authorized representative of the claimant when, and only when, such claim is filed electronically.

Dated: May 24, 2004.

Marybeth Peters,

Register of Copyrights.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Part 440

[CMS–2132–F]

RIN 0938–AM26

Medicaid Program; Provider Qualifications for Audiologists

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule.

SUMMARY: This final rule will revise the requirements for audiologists furnishing services under the Medicaid program. As a result, the requirements will create consistency with the Medicare program's definition of a qualified audiologist by recognizing State licensure in determining provider qualifications. These revised standards will expand State flexibility in choosing qualified audiologists.

DATES: *Effective Date:*

These regulations are effective on June 28, 2004.

FOR FURTHER INFORMATION CONTACT: Mary Clarkson, (410) 786–5918.

SUPPLEMENTARY INFORMATION:

I. Background

A. Medicaid Requirements

Medicaid is the Federally assisted State program authorized under title XIX of the Social Security Act (the Act) that provides funding for medical care provided to certain needy aged, blind, and disabled persons, families with dependent children, and low-income pregnant women and children. Each State determines the scope of its program, within limitations and guidelines established by the law and implementing regulations at 42 CFR chapter IV, subchapter C. Each State submits a State plan that, when approved by us, provides the basis for granting Federal funds to cover part of the expenditures incurred by the State for medical assistance and the administration of the program.

Section 1902(a) of the Act specifies the eligibility requirements that individuals must meet in order to receive Medicaid. Other sections of the Act describe the eligibility groups in detail and specify limitations on what may be paid for as ''medical assistance.'' Under section 1905(a) of the Act, States must provide certain basic services. Section 1905(a) of the Act also identifies categories of services States may provide as medical assistance.

Audiology Services

Under the Medicaid program, States have the option of providing services for individuals with speech, hearing, and language disorders. Services for individuals with speech, hearing, and language disorders historically have been permitted under the Secretary's discretionary authority under section 1905(a)(11) of the Act, which authorizes the Medicaid program to make Federal funding available for State expenditures under an approved State Medicaid plan for audiology services for eligible individuals provided by audiologists meeting the provider requirements stipulated in Federal regulations at 42 CFR 440.110(c). States have discretion to further define audiology services by specifying the amount, duration, and scope of the service. Furthermore, while States can elect whether they plan to provide audiology services to their adult Medicaid population, they are mandated to provide all medically necessary services to Medicaid-eligible persons under 21 years of age under the Federally mandated Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) program. Combined with requirements for providing services to children with disabilities under the Individuals with Disability Education Act (IDEA) (Pub. L. 105–17, enacted on June 4, 1997), Medicaid is responsible for payment of a substantial number of school-based speech, hearing, and language services provided by, or under the direction of, qualified providers defined at § 440.110(c).

Under Medicaid, States are permitted the flexibility to provide audiology services under a variety of benefits. The majority of States offering audiology services do so under their home health benefit defined at § 440.70, or under optional benefits such as the therapies benefit defined at § 440.110, the rehabilitation benefit defined at § 440.130(d), or the clinic benefit defined at § 440.90. However, regardless of the benefit used to provide audiology services, the specific provider requirements at § 440.110(c) must be adhered to. Current Medicaid rules governing audiology services also permit States the flexibility to provide audiology services by, or under the direction of, a qualified audiologist. This flexibility is recognized and widely used by States to provide audiology services to Medicaid-eligible children under IDEA in school-based settings.

Existing regulations at § 440.110(c)(2) require audiologists to hold a certificate of clinical competency from the American Speech-Hearing-Language Association (ASHA), or its equivalent, to furnish audiology services. Individuals with speech, hearing, and language disorders must be referred by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law.

B. Medicare Audiology Requirements

Before the Social Security Amendments of 1994 (Pub. L. 103–432, enacted on October 31, 1994), statutory requirements governing the Medicare program required speech pathologists and audiologists to meet the academic and clinical experience requirements for a Certificate of Clinical Competence (CCC–A) granted by ASHA. In accordance with section 146 of the Social Security Amendments of 1994, Medicare revised its statutory requirements for speech pathologists and audiologists, removing the requirement for ASHA certification and placing primary reliance for determining provider qualifications on State licensure.

In summary, section 1861(ll)(3)(B) of the Act currently governing Medicare audiology services, defines an audiologist as an individual with a master's or doctoral degree who is licensed by the State or who meets specific academic and clinical requirements if providing services in a State that does not license audiologists.

Unlike the Medicaid program, Medicare does not permit audiology services to be provided under the direction of a qualified audiologist.

