



November 26, 2007

Herb B. Kuhn
Acting Deputy Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Mail stop C5-01-14
Baltimore, MD 21244

Dear Mr. Kuhn:

On behalf of the American Academy of Audiology, I am writing in response to the Centers for Medicare and Medicaid Services' (CMS) report to Congress regarding its legal authority to allow direct access to licensed audiologists under Medicare Part B. In the report, the CMS concludes that it does not have "clear and unqualified legal authority" to allow direct access. The CMS concedes that the physician referral requirement is not explicitly mandated by the Social Security Act, however, CMS claims that, without the physician referral requirement, it would not be able to comply with the statute's prohibition against paying for services that are not reasonable and necessary. We do not agree..

Section 1862(a)(1)(A) of the Social Security Act [42 U.S.C. 1395y(a)(1)(A)] prohibits payment for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." We believe that the CMS conclusion is more a matter of policy than law. There is nothing in the statute that compels physician referral as a condition for coverage of audiology diagnostic tests. Instead, the physician referral requirement is best understood as a policy that CMS uses to avoid paying for medically unnecessary services, such as screening tests and tests solely for the purpose of fitting a hearing aid.

The CMS report does not point to any statutory provision that explicitly requires physician referral as a precondition for coverage of audiology diagnostic tests. In fact, the report states that there is no statutory provision requiring physician referral or prohibiting direct access to audiologists: "Medicare's referral requirements are set forth in regulation, not in statute..." CMS, *Report to Congress: Direct Access to Licensed Audiologists under the Fee for Service Medicare Program Medicare Funding of Second Year* (2007), p. 3. Nor does CMS contend that Congress intended that physician referral be a precondition for coverage of audiology diagnostic tests. Instead, CMS suggests that physician referral for diagnostic tests is a requirement that CMS has adopted as a

“means” or “mechanism” to enable CMS to comply with the statutory prohibition against paying for items or services that are not medically necessary. According to the report, if direct access to audiologists for diagnostic testing were allowed, CMS would not be able to comply with this prohibition:

The physician or practitioner referral policy is a key means by which the Medicare program assures that beneficiaries are receiving medically necessary services, and avoids potential payment for asymptomatic screening tests that are not covered by Medicare.... Medicare has used the ordering requirement for diagnostic tests as the principal means to ensure that Medicare does not pay for medically unnecessary screening tests in contravention of the statute and regulations.... We are not aware of a reasonable alternative mechanism to assure that Medicare avoids payment for screening tests not allowed by the statute.

CMS also claims that allowing direct access to audiologists would have serious budget repercussions. The implication is that eliminating the physician referral requirement would result in increased utilization of hearing and balance tests. Moreover, CMS states it could not remove the physician referral requirement for audiology diagnostic tests without doing the same for all covered diagnostic tests, and this would produce “significant budgetary consequences.”

The report concludes that “under the governing statutes, we cannot say that CMS has clear and unqualified legal authority to allow Medicare beneficiaries direct access to audiologists.” We believe CMS’s conclusion that it lacks the statutory authority to allow direct access to audiologists is incorrect. It misstates the relationship between Congress and administrative agencies. Where Congress has directly spoken to an issue, either in a statute or in its legislative history, an administrative agency is indeed bound. However, where Congress has not so spoken, an administrative agency is free to interpret the statute, provided its interpretation is based on a permissible construction of the statute. As the Supreme Court has explained:

If the intent of Congress is clear, that is the end of the matter.... the agency must give effect to the unambiguously expressed intent of Congress. If, however, the court determines Congress has not directly addressed the precise question at issue.... there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation.

Chevron, U.S.A., Inc. v. Natural Resources Defense Council, 467 U.S. 837 (1984).

The Social Security Act is silent on direct access to audiologists. Hearing and balance diagnostic tests are covered by Medicare as “other diagnostic tests” under 42 U.S.C. 1395x(s)(3). As CMS acknowledges, there is nothing in the Social Security Act that predicates such coverage on physician referral. While the statute does prohibit Medicare payment for services that are not medically necessary, there is nothing in the statute that compels CMS to impose a physician referral as the means to avoid paying for medically

unnecessary services. CMS could just as easily have concluded that diagnostic tests are reasonable and necessary when furnished without a physician referral, and there is nothing in the statute that would have forbidden this result. CMS may not choose to use its authority to allow direct access, but it has the authority.

