ISSUE BRIEF

Medicare/Medicaid Technical Assistance #76

Selected Provisions in the Medicare Prescription Drug Package Impacting Federally Qualified Health Centers, Including Effective Dates

February 2004

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Supported by a grant from the U.S. Department of Health and Human Services, Health Resources and Services Administration, Bureau of Primary Health Care
Introduction

President Bush signed the Medicare Prescription Drug Improvement and Modernization Act [MMA] (P.L. 108-173) into law in December 2003. Among other things, this legislation creates a Medicare prescription drug benefit and makes programmatic and reimbursement changes in the larger Medicare program. Several of the provisions in the bill will directly impact health center grantees (also known as Federally qualified health centers, or FQHCs) and FQHC Look-Alikes.

Although each of these provisions were included in the MMA, NACHC urges health centers to be cautious when dealing with Medicare managed care plans or skilled nursing facilities, and not presume that these policies will take place before the statutorily-determined effective dates.

Although two of the provisions (and possibly all three) have delayed effective dates\(^1\), health centers should not overlook the important victories that these policies represent and the certain financial benefit that they will have once they become effective. In each of these cases, health centers will be in a much better situation than if the provisions had never been enacted.

In addition, NACHC urges health centers to use this time to begin to build relationships with Medicare managed care plans and skilled nursing facilities, and with appropriate entities for potential safe-harbor arrangements, so that they are prepared to make full use of the benefits of these policies once they become effective.

This issue brief is the second in a series intended to educate health centers about relevant provisions of the MMA. Future issue briefs will examine Medicare-approved discount drug cards, the impact on health center-operated pharmacies and the permanent Medicare prescription drug benefit.

Major FQHC-Specific Provisions included in the MMA

A. REIMBURSEMENT FOR FEDERALLY QUALIFIED HEALTH CENTERS PROVIDING SERVICES UNDER MEDICAREADVANTAGE PLANS (AKA MEDICARE WRAP-AROUND)

Section 237 of P.L. 108-173, entitled “Reimbursement for Federally qualified health centers providing services under MA plans,” ensures that health centers recover their reasonable costs for providing services to their patients who are enrolled in Medicare managed care plans.

The Medicare wrap-around serves the same purpose as the Medicaid wrap-around payment that was provided to FQHCs by Congress under the Balanced Budget Act of 1997 by ensuring that centers do not lose money in caring for managed care patients, thereby forcing centers to use their grant dollars to subsidize inadequate managed care payments.

Under Section 237, Medicare Advantage plans (formerly known as “Medicare+Choice” plans) are required to pay health centers with which they contract at a level that is equivalent to their payments to other providers for similar services. CMS then makes payments directly to the health center that “wrap-around” the managed care plan.

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\(^1\) See Section C and footnote 4 of this Issue Brief addressing health center safe harbor effective date.
reimbursements up to the reasonable cost amount.\textsuperscript{2} These Medicare payments must be made no less than quarterly.

\textit{It is important to note that, once the policy takes effect, Medicare Advantage plans are not required to reimburse health centers at their reasonable cost rate – rather Medicare makes the supplemental payment that will make the health centers whole.}

\textbf{Effective Date: For services provided on or after January 1, 2006 and contract years beginning on or after such date}

\textbf{B. EXCLUSION OF CERTAIN...FEDERALLY QUALIFIED HEALTH CENTER SERVICES FROM THE PROSPECTIVE PAYMENT SYSTEM FOR SKILLED NURSING FACILITIES}

Section 410 of P.L. 108-173 allows health centers to bill Medicare directly for their reasonable cost rate for services provided to an FQHC patient at skilled nursing facilities (SNFs). Before enactment of this legislation, payment for FQHC services were built into the skilled nursing facility’s payments, thus requiring centers to recoup payments from the SNF rather than billing Medicare directly for services provided.

This issue has been a particular problem for rural federally qualified health centers (and Rural Health Clinics) that “share” clinical staff with nursing facilities or hospitals. Because the health center’s clinician may do rotations through these facilities, it is important that Medicare directly reimburse the center for these services. However, because of an oversight when Congress drafted the law in 1997, the health center is forced to negotiate with the SNF to receive payments for these services. Because there is no statutory compulsion for SNFs to pay centers for these services, in some cases, health centers did not receive any payments for such services.