C. Creating Consistency With the Medicare Program

As noted in our April 2, 2003, proposed rule (68 FR 15974), the revision of the Medicare requirements in 1994 prompted letters from audiology professionals and interested congressional members urging us to create consistency in the Medicaid and Medicare programs' definition of a qualified audiologist by adopting the Medicare definition of qualified audiologist to recognize the role of State licensure in defining a Medicaid qualified audiologist. Proponents recommending the change stated that

the Medicaid definition had not changed in over 20 years and predated the national trend toward greater reliance on State determinations of professional qualifications through licensure. Our April 2, 2003, proposed rule noted that our initial responses to letters urging consistency expressed reluctance to change the Medicaid requirements due to the potential of adversely affecting quality and access to care as well as State flexibility. In addition, we noted our concern about adversely impacting services provided to children receiving school-based audiology services under IDEA since school providers are often exempt from State licensure laws.

As we discussed, continued requests to reconcile the differing definitions prompted us to consider options for changing the Medicaid regulations in a manner that would not compromise State flexibility and quality of care. As we stated in our April 2, 2003, proposed rule, the revised requirements are a result of meetings and interviews with parties most likely to be affected by such a change.

As in the April 2, 2003, proposed rule, we again note that this rule addresses the qualifications of audiologists as defined under § 440.110(c). The requirements under § 440.110(c)(2) addressing qualified speech-language pathologists (SLPs) remain as defined in existing regulations.

II. Provisions of the Proposed Regulations

On April 2, 2003, we published a proposed rule in the **Federal Register** that specified our intent to revise the existing Medicaid regulations governing audiologists to adopt the Medicare standards to recognize State licensure as a qualifying provider standard. Unlike Medicare's standards, however, we proposed to apply the ''default'' standards to States that license, as well as to those States that do not license audiologists or that have specific licensure exemptions. Thus, all audiologists are required to have met specific academic and clinical standards, regardless of whether they practice in a State that has a licensure program, no licensure program, or that exempts certain audiologists from licensure. As we indicated in the April 2, 2003, proposed rule, the revised requirements also serve to recognize the autonomy of the professions of audiology and speech-language pathology by adding a new paragraph (c)(3) § 440.110 to separately define a qualified audiologist. We also stated that the revised audiology requirements increased State flexibility in determining who is qualified to provide Medicaid audiology services. We noted that our research of national audiology usage and review of currently approved Medicaid State Plans also led us to conclude that most, if not all, qualified audiologists currently enrolled in the Medicaid program will continue to be qualified as a result of the continued flexibility in this rule. We commented on our expectation that States will continue to provide audiology services using the flexibility already granted under the Medicaid program to provide audiology services using individuals meeting State provider qualifications and working within State practice acts ''under the direction of'' a qualified Medicaid audiologist.

Additionally, we noted that conforming the Medicare and Medicaid provider requirements serve to eliminate the confusion providers may experience in complying with Federal rules and help to reduce or eliminate conflict where audiologists provide services to both the Medicaid and Medicare populations. We also pointed out that the revised standards eliminate inconsistencies in Medicaid provider standards and eliminate the need for equivalency rulings, which were administratively burdensome and time-consuming for States to obtain.

Finally, because the authority to provide services under direction remains unchanged, the preamble of the April 2, 2003, proposed rule included our guidance on providing audiology services ''under the direction of.'' We included the guidance in response to requests for our interpretation of acceptable standards of practice when providing services under the direction of a qualified audiologist.

III. Analysis of and Responses to Public Comments

We received 107 timely letters containing over 1,323 public comments in response to the April 2, 2003, proposed rule. The comments came from a variety of correspondents, including professional associations, physicians, health care workers, State Medicaid programs, and members of the Congress. We reviewed each commenter's letter and grouped like or related comments. After associating comments, we placed them in categories based on subject matter or based on the section(s) of the regulations affected and then reviewed the comments. All comments relating to general subjects, such as the format of the regulations, were similarly reviewed. This process identified areas of the proposed regulation that required review in terms of their effect on policy, consistency, or clarity. The following is a summary of the comments received and our response to those comments.

Reconciling Medicare and Medicaid Definitions

Comment: Fifty-two commenters stated they thought it important for us to speak with one voice on who is a qualified audiologist to reconcile the Medicare and Medicaid rules.

Response: As stated in the April 2, 2003, proposed rule, the primary purpose for revising the existing audiology provider requirements is to reconcile the Medicare and Medicaid definitions. We agree it is important for us to create consistency in the Medicare and Medicaid programs wherever possible. We believe our proposal incorporating State licensure as a standard defining a qualified Medicaid audiologist helps to bring the two definitions into closer conformity and creates increased flexibility for States and providers of audiology services.

