You requested our views on whether the Centers for Medicare & Medicaid Services (CMS) has authority to allow audiologists to furnish Medicare-covered diagnostic audiology services without first obtaining a physician order. You further asked that, if we conclude audiologists are permitted to provide such diagnostic services without a physician’s order, we articulate the legal theory and mechanism for so doing.

We conclude that CMS possesses authority to allow audiologists to furnish diagnostic audiology services without a physician’s order. Our analysis and the mechanism for achieving this result follow.

Requiring a physician order for diagnostic audiology tests is a policy choice and, as such, CMS can change its policy to eliminate the physician order requirement.

1. Statutory background

The Medicare statute does not require that diagnostic tests be referred by a physician. Diagnostic tests are included in the statutory definition of “medical and other health services,” which is a category of Medicare benefits. By virtue of being in a Medicare benefit category, diagnostic

1 We are assuming that all such services would be furnished within the audiologist’s scope of practice under state law.
2 Social Security Act (SSA) § 1861(s)(3).
3 See SSA § 1832(a)(2)(B).
tests are covered unless they are excluded from coverage by virtue, for example, of not being reasonable and necessary.4

Similarly, the Medicare statute does not require a physician order for audiology services. Rather, the statute defines the term “audiology services” as “such hearing and balance assessment services furnished by a qualified audiologist as the audiologist is legally authorized to perform under State law . . . .), as would otherwise be covered if furnished by a physician.”5 CMS considers audiology services to be diagnostic tests.6 As such, as explained above, they are covered by Medicare unless otherwise excluded.

2. Regulatory history

Absent a statutory requirement that diagnostic tests or audiology services be ordered by a physician, or a prohibition on such tests or services being provided without a physician order, CMS possesses discretion to permit audiologists to furnish diagnostic audiology services without a physician order.

The history of the regulation requiring a physician order for diagnostic tests confirms this conclusion. The requirement for a physician order for diagnostic tests appears in a regulation stating that diagnostic tests “must be ordered by the physician who is treating the beneficiary . . . .”7 CMS adopted this requirement through a regulation promulgated in 1996, more than 30 years after enactment of the Medicare statute.8 While this time gap alone strongly suggests that the physician order requirement is an exercise of CMS’s discretionary authority rather than a statutory mandate, what CMS said in the rule-making process cements this conclusion.

In the preamble discussion to the proposed rule amending the Medicare regulations to require that diagnostic tests be ordered by the treating physician, CMS did not cite to a specific statutory provision as the source. Rather, CMS explained that it was relying on a manual provision, which provided

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4 See SSA § 1862(a).
5 SSA § 1861(ll)(3).
7 42 C.F.R. § 410.32(a) (2016).
8 Prior to promulgation of the 1996 regulation requiring that all diagnostic tests be ordered by the treating physician, Medicare rules addressed the level of supervision required for diagnostic x-rays and the types of entities that could provide diagnostic laboratory tests. The rules did not require or even mention a physician order for those tests. See 42. C.F.R. § 410.32 (1996).
that for a diagnostic test to be covered, the service must be related to a patient's illness or injury (or symptom or complaint) and ordered by a physician. . . . The results of the test were to be used to treat the patient or refer him or her for treatment. It has come to our attention . . . that, in some cases, the intent of this instruction has been frustrated. We have heard of instances in which a physician . . . has no relationship to the beneficiary, and it is highly likely that tests by this physician would not be medically necessary. We believe this practice generates unnecessary diagnostic tests and places Medicare beneficiaries at needless risk both medically and financially. We propose to further clarify this long-standing manual instruction requirement that tests be ordered by a physician by specifying that the physician ordering the test must be the physician treating the patient. This proposed policy would link the ordering of the diagnostic test to the physician who will use the test results to treat the patient.9

This discussion confirms that the requirement for a physician order is not a statutory one; rather, CMS chose to require that diagnostic tests be ordered by a physician “to assure that beneficiaries receive medically necessary services and to prevent patterns of abuse . . . .”10