Although relatively small and technical in nature, this provision will ensure that health centers are reimbursed for FQHC services provided to patients in off-site skilled nursing facility settings.

\textbf{Effective Date: For services furnished on or after January 1, 2005\textsuperscript{3}}

\textbf{C. PROVIDING SAFE HARBOR FOR CERTAIN COLLABORATIVE EFFORTS THAT BENEFIT MEDICALLY UNDERSERVED POPULATIONS}

Section 431 of P.L.108-173 “safe harbors” from prosecution under Federal anti-kickback laws certain arrangements between health centers and other entities that result in free or discounted items or services to the health center’s patients, as long as certain conditions are met.

\textsuperscript{2} According to the statute, the wrap-around payment will not factor in any financial incentives received by the center from the MA plan, such as risk-pool payments, bonuses, or withholds, that is, in calculating how much CMS must reimburse a FQHC, CMS may not factor in financial incentive payments the center has received from the plan.

\textsuperscript{3} Although the conference report indicates that January 1, 2004 is the effective date, the statutory date takes precedence.
The intent of this safe harbor is to allow health centers to receive free, discounted or
donated items or services (i.e. sliding fee laboratory services for indigent patients, discounts
on rented office space, or donated services from other health care professionals) that help
maintain or expand the availability, or enhance the quality, or services provided to a health
center’s medically underserved community.

According to NACHC’s legal counsel, as many as 2/3rds of all health centers are have been
approached, have considered, or have entered into such arrangements. However, because
of Federal anti-kickback laws, health centers are often advised not to enter into these
arrangements because of the potential of prosecution by the Office of Inspector General.
NACHC estimates that not having access to these arrangements under a safe harbor cost
health centers millions of dollars annually, provided an unnecessary drain on health centers’
grant resources, and increased Medicare and Medicaid costs to Federal and State
governments.

Effective Date: The Secretary shall publish final regulations establishing the
standards under the safe harbor no later than 1 year after the date of enactment
(the legislation was enacted on December 8, 2003). 4

Conclusion

Each of these provisions -- the MedicareAdvantage Wrap-around, health center safe harbor,
and SNF billing provision -- will provide significant relief and assistance to Federally qualified
health centers and their millions of Medicare and uninsured patients. With the delayed
implementation dates, health centers will have the opportunity to lay the groundwork, build
relationships, and financially prepare for the fiscal and operational impact of these provisions.

NACHC will continue to monitor and educate health centers about these provisions as the
Centers for Medicare and Medicaid Services promulgates rules to implement them.

For questions about Federal Medicare Policy (wrap-around and SNF), contact Chris Koppen,
NACHC’s Director of Health Care Financing Policy, at ckoppen@nachc.com. For questions
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Appendices

Appendix A: Statutory Language for FQHC Provisions in the MMA (page 5)
Appendix B: Conference Report Language for FQHC Provisions in the MMA (page 9)

4 NACHC is working with the Department of Health and Human Services’ Office of the Inspector General to
determine whether the safe harbor is effective as of the date of enactment (December 8, 2003) or from the date of
subsequent regulatory promulgation. We will notify health centers and Primary Care Associations once we have
been able to resolve this issue. Of course, health centers should recognize that their existing arrangements are not
necessarily de facto illegal because the safe harbor may not currently be in effect. Of course, health centers should
consult with qualified counsel to minimize kickback exposure and leave room to modify agreements as may be
appropriate to secure safe harbor protection when the OIG issues the implementing regulations.
SEC. 237. REIMBURSEMENT FOR FEDERALLY QUALIFIED HEALTH CENTERS PROVIDING SERVICES UNDER MA PLANS.

