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The Honorable Pete Stark
Ranking Minority Member
Subcommittee on Health
Committee on Ways and Means
House of Representatives

Subject: Use of Program Safeguard Contractors (PSC) Under the Medicare Integrity Program (MIP) to Establish Local Coverage Policy

Dear Mr. Stark:

This responds to your May 11, 1999, letter regarding the Health Care Financing Administration's (HCFA's) plans for operating the Medicare Integrity Program (MIP). Essentially, you asked if the law authorizing the MIP permits HCFA to assign responsibility for local Medicare coverage policy to the payment safeguard contractors (PSCs) who will run MIP under contract to HCFA. You also asked if HCFA's proposed MIP regulations would provide an adequate legal basis for HCFA to conduct local coverage policy-making through the PSCs.

Whether a particular service or product is reimbursable under Medicare is currently determined through a combination of decision-making by HCFA and its contractors. HCFA sets broad coverage policy on a national level. Within the limits established by statute and HCFA guidance, however, local policies are permitted to vary based on local variations in clinical practice. At present, the medical directors of the Medicare carriers, which are the contractors that administer Medicare for HCFA, set local coverage policy. HCFA has said that it is possible that in the future, the setting of local coverage policy will be done through a unit within the PSC, although the carrier medical directors will remain involved.

In our view, while the law establishing the MIP and its legislative history are silent concerning the responsibility for local coverage policy-making under Medicare, the law can reasonably be read, as HCFA does, to make this a legitimate function under MIP. Section 1893 of the Social Security Act makes "medical review" of provider activity a function of the PSCs, and "medical review" has been consistently interpreted by HCFA to include determination of local coverage policy. Similarly, we believe that the proposed MIP regulations provide an adequate basis for HCFA's action. A more detailed discussion follows.

The MIP was authorized by section 1893 of the Social Security Act, as added by the Health Insurance Portability and Accountability Act of 1996, to prevent and combat Medicare fraud and abuse.¹ Under this law, HCFA is authorized (as designee of the Secretary of Health and Human Services) to enter into contracts with eligible private entities, which HCFA calls PSCs, to carry out specified activities promoting the integrity of the Medicare program. One of these activities is “medical review.”²

Although neither HIPAA nor its legislative history expressly mentions local Medicare coverage policy-making in the context of the MIP, the authority for PSCs to conduct medical review of provider activity provides a reasonable basis for HCFA’s position that local coverage decisions may be made within the MIP framework. “Medical review” involves ensuring that medical services provided to beneficiaries are necessary and appropriate, which in turn describes setting local coverage policy. As the HCFA Administrator said in her April 20, 1999, letter responding to your inquiry to her about this issue, HCFA defines “medical review” as “the processes necessary to ensure both the appropriate utilization of services and that services meet professionally recognized standards of care” HCFA says further that “[i]ssuing local medical review policies is an integral part of medical review” that “has always been paid for and developed . . . as part of the program safeguard budget”

HCFA’s interpretation is reasonable even though we found no evidence in the law or its history that, in providing for the PSCs to conduct medical review, Members of Congress expected or were aware that the effect would be to allow HCFA to give the PSCs a major role in setting local coverage policy. HCFA’s use of the term “medical review” to include local coverage determinations has been consistent; it was not adopted solely to support its current interpretation of the MIP authority. For example, HCFA said in December 1996 (after enactment of HIPAA but before implementation of the MIP program) that managed care plans must abide by both national coverage decisions and “specific written policies made by the Medicare carrier or intermediary with jurisdiction for claims in the geographic area served by the plan . . . sometimes called ‘local medical review determinations.’”³

¹ Pub. L. No. 104-191, § 202, 110 Stat. 1936, 1996-98 (classified as 42 U.S.C. § 1395ddd).

² Specifically, MIP contractors are authorized to conduct “[r]eview of activities of providers of services or other individuals and entities furnishing items and services [under Medicare] including medical and utilization review and fraud review” Section 1893(b)(1).

³ HCFA Operational Policy Letter No. 46, December 19, 1996. In the same vein, this document goes on to use the term “medical review policies” as a synonym for “local coverage policies”: “the plan must apply the medical review policies of the contractor in the area where the beneficiary lives.”

By the same token, HCFA's proposed rule is broad enough to permit local coverage policy-making to be conducted through the PSCs. On March 20, 1998, HCFA published a proposed rule⁴ to implement section 1893 of the Social Security Act, as added by HIPAA. Under the rule, contracts between HCFA and the PSCs would set forth generally what functions a PSC is to perform, with specifics to be spelled out in task orders. As authorized by section 1893,⁵ the proposed rule includes medical and utilization reviews among the functions that may be included in such a contract. Moreover, the preamble to the rule indicates that the PSC may perform some or all of the functions currently performed by fiscal intermediaries or carriers.⁶

If you or your staff have any questions, please contact me at (202) 512-5400 or Craig Winslow, Assistant General Counsel, at (202) 512-8225.

Sincerely yours,

Robert Murphy
General Counsel

⁴ 63 Fed. Reg. 13,590.

⁵ See *supra*, note 2.

⁶ We understand that thirteen eligible entities were recently selected to serve as PSCs and six task orders were issued at that time. None of these task orders provides for PSCs to engage in local coverage policy-making, and HCFA officials said that they have no plans at this time to issue such task orders.