furnishing of care to a new patient with respect to the FQHC, including all sites that are part of the FQHC, or to a beneficiary receiving a comprehensive initial Medicare visit (that is an initial preventive physical examination or an initial annual wellness visit). A new patient is one that has not been seen in the FQHC's organization within the previous 3 years.

78 Fed. Reg. at 58,410.

CMS explained in the preamble that it considered other adjustment factors for the PPS rate, but found the adjustments "to have limited impact on costs or to be too complex and largely unnecessary for the FQHC PPS." 78 Fed. Reg. at 58,395. CMS notes that it considered adjustments based on demographics, clinical conditions, and duration of the encounter.

Comments:

NACHC supports CMS's decision to design the PPS as a single bundled rate reflecting, on a per-visit basis, 100 percent of health centers' total reasonable costs of providing the FQHC services included in the PPS rate. We also support CMS's decision to provide for an adjustment based on geographical factors, and for an adjustment to reflect the increased cost of the AWV and IPPE. We do recommend several technical changes to each type of adjustment.

1. Geographic Adjustment Factor

To take into account regional variations in the costs of care, CMS proposes to use the Geographic Practice Cost Indices (GPCIs) that are presently used under the PFS. After application of the GPCIs, health centers in urban areas and states with a higher cost of living will have a base PPS rate exceeding the national mean cost per visit; health centers in rural areas and states with lower costs of living will have a base PPS rate less than the national mean. 78 Fed. Reg. at 58,395, 58,413-414.

In general, NACHC does not object to use of the GPCIs. The factors informing geographic adjustments for services provided under the PFS, however, are not identical to the factors relevant for FQHCs. As a result, application of the GPCIs does not fairly consider the operating costs of FQHCs located in rural areas. NACHC therefore recommends that CMS modify the factors taken into account in the GPCIs.

The first geographical factor unique to health centers is the fact that the costs included in the health center's bundled FQHC rate include allowable administrative costs of operating the facility. FQHCs located in rural areas often face higher operating costs (including utilities and transportation costs) than health centers in urban areas. In addition, predominantly rural FQHCs often have fewer sites than urban health centers and thus benefit less from economies of scale that can reduce costs per visit.

The second factor unique to health centers is the challenge of recruiting clinicians in rural areas. FQHCs that are not operated by a tribe or tribal organization are required to be located in a federally-designated medically underserved area, or treat people from a medically-underserved population. FQHCs located in remote areas usually need to incorporate payment incentives in order to attract qualified physicians and midlevel clinicians.

We recommend that the geographical indices be modified to take into account challenges faced by rural health centers which would not necessarily be shared by a rural physician practice. NACHC will be glad to work with CMS on modifications to the GPCIs so that this index will more accurately reflect the geographical factors that impact health centers' service costs.

2. New Patient or Initial Medicare Visit

CMS found, based on analysis of claims data by its contractor, the Arbor Research Collaborative for Health, that the estimated cost per encounter for an FQHC visit was approximately 33 percent higher when an FQHC furnished care to a patient who is new to the FQHC or to a beneficiary receiving a comprehensive initial Medicare visit (*i.e.,* the Initial Patient Physical Exam (IPPE) and the initial Annual Wellness Visit (AWV) at the health center). CMS proposes to adjust the encounter rate to reflect the greater costs of providing these services. 78 Fed. Reg. at 58,395.

NACHC supports this provision, with one qualification. The IPPE and AWV are required preventive services that were added to the FQHC benefit through PPACA § 10501(i). They are an important component of the ACA's emphasis on prevention. Given that the goal is to improve health outcomes by making preventive services more readily available, ensuring that providers do not lose money on these services is critical.

Both the IPPE and each annual wellness visit are associated with increased intensity for the health center, in terms of the duration of the visit and the number of ancillary services or procedures performed. For example, the AWV is a high-intensity office visit including the establishment of or update to a screening schedule for the next five to ten years and the development of a list of risk factors for which interventions are recommended. *See* SSA § 1861(hhh). NACHC therefore recommends that CMS apply the adjusted rate (133 percent to the base PPS rate) to each AWV, not just the initial AWV.