Where Congress has not directly addressed the precise question at issue, a court reviewing an agency decision generally only asks whether the agency decision represents a “reasonable interpretation” of the statute. The agency’s interpretation need not be the only permissible interpretation. In the absence of an unambiguous expression of Congress’ intent, CMS was free to adopt any “reasonable interpretation” of the statute. The physician referral requirement for audiology diagnostic tests originated as a manual provision and was promulgated as a regulation, 42 C.F.R. 410.32, by CMS in 1996. 61 Fed. Reg. 59490 (Nov. 22, 1996). In doing so, CMS explained that audiology tests performed without a physician referral are not reasonable and necessary, but the agency provided no explanation for this conclusion. At the same time, CMS determined that a physician referral would not be required for diagnostic tests furnished by certain other non-physician practitioners, including clinical psychologists, clinical social workers, and nurse practitioners. 42 C.F.R. 410.32(a)(3).

Physician referral is not required for diagnostic tests performed by non-physician practitioners “who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of their authority under State law and within the scope of their Medicare statutory benefit...” Audiology diagnostic tests, except for the fact that they are not an enumerated statutory benefit, meet all of the criteria for exemption from the physician referral requirement. Therefore, it is not at all clear why CMS insists so strongly on the physician referral requirement for audiology tests.

The physician referral requirement for audiology services is a policy that CMS has adopted to fulfill certain statutory mandates. It was not required by Congress, and CMS has the legal authority to do away with it. It is a mischaracterization to argue that the physician referral requirement is compelled by statute. Moreover, while federal agencies have great latitude in choosing which policies are best to effectuate their statutory responsibilities, CMS has never offered a persuasive justification for the policy. In our view, not only is the physician referral requirement for audiology services not compelled by the statute, it is not even clear that it represents a reasonable interpretation of the statute.

This report represents the first time that CMS has clearly stated that it lacks the statutory authority to allow direct access to audiologists. In previous correspondence, CMS has refused to eliminate the physician referral requirement, but it has never explicitly stated that it lacks legal authority to do so. For example, in a 2000 letter, CMS stated the following:

The Social Security Act (the Act) permits Medicare to pay for only those services that are necessary and reasonable. To ensure that a diagnostic service is necessary and reasonable, the Health Care financing Administration (HCFA) [the predecessor agency to CMS] requires all diagnostic tests, including audiologic tests, to be ordered by physicians or other practitioners specifically authorized by the Act to perform physician services. HCFA has no plans to change this long-standing policy.

Letter from Robert Berenson, Director, Center for Health Plans and Providers, HCFA to Sharon Fujikawa, President, American Academy of Audiology dated Jan. 24, 2000.

In a 2002 letter, CMS stated that the physician referral requirement is “fundamental [to the] coverage and payment of diagnostic tests” and recommended that audiologists seek “a statutory change from Congress,” but stopped short of claiming that it lacked the statutory authority to allow direct access (Letter from Sean Tunis, Director, Coverage and Analysis Group, Office of Clinical Standards and Quality, CMS to Robert Leibenluft, Counsel to Academy of Dispensing Audiologists, dated Jan. 11, 2002, denying a request for a national coverage determination allowing Medicare beneficiaries direct access to audiologists).

In conclusion, we believe CMS’ assertion that it lacks statutory authority to allow direct access to audiologists is incorrect. Again, we believe that there is nothing in the statute that compels physician referral as a condition of coverage of audiology diagnostic tests. Instead, the physician referral requirement is best understood as a policy that CMS uses to avoid paying for medically unnecessary services, such as screening tests and tests solely for the purpose of fitting a hearing aid. Further, the CMS report does not point to any statutory provision that explicitly requires physician referral as a precondition for coverage of audiology diagnostic tests. In fact, the report states that there is no statutory provision requiring physician referral or prohibiting direct access to audiologists.

Therefore, on behalf of the Academy, we urge CMS to reconsider its policy of imposing a physician referral as a precondition for coverage of audiology diagnostic tests. We request an opportunity to meet with you to discuss this further. In the meantime, if you have any questions, please contact Phil Bongiorno, Senior Director, Government Relations at 202-544-9335 or pbongiorno@audiology.org

Sincerely,

A handwritten signature in black ink, appearing to read 'Alison Grimes', with a long horizontal flourish extending to the right.

Alison Grimes, AuD
President