Moreover, although the discussion in the preamble to the 1996 proposed rule demonstrates that the statute does not require a physician order for a diagnostic test, the preamble discussion to the 1997 revision of the rule provides additional proof. In explaining revisions to the physician order requirement in 1997, CMS stated:

[C]ommenters have asked about the statutory basis for denial of claims under the ordering rule adopted in the 1996 physician fee schedule final rule. We have determined that tests are not demonstrably reasonable and medically necessary unless they are ordered by the patient’s physician who will employ the tests to manage the patient’s care. Thus, we are clarifying in § 410.32(a) that the denials are based on the exclusion in section 1862(a)(1)(A) of the Act, and contained in § 411.15(k)(1), that is, the services “are not reasonable and necessary for the diagnosis and treatment of illness or injury or to improve the functioning of a malformed body member.”11

The language CMS employed in amending the text of the regulation was: “Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary (see § 411.15(k)(1) . . . ).”12 The regulatory citation is to what is commonly referred to as the “reasonable and necessary” requirement for Medicare coverage. As noted above in CMS’s

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10 61 Fed. Reg. 59,490, 59,497 (Nov. 22, 1996). Indeed, the regulation ultimately adopted stated: “All diagnostic x-ray tests, diagnostic laboratory tests, and other diagnostic tests must be ordered by the physician who treats the beneficiary, that is, the physician who is actively furnishing a consultation or treating a beneficiary for a specific medical problem(s) and uses the results in the management of the beneficiary’s specific medical problem(s).” 42 C.F.R. § 410.32(a) (1997).
12 Id. at 59,098.
discussion of the 1997 rule, that requirement is derived from a statutory prohibition on Medicare paying for items or services “not reasonable and necessary for the diagnosis or treatment of illness or injury . . .”13 The fact that the requirement for a physician order is based on a *general prohibition* against paying for services that are not reasonable and necessary, rather than on explicit statutory text, establishes that CMS made a policy choice in concluding that diagnostic tests must be ordered by treating physicians.

3. Changing the policy

Because CMS made a policy choice to require a physician order, it could change its policy to permit audiologists to furnish diagnostic services without a physician order. That is, CMS could change its view and conclude that it is reasonable and necessary for diagnostic audiology services to be furnished by an audiologist without a physician order.

Indeed, CMS has already reached this conclusion for certain nonphysician practitioners. The regulations requiring a physician order for a diagnostic test contain two exceptions, one of which is for nonphysician practitioners.14 That exception provides:

> Nonphysician practitioners (that is, clinical nurse specialists, clinical psychologists, clinical social workers, nurse midwives, nurse practitioners, and physician assistants) 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, may be treated the same as physicians treating beneficiaries for the purpose of this paragraph.15

Even though this regulation does not specifically list audiologists as nonphysician practitioners, CMS has treated audiologists as nonphysician practitioners in the past.16 Hence, it would be reasonable for CMS to conclude that audiologists should be included in the nonphysician practitioner exception to the physician referral requirement. There are several ways this might be accomplished.

The fastest and simplest way for audiologists to be able to provide diagnostic tests to Medicare beneficiaries without a physician order would be for CMS to change its manuals to make clear

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13 SSA § 1862(a)(1)(A).
15 *Id.*
16 See, e.g., 42 C.F.R. § 424.518(a)(i), which designates certain providers and suppliers as low risk for Medicare enrollment screening purposes (“Physician or nonphysician practitioners (including nurse practitioners, CRNAs, occupational therapists, speech/language pathologists, and audiologists) and medical groups or clinics.” (Emphasis added.)).
that audiologists are nonphysician practitioners for purposes of ordering diagnostic tests. If, however, the agency were to determine that a change in regulations is needed to allow audiologists to furnish diagnostic services without a physician order, it could undertake rulemaking explicitly to include audiologists among the practitioners excepted from the physician order requirement. CMS could do this either by expanding the list of nonphysician practitioners in 42 C.F.R. § 410.32(a)(2) to include audiologists or by establishing an additional exception to the physician order requirement.