In addition, as reflected in our comments above, NACHC wishes to confirm that in light of CMS's instruction to health centers to waive the coinsurance for the IPPE and AWV, CMS intends to make payment to health centers for these services at 100 percent of the PPS rate for these services, as well as for medical nutrition therapy services. We also emphasize that we urge CMS to formalize these instructions in regulation.

F. Implementation Schedule for PPS and Transition Period (42 C.F.R. § 405.2467; preamble Sections II.A.2, II.E.1)

Provisions of the Proposed Rule:

The Proposed Rule requires the PPS to take effect "for cost reporting periods beginning on or after October 1, 2014." Proposed 42 C.F.R. § 405.2467(a); *see also* SSA § 1834(o)(2)(A). In the preamble, CMS states that "a change in cost reporting periods that is made primarily to maximize reimbursement would not be acceptable under established cost reporting policy," and therefore, a health center will transition into PPS at the outset of its next cost reporting period. 78 Fed. Reg. at 58,397.

As for the MEI update to the base rate, since most of the cost reports that CMS used to compute the base PPS rate were for fiscal years ending on or before June 30, 2012, CMS proposes to apply the MEI to the fifteen-month period from July 1, 2012 through September 30, 2014. The resulting initial PPS rate obtained from this analysis is $155.90. 78 Fed. Reg. at 58,396-58,397.

Comments:

NACHC agrees with CMS's reasoning and implementation.

NACHC agrees with CMS that the use of more recent cost reports would provide for a more accurate PPS rate. If CMS can obtain cost report information for years ending on or before June 30, 2013, NACHC recommends that CMS use the newer data and adjust the MEI accordingly.

G. Preparation of Annual Cost Reports and Development of FQHC-Specific Inflation Index (42 C.F.R. § 405.2467(d)(2); preamble section II.C.5)

Provisions of the Proposed Rule:

CMS explains that health centers will continue to be required to submit annual cost reports, as before. The cost reports will be used for limited purposes: for reasonable cost reimbursement for influenza and pneumococcal vaccines and their administration, and for allowable graduate medical education costs and bad debts. CMS notes that it is also "considering the types of cost data that would facilitate the potential development of a FQHC market basket that could be used in base payment updates after the second year of the PPS." 78 Fed. Reg. at 58,398.

Comments:

NACHC encourages CMS to develop an inflation index based on an FQHC-specific market basket of services, rather than applying the MEI. We note that the statute requires CMS to implement such an index if available beginning in the second year after the implementation of the PPS (see SSA § 1834(o)(2)(B)(ii)(II)).

A 2005 GAO report expressed concern that the MEI is an inadequate measure of inflation for health centers. GAO concluded:

> The MEI is designed to estimate the increase in the total costs for the average physician to operate a medical practice for the purpose of updating physician payment rates under Medicare. As such, the MEI is intended to be an equitable measure of cost changes associated with physician time and operating expenses. . . . FQHCs' and RHCs' costs may not be comparable to those of the average physician. FQHCs provide additional services, including enabling services (such as outreach and translation). . . .

GAO, *Health Centers and Rural Clinics: State and Federal Implementation Issues for Medicaid's New Payment System,* at 30-31 (June 2005). GAO went on to recommend that an FQHC-specific inflation index be developed. GAO noted that other PPS payment methodologies incorporate an inflation index specifically designed to reflect changes in the cost of services paid for under the PPS.

For the same reasons stated in the GAO report, we urge CMS to move quickly to implement an FQHC-specific inflation index based on data from health center cost reports. NACHC will be glad to work with CMS on the development of such an index.

We also encourage CMS to continue to review the PPS rate, especially as new services are added to the Medicare program, to ensure a fair and accurate reimbursement for these additional services.

We also note that as written, the draft regulations do not appear to contain a provision requiring health centers to prepare an annual cost report. For purposes of clarity, CMS should consider adding such a provision to 42 C.F.R. § 405.2467.

H. Medicare Advantage Organizations (42 C.F.R. § 405.2469)

Provisions of the Proposed Rule:

As CMS notes in the preamble, the ACA amended the statutory provisions concerning supplemental payments in the MA context so that a health center providing services under a contract with an MA plan would "be paid at least the same amount they would have received for the same service under the FQHC PPS." 78 Fed. Reg. at 58,398; *see also* PPACA § 10501(i)(2)(C) (amending SSA § 1833(a)(3)(B)(i)(II)).