State Licensure

Comment: Sixty-three commenters stated that deferring to State licensure is the most appropriate course of action since many new audiology graduates are declining to purchase private certification and many who previously purchased their private certification are no longer doing so, choosing instead to rely on State licensure. Many also stated that State licensure, rather than private certification, is the most widespread system for determining the qualifications of health care professionals and best serves the goal of consumer protection. The majority of these commenters also said that recognition of State licensure serves to improve access to audiology services, particularly in rural States where ASHA-certified individuals are not always available.

Response: As proposed, the revised Medicaid standards incorporate recognition of State licensure in defining a qualified Medicaid audiologist. As we stated in the proposed rule, we believe recognition of State licensure will afford States increased flexibility in determining who is qualified to provide Medicaid audiology services, thereby increasing the provider pool of ''qualified'' individuals.

Comment: Two commenters expressed support of the proposal to recognize State licensure, but stated that if private certification is mentioned in our rules, the American Board of Audiology certification must be included.

Response: While we appreciate the intention behind this suggestion, we do not plan to specifically cite the American Board of Audiology certification as a qualifying standard since the primary purpose in revising the Medicaid audiology standards is to recognize the role of State licensure. Continued reference and reliance on the ASHA CCC–A in the final rule serves to continue our recognition of individuals currently qualified and enrolled in the Medicaid program by virtue of their ASHA certification. In addition, retention of ASHA certification as a provider standard helps ensure that those individuals who are dually certified as speech-language pathologists and audiologists do not face additional compliance burdens by having to comply with two different standards within the Medicaid program itself.

Comment: Twenty-seven respondents stated they supported the generic definition of an audiologist in instances where State licensure does not exist or where there are special provider exemptions. One commenter felt the proposed standardized definition would enhance access to services by virtue of removing any confusion regarding the qualifications of the individuals(s) providing the needed services. Others commented that the generic definition of an audiologist is very important for those States, and those circumstances, where licensure does not exist or apply, particularly since a State license should determine ability to practice—not membership in a political lobbying group. A few commenters who expressed support of the generic definition also stated that the generic definition helped resolve concerns around licensure exemptions of school-based audiology providers.

Response: We agree that the generic definition of an audiologist is very important for those States, and in those circumstances, where licensure does not exist or apply. As we noted previously, the proposed ''generic standards'' serve to provide additional consumer protections by ensuring that Medicaid audiology services continue to be provided by, or under the direction of, professionally recognized individuals who have completed academic and clinical training programs consisting of demonstrated high quality industry standards.

Comment: Two respondents expressed overall support of the revised standards but strongly encouraged us to recognize State licensure as the *sole* national standard for defining qualified audiologists.

Response: We do not believe recognition of State licensure as the *sole* national standard for defining qualified audiologists is in the best interests of the Medicaid population. As stated in the April 2, 2003, proposed rule, because many States either choose not to license audiologists or exempt audiologists practicing in specific settings from licensure, we believe it imperative that we also incorporate quality standards defining qualified audiologists that guarantee Medicaid-eligible individuals receive services from recognized, qualified professionals in their field.

Comment: One respondent supported the April 2, 2003, proposed rule but expressed concern that the requirement of 350 clock-hours of supervised clinical practicum creates a more restrictive environment than current State licensure requirements. The respondent stated that ''this restriction would reduce the number of audiologists available to the Medicaid population and increase the provider registration burden to the local program to verify training hours rather than simply verifying licensure.''

Response: As stated in the April 2, 2003, proposed rule, we believe the inclusion of minimum standards relating to the provision of Medicaid audiology services serves to address concerns about quality of care in instances where State licensing does not apply. In addition, the proposed Medicaid standards are consistent with the Medicare program standards, helping to further create consistency between the two programs.

We note, however, that we are unclear as to this comment since States currently are required to meet the existing Medicaid requirements at § 440.110(c), which require that an individual be ASHA-certified or working toward certification. Since ASHA certification requires a minimum of 375 clock-hours of clinical practicum, we do not believe the proposed requirement of 350 clinical clock-hours is more restrictive. In addition, we believe States continue to enjoy the additional flexibility afforded them under the Medicaid program since the proposed standards retain the provision permitting audiology services to be provided under the direction of a qualified audiologist.

We also should point out that as a usual and customary business activity, the Medicaid program requires States to ensure that enrolled Medicaid providers meet all qualification requirements set forth in Federal and State law. Providers of Medicaid services must be in compliance with any relevant Federal provider requirements at the time services are furnished to appropriately claim and receive Medicaid reimbursement.