(a) REIMBURSEMENT- Section 1833(a)(3) (42 U.S.C. 1395l(a)(3)) is amended to read as follows:

`(3) in the case of services described in section 1832(a)(2)(D)--

`(A) except as provided in subparagraph (B), the costs which are reasonable and related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations, including those authorized under section 1861(v)(1)(A), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A), but in no case may the payment for such services (other than for items and services described in section 1861(s)(10)(A)) exceed 80 percent of such costs; or

`(B) with respect to the services described in clause (ii) of section 1832(a)(2)(D) that are furnished to an individual enrolled with a MA plan under part C pursuant to a written agreement described in section 1853(a)(4), the amount (if any) by which--

`(i) the amount of payment that would have otherwise been provided under subparagraph (A) (calculated as if `100 percent' were substituted for `80 percent' in such subparagraph) for such services if the individual had not been so enrolled; exceeds

`(ii) the amount of the payments received under such written agreement for such services (not including any financial incentives provided for in such agreement such as risk pool payments, bonuses, or withholds), less the amount the federally qualified health center may charge as described in section 1857(e)(3)(B);'.

(b) CONTINUATION OF MONTHLY PAYMENTS-

(1) IN GENERAL- Section 1853(a) (42 U.S.C. 1395w-23(a)) is amended by adding at the end the following new paragraph:

`(4) PAYMENT RULE FOR FEDERALLY QUALIFIED HEALTH CENTER SERVICES- If an individual who is enrolled with an MA plan under this part receives a service from a federally qualified health center that has a written agreement with the MA organization that offers such plan for providing such a service (including any agreement required under section 1857(e)(3))--

`(A) the Secretary shall pay the amount determined under section 1833(a)(3)(B) directly to the federally qualified health center not less frequently than quarterly; and
'(B) the Secretary shall not reduce the amount of the monthly payments under this subsection as a result of the application of subparagraph (A).'.

(2) CONFORMING AMENDMENTS-

(A) Section 1851(l) (42 U.S.C. 1395w-21(l)) is amended--

(i) in paragraph (1), by inserting `1853(a)(4),' after `Subject to sections 1852(a)(5),' and

(ii) in paragraph (2), by inserting `1853(a)(4),' after `Subject to sections'.

(B) Section 1853(c)(5) is amended by striking `subsections (a)(3)(C)(iii) and (i)' and inserting `subsections (a)(3)(C)(iii), (a)(4), and (i)'.

(c) ADDITIONAL CONTRACT REQUIREMENTS- Section 1857(e) (42 U.S.C. 1395w-27(e)) is amended by adding at the end the following new paragraph:

'(3) AGREEMENTS WITH FEDERALLY QUALIFIED HEALTH CENTERS-

'(A) PAYMENT LEVELS AND AMOUNTS- A contract under this section with an MA organization shall require the organization to provide, in any written agreement described in section 1853(a)(4) between the organization and a federally qualified health center, for a level and amount of payment to the federally qualified health center for services provided by such health center that is not less than the level and amount of payment that the plan would make for such services if the services had been furnished by an entity providing similar services that was not a federally qualified health center.

'(B) COST-SHARING- Under the written agreement referred to in subparagraph (A), a federally qualified health center must accept the payment amount referred to in such subparagraph plus the Federal payment provided for in section 1833(a)(3)(B) as payment in full for services covered by the agreement, except that such a health center may collect any amount of cost-sharing permitted under the contract under this section, so long as the amounts of any deductible, coinsurance, or copayment comply with the requirements under section 1854(e).'.

(d) SAFE HARBOR- Section 1128B(b)(3) (42 U.S.C. 1320a-7b(b)(3)), as amended by section 101(f)(2), is amended--

(1) in subparagraph (F), by striking `and' after the semicolon at the end;

(2) in subparagraph (G), by striking the period at the end and inserting `; and'; and

(3) by adding at the end the following new subparagraph:

`'(H) any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1853(a)(4).'.

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(e) EFFECTIVE DATE- The amendments made by this section shall apply to services provided on or after January 1, 2006, and contract years beginning on or after such date.

SEC. 410. EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES FROM THE PROSPECTIVE PAYMENT SYSTEM FOR SKILLED NURSING FACILITIES.