The regulation, as amended, states: "The supplemental payment for FQHC covered services provided to Medicare patients enrolled in MA plans is based on the difference between . . . Payments received by the FQHC from the MA plan as determined on a per visit basis and the FQHC PPS rate as set forth in this subpart, less any amount the FQHC may charge as described in section 1857(e)(3)(B) of the Act [*i.e.,* permitted cost-sharing under the MA plan]."

Comments: NACHC recommends that CMS clarify this provision in two respects.

First, CMS should clarify its reference to "the FQHC PPS rate as set forth in this subpart," at proposed 42 C.F.R. § 405.2469(b)(2).

As NACHC interprets the relevant ACA language, the statute requires that supplemental payments be established with respect to the PPS rate that a health center would be paid under Section 1834(o)(2) of the Act, as modified by any adjusters contemplated under Section 1834(o)(1) – *i.e., before* the application of the lesser-of provision, which is set forth at Section 1833(a)(1)(Z). We reach this conclusion because PPACA amended Social Security Act § 1833(a)(1)(B) to incorporate by reference the payment amount described in Section 1834(o). It did not incorporate by reference Section 1833(a)(1)(Z), which contains the lesser-of limitation. Hence, that limitation would not have any bearing on wraparound payments for services provided under a contract with an MA organization. We request that CMS specify that point in the final rule.

Second, NACHC wishes to request that CMS issue guidance concerning the imposition of deductibles under Medicare Advantage plans. We understand that under Section 1857(e)(3)(B) of the Act, permissible cost-sharing under MA plans includes deductibles, coinsurance, and copayments. Nonetheless, Congress chose in fee-for-service Medicare to bar application of the deductible for services provided by FQHCs. NACHC urges CMS to issue guidance discouraging MA plans from applying any deductible under the plan to FQHC services.

I. Other Aspects of Medicare FQHC Payment Methodology CMS Should Consider in Promulgating a Final Rule

In the Proposed Rule, CMS is rewriting the Medicare payment regulations for FQHCs. In light of the wide-ranging overhaul of the regulations that CMS is undertaking, we recommend that CMS consider additional amendments to the regulations, as well as operational changes in its administration of the FQHC benefit.

1. Use of Multiple MACs

Under the present system, multiple MACs (formerly, fiscal intermediaries) process FQHC claims. This has given rise to sometimes-conflicting guidance, as each MAC issues different instructions on claiming issues. NACHC recommends that CMS task one MAC with processing FQHC claims.

2. Billing for Technical Components of FQHC Services and for Vaccines

Provisions of the Proposed Rule:

CMS notes in the preamble to the Proposed Rule that laboratory services and diagnostic tests "are generally not within the FQHC benefit, as defined under Section 1861(aa) of the Act." 78 Fed. Reg. at 58,394. CMS states that it has instructed FQHCs, "for services that can be split into professional and technical components, . . . to bill the professional component as part of the AIR, and separately bill the Part B MAC under different identification for the technical portion of the service on a Part B practitioner claim." If FQHCs operate a laboratory, they are instructed to adjust their cost reports to carve out the costs of associated space, equipment, *etc.*

CMS states in the preamble that it is considering changes to its claims processing system that would reject claims in which the qualifying visit describes a service that is outside the FQHC benefit and would reject line items for technical components such as x-rays, laboratory tests, and durable medical equipment which "would be billed separately to Part B." 78 Fed. Reg. at 58,397.

With respect to vaccines, CMS notes in the preamble that it will continue to reimburse influenza and pneumococcal vaccines at 100 percent of reasonable costs through the cost report, and that the vaccines will not be included in the PPS rate. 78 Fed. Reg. at 58,394.

Comment: NACHC does not object to CMS's proposal to reimburse health centers for certain laboratory services and diagnostic tests through separate billing under Part B. We also support CMS's decision to continue to reimburse vaccines at cost.

However, NACHC requests that CMS clarify several aspects of these rules in revisions to the regulations, because the regulations do not currently address this issue. We disagree with CMS's conclusion that laboratory services are by definition excluded from the FQHC benefit. The regulations addressing preventive services included in the FQHC benefit (42 C.F.R. §§ 405.2448 and 405.2449) include the entire scope of the listed preventive services within the statutory FQHC benefit and do not distinguish technical components that should be billed separately.