ASHA Certification

Comment: Twenty-three respondents expressed support for the April 2, 2003, proposed rule and retention of the CCC–A. The respondents stated they are pleased that we recognize the need to retain the CCC–A as the professional industry standard that ensures quality services continue to be provided to Medicaid beneficiaries. Many specifically stated concern that removal of the CCC–A would present a special problem for Medicaid services furnished in the school setting, especially where a teacher's certificate is used in lieu of State licensure. Four additional commenters felt that continued reliance on the ASHA CCC–A retains compliance for dually certified individuals and ensures reciprocity.

Seventeen commenters supported retaining ASHA certification, specifically because they believe State licensure alone is not a sufficient tool to establish competency. They stated that because not all States license audiologists and because not all States have universal licensure, reliance on State licensure results in audiology services being provided by lesser or unqualified individuals.

Two commenters stated that we should retain the current rule and reliance on ASHA. They believe that the CCC–A should continue to be the primary credentialing authority so as not to weaken the quality of the workforce and quality of care.

Response: Our proposed definition of a qualified audiologist continues recognition of the CCC–A as a standard for determining qualifications to provide Medicaid audiology services. As we noted, the existing requirements at § 440.110(c)(2), which rely on ASHA certification or its equivalent to define a Medicaid speech-language pathologist, remain unchanged. Therefore, retention of the CCC–A serves to maintain consistency in provider standards within the Medicaid program, as well as limit the administrative burden to States and to individuals who are dually certified. In addition, as we stated above, we believe the standards requiring specific academic achievements and clinical training proposed in this rule serve as added protection to ensure services are provided by professionally recognized and qualified audiologists.

Comment: We received nine comments in support of the proposed rule but objecting to mandating

affiliation with ASHA or any credentialing bodies to receive reimbursement for Medicaid audiology services. Three additional respondents stated they do not support continued reliance on ASHA stating that it is a monopoly with no value to its membership.

Response: While it is not our role to comment on the personal merits of membership in national organizations, it is our role to ensure that Medicaid beneficiaries receive services from professionally recognized, highly qualified individuals in the field of audiology. Federal and private deeming agencies have recognized the CCC–A as a quality credentialing program for over 30 years. Thus, Medicare and Medicaid regulations governing speech, language, and hearing services have historically placed reliance on the knowledge and skills inherent with ASHA certification. Our intent in revising the Medicaid standards is not to eliminate reliance on those quality standards but to conform the Medicare and Medicaid programs through recognition of State licensure to define a qualified audiologist. Our revised standards continue recognition of ASHA certification, not only because it is a recognized industry quality standard, but more importantly because it ensures continuity and reciprocity for those providers who are dually certified and/or currently enrolled in the Medicaid program by virtue of certification. Thus, ASHA certification is no longer mandated, but is retained as one method by which individuals qualify to provide, or continue to provide, Medicaid audiology services.

Support April 2, 2003, Proposed Rule

Comment: We received a considerable number of comments in support of the April 2, 2003, proposed rule overall. In summary, seventy-three commenters wrote in strong support of the rule and urged us to finalize. Forty-five of these same commenters stated they believe the April 2, 2003, proposed rule would improve access to Medicaid audiology services. Sixty-three stated they supported recognition of State licensure, twenty-seven thought the generic definition of an audiologist very important in States and instances where licensure does not exist or apply, and fifty-two said they thought it important that we reconcile the Medicare and Medicaid rules defining a qualified audiologist.

Opposed to April 2, 2003, Proposed Rule

Comment: We received a total of thirteen timely letters containing a variety of comments in opposition to the April 2, 2003, proposed rule. Eight commenters expressed opposition to the April 2, 2003, proposed rule ''urging CMS to make significant revisions to correct the severe flaws in this regulation'' and stating the rule ''inappropriately and broadly expands the scope of practice of audiologists, presenting grave patient care concerns and devastating consequences on the quality of health care available to Medicaid patients with hearing disorders.''

Several others also commented that the April 2, 2003, proposed rule subverts a physician's role as the first point of patient contact. Specifically, commenters stated that hearing and balance disorders are medical conditions that require a full history and physical examination by a physician and a medical diagnosis with medical management and treatment options presented and pursued by a physician. Other commenters stated that audiologists do not and should not engage in prescribing care for hearing and balance disorders. Several commenters stated, ''audiologists and speech-language pathologists, as non-physician health professionals, simply do not possess the training necessary to carry out medical responsibilities that physicians do.'' Five commenters stated the rule should specifically include physicians as providers.

Two commenters opposed the rule stating that we should retain the current rule and the ASHA CCC–A to avoid weakening the quality of workers and care.