(a) IN GENERAL- Section 1888(e)(2)(A) (42 U.S.C. 1395yy(e)(2)(A)) is amended--

(1) in clause (i)(II), by striking `clauses (ii) and (iii)' and inserting `clauses (ii), (iii), and (iv)'; and

(2) by adding at the end the following new clause:

`(iv) EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES- Services described in this clause are--

`(I) rural health clinic services (as defined in paragraph (1) of section 1861(aa)); and

`(II) federally qualified health center services (as defined in paragraph (3) of such section);

that would be described in clause (ii) if such services were furnished by an individual not affiliated with a rural health clinic or a federally qualified health center.'.

(b) EFFECTIVE DATE- The amendments made by subsection (a) shall apply to services furnished on or after January 1, 2005.

SEC. 431. PROVIDING SAFE HARBOR FOR CERTAIN COLLABORATIVE EFFORTS THAT BENEFIT MEDICALLY UNDERSERVED POPULATIONS.

(a) IN GENERAL- Section 1128B(b)(3) (42 U.S.C. 1320a-7(b)(3)), as amended by section 101(e)(2), is amended--

(1) in subparagraph (F), by striking `and' after the semicolon at the end;

(2) in subparagraph (G), by striking the period at the end and inserting `; and'; and

(3) by adding at the end the following new subparagraph:

`(H) any remuneration between a health center entity described under clause (i) or (ii) of section 1905(l)(2)(B) and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement
contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity.'.

(b) RULEMAKING FOR EXCEPTION FOR HEALTH CENTER ENTITY ARRANGEMENTS-

(1) ESTABLISHMENT-

(A) IN GENERAL- The Secretary shall establish, on an expedited basis, standards relating to the exception described in section 1128B(b)(3)(H) of the Social Security Act, as added by subsection (a), for health center entity arrangements to the antikickback penalties.

(B) FACTORS TO CONSIDER- The Secretary shall consider the following factors, among others, in establishing standards relating to the exception for health center entity arrangements under subparagraph (A):

(i) Whether the arrangement between the health center entity and the other party results in savings of Federal grant funds or increased revenues to the health center entity.

(ii) Whether the arrangement between the health center entity and the other party restricts or limits an individual's freedom of choice.

(iii) Whether the arrangement between the health center entity and the other party protects a health care professional's independent medical judgment regarding medically appropriate treatment.

The Secretary may also include other standards and criteria that are consistent with the intent of Congress in enacting the exception established under this section.

(2) DEADLINE- Not later than 1 year after the date of the enactment of this Act the Secretary shall publish final regulations establishing the standards described in paragraph (1).
Appendix B

Section 237. Reimbursement for Federally Qualified Health Centers (FQHCs) providing services under MA plans

Present Law

Services provided by FQHCs to Medicare enrollees are reimbursed at no more than 80% of the reasonable costs of providing such services less any beneficiary cost sharing amounts collected. People who knowingly and willfully offer or pay a kickback, a bribe, or rebate to directly or indirectly induce referrals or the provision of services under a Federal program may be subject to financial penalties and imprisonment. Certain exceptions or safe harbors that are not considered violations of the anti-kickback statute have been established.

House Bill

No provision.

Senate Bill

Section 615. FQHCs would receive a wrap-around payment for the reasonable costs of care provided to Medicare managed care patients served at such centers. The provision would raise reimbursements to FQHCs, so that when they are combined with M+C payments and cost-sharing payments from beneficiaries, they would equal 100% of the reasonable costs of providing such services.

This provision would extend the safe harbor to include any remuneration between a FQHC (or entity control by and FQHC) and an MA organization.

Conference Agreement

Section 237. FQHCs will receive a wrap-around payment for the reasonable costs of care provided to Medicare managed care patients served at such centers. The provision raises reimbursements to FQHCs, so that when they are combined with MA payments and cost-sharing payments from beneficiaries, they equal 100% of the reasonable costs of providing such services.

This provision extends the safe harbor to include any remuneration between a FQHC (or entity control by an FQHC) and an MA organization.