In particular, PPACA § 10501(i)(2)(A) amended the statutory definition of "federally-qualified health center services" to make clear that such services include "preventive services (as defined in section 1861(ddd)(3)." Social Security Act § 1861(ddd)(3), in turn, includes "the screening and preventive services described in subsection (www)(2)," other than electrocardiogram. Section 1861(ww)(2), finally, includes a variety of screening tests that involve technical components. None of these provisions excludes the technical components of those screenings from "FQHC services," except in the context of the IPPE. CMS's statement on that point in the preamble to the Proposed Rule appears to be inaccurate.

NACHC nonetheless does not disagree with CMS's proposal to reimburse technical components of services separately. But NACHC urges CMS to clarify through regulation the services that are included in the PPS and the services (or "technical components" thereof) that will be subject to other payment methodologies.[12] This is necessary in order to make the rules clear for health centers, so they can bill

[12] The Medicare manuals are contradictory on this point. The Medicare Benefit Policy Manual, at ¶ 60.1, states that technical components of an FQHC service are to be "billed to the FI/AB MAC" as part of the visit. The Medicare Claims Processing Manual states at ¶ 100, contrarily:

> The core services of the benefits are professional, meaning the hands-on delivery of care by medical professionals. Some preventive services, however, are also encompassed in primary care under the benefits, and these services may have a technical component, such as a

appropriately, and also to test the soundness of CMS's assumptions as to the statutory basis for the non-PPS payment methodologies. This clarity is particularly important since CMS states in the preamble that it plans to evaluation claims more rigorously to determine if health centers are erroneously including in PPS claims services or procedures that should be billed separately. This would be fair only if CMS first provides clear rules on the topic.

Further, NACHC wishes to confirm our understanding that for the technical components of the preventive services benefit billed under the physician fee schedule to which the waiver of coinsurance pursuant to PPACA § 10406 applies, the health center can collect payment from the Medicare equal to 100 percent of the PFS amount. Our understanding is that such laboratory tests would be eligible for 100 percent reimbursement pursuant to Social Security Act § 1833(a)(1)(D) and (Y).

3. Telehealth and "Visit" Definition

On April 9, 2013, NACHC submitted comments on CMS Notice of Proposed Rulemaking CMS-3267-P (Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction). Among other suggestions, NACHC recommended that CMS revise the definition of "visit" at 42 C.F.R. § 405.2463 in order to encourage the provision of telehealth services in Medicare. CMS has not yet finalized that rule.

Revising the "visit" definition to encourage telehealth services would be consistent with CMS's goals in the Proposed Rule of facilitating access to services and encouraging efficiency in health centers' delivery of care. We urge CMS to include the proposed revisions in its revisions to the Medicare FQHC regulations.

* * * *

NACHC appreciates the opportunity to comment on this Proposed Rule. NACHC applauds CMS's goals, in implementing the Medicare PPS, of ensuring that FQHCs are "fairly reimbursed for the services that they provide to Medicare patients in the least burdensome manner possible, so that they may continue to provide primary and preventive health services to the communities they serve." We appreciate CMS's eagerness to work with HRSA and with the health center community on the rule, and we commend CMS for implementing the Medicare PPS rate as a single per-encounter rate incorporating the average costs of providing FQHC services. We nonetheless recommend that CMS make some changes to the Proposed Rule in order to take into account issues that may have been overlooked in the rule and supporting analysis.

> laboratory service or use of diagnostic testing equipment. For FQHCs only: Certain mandated preventive services include a laboratory test that is included in the FQHC visit rate. . . . In general, *if NOT part of the RHC or FQHC benefits*, technical services, (or technical components of services with both professional and technical components) are not billed on RHC/FQHC claims. All services in the RHC and FQHC benefits are reimbursed through the all-inclusive rate paid for each patient encounter or visit.

As shown by the above, health centers have received guidance that is at best confusing and at worst contradictory on this important point.

We appreciate CMS's consideration of 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 require any clarification on the comments.

Sincerely,

Roger Schwartz
Associate Vice President of Executive Branch Liaison