Section 431. Exclusion of Certain Rural Health Clinic and Federally Qualified Health Center Services from the Prospective Payment System for Skilled Nursing Facilities (Section 410 of the Conference Report and 408 of the House Bill and Section 429 of the Senate Bill)

Present Law
Under Medicare’s prospective payment system (PPS), skilled nursing facilities (SNFs) are paid a predetermined amount to cover all services provided in a day, including the costs associated with room and board, nursing, therapy, and drugs; the daily payment will vary depending upon patient’s therapy, nursing and special care needs as established by one of 44 resource utilization groups (RUGs). Certain services and items provided a SNF resident, such as physicians’ services, specified ambulance services, chemotherapy items and services, and certain outpatient services from a Medicare-participating hospital or critical access hospital, are excluded from the SNF-PPS and paid separately under Part B.

**House Bill**

Services provided by a rural health clinic (RHCs) and a federally qualified health center (FQHC) after January 1, 2004 would be excluded from SNF-PPS if such services would have been excluded if furnished by an physician or practitioner who was not affiliated with a RHC or FQHC. The provisions would apply to services furnished on or after January 1, 2004.

**Senate Bill**

Services provided by a rural health clinic (RHC) and a federally qualified health center (FQHC) after January 1, 2005 would be excluded from SNF-PPS if such services would have been excluded if furnished by an physician or practitioner who was not affiliated with a RHC or FQHC. Outpatient services that are beyond the general scope of SNF comprehensive care plans that are provided by an entity that is 100% owned as a joint venture by two Medicare participating hospitals or critical access hospitals would be excluded from the SNF-PPS. The provision would apply to services furnished on or after January 1, 2005.

**Conference Agreement**

Services provided by a rural health clinic (RHCs) and a federally qualified health center (FQHC) after January 1, 2004 would be excluded from SNF-PPS if such services would have been excluded if furnished by an physician or practitioner who was not affiliated with a RHC or FQHC. The provisions would apply to services furnished on or after January 1, 2004.

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*Section 431. Providing Safe Harbor for Certain Collaborative Efforts that Benefit Medically Underserved Populations (Section 431 of the Conference Agreement and Section 412 of the House Bill).*

**Present Law**

People who knowingly and willfully offer or pay a kickback, a bribe, or rebate directly or indirectly to induce referrals or the provision of services under a Federal program may be subject to financial penalties and imprisonment. Certain exceptions or safe harbors that are not considered violations of the anti-kickback statute have been established.

**House Bill**

Remuneration in the form of a contract, lease, grant, loan or other agreement between a public or non-profit private health center and an individual or entity providing goods or services to the health center would not be a violation of the anti-kickback statute if such an agreement would contribute to the ability of the health center to maintain or increase the availability or quality of
services provided to a medically underserved population. The Secretary would be required to establish standards, on an expedited basis, related to this safe harbor that would consider whether the arrangement (1) resulted in savings of Federal grant funds or increased revenues to the health center; (2) expanded or limited a patient's freedom of choice; and (3) protected a health care professional's independence regarding the provision of medically appropriate treatment. The Secretary would also be able to include other standards that are consistent with Congressional intent in enacting this exception. The Secretary would be required to publish an interim final rule in the Federal Register no later than 180 days from enactment that would establish these standards. The rule would be effective immediately, subject to change after a public comment period of not more than 60 days. The provision would be effective upon enactment.

Senate Bill

No provision.

Conference Agreement

Remuneration in the form of a contract, lease, grant, loan or other agreement between a public or non-profit private health center and an individual or entity providing goods or services to the health center would not be a violation of the anti-kickback statute if such an agreement would contribute to the ability of the health center to maintain or increase the availability or quality of services provided to a medically underserved population. The Secretary would be required to establish standards, on an expedited basis, related to this safe harbor that would consider whether the arrangement (1) results in savings of Federal grant funds or increased revenues to the health center; (2) expands or limits a patient's freedom of choice; and (3) protects a health care professional's independence regarding the provision of medically appropriate treatment. The Secretary would also be able to include other standards that are consistent with Congressional intent in enacting this exception. The Secretary would be required to publish a final regulation establishing these standards no later than 1 year from the date of enactment.