Response: The requirements finalized in this rule address our commitment to conform the Medicare and Medicaid programs through recognition of State licensure as a qualifying Medicaid standard. It does not change the scope of practice of professional audiology services. It also does not alter the current role of physicians in evaluating and determining an individual's need for audiology services. Existing regulations at § 440.110(c) require that an individual be referred by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law before the receipt of audiology services. Therefore, physicians and other licensed practitioners practicing within the scope of State law continue to play an important role in ensuring that individuals receive appropriate medical evaluations and assessments to diagnose the need for audiology services. We agree with the comment that audiologists do not possess the training necessary to carry out the medical responsibilities of physicians and therefore should provide only those audiology services within the scope of practice governing their profession.

Also in response to the above comments, we again point out that the Medicaid program permits speech-language and hearing services to be provided by physicians or under the supervision of physicians, under Medicaid's physician services benefit in accordance with regulations at § 440.50. Audiology services may be provided under this benefit as the qualifications of a physician can be construed as including those of providers of speech-language and hearing services as long as their services are provided ''within the scope of practice of medicine or osteopathy as defined by State law * * * or under the personal supervision of an individual licensed under State law to practice medicine or osteopathy.''

Thus, in response to the comment to include physicians in our final rule, we do not plan to adopt this suggestion. As noted above, Medicaid regulations continue to require a physician referral before receipt of audiology services as defined under § 440.110(c). In addition, Medicaid regulations at § 440.50 permit physicians working within State practice acts to provide, or supervise the provision of, audiology services.

In response to the comments opposing the April 2, 2003, proposed rule in favor of retaining the existing requirement for ASHA certification due to quality concerns, we believe our proposed standards, which include recognition of State licensure, combined with specific academic and clinical training standards and continued recognition of ASHA certification, continues our commitment to ensure a quality workforce and quality care.

Comment: We received seven comments in opposition to the April 2, 2003, proposed rule because ''it established a gatekeeper role and impedes access to hearing health care services by facilitating establishment of a gatekeeper system of care and inappropriately placing audiologists as gatekeepers to Medicaid hearing services.''

Response: See our detailed response to comments on physician involvement above. We do not believe the April 2, 2003, proposed rule inappropriately places audiologists as gatekeepers to Medicaid hearing services since § 440.110(c) continues to require a referral by a physician or other licensed practitioner of the healing arts before receipt of audiology services. Our proposed standards address reconciling the Medicare and Medicaid provider requirements through recognition of State licensure and do not authorize

broadening the scope of audiology services beyond the parameters of the profession.

Regarding the above, we wish to note our concern that a number of the comments we received regarding the role of physicians in providing Medicaid audiology services are the result of the guidance included in the preamble of the April 2, 2003, proposed rule, which offered our interpretation for appropriately providing services under the direction of a qualified audiologist. We believe we may have inadvertently caused some confusion by using terminology typically associated with physician services, and not audiology services. Specifically, our use of phrases such as ''*prescribe* the type of care provided'' and ''to ensure beneficiaries are receiving services in a safe and efficient manner in *accordance with accepted standards* of *medical practice*,'' apparently gave some readers the impression that we intend to expand the scope of practice for participating audiologists. We did not intend to do so.

Therefore, as noted below, the guidance regarding services provided ''under the direction of'' in this final rule has been revised to include language more appropriately reflecting the nature and scope of professional practice for audiologists providing Medicaid services.

Miscellaneous Comments

Comment: One commenter expressed concern that the April 2, 2003, proposed rule eliminates hearing aid specialists from Medicaid stating that ''hearing aid specialists are integral members of the hearing healthcare team as they assess hearing and select, fit, and dispense hearing aids and related devices while providing instruction, rehabilitation, and counseling in the use and care of hearing aids and related devices.''

Response: We do not agree that this final rule eliminates hearing aid specialists from participation in the Medicaid program. Further, this final rule will not affect the ability of hearing aid specialists to provide Medicaid-funded services. Currently, under Medicaid, it is possible for a hearing aid specialist to provide and receive Medicaid payment for services if he or she meets the provider requirements at § 440.110(c) and if the State offers those services under its Medicaid program. Individuals not meeting the specific requirements at § 440.110(c) may still be eligible to provide services ''under the direction of'' if so permitted within their scope of practice under State law. In addition, hearing aid services may be reimbursed depending upon the method in which they are covered under a State's Medicaid plan. For example, if hearing services are being provided by individuals licensed in the State as physicians, or under the supervision of a physician as defined in the Medicaid's physician services benefit at § 440.50, then providers must meet the provider qualifications applicable to those requirements. Providers must meet those qualifications because the qualifications of a physician can be construed as subsuming those of providers of speech-language and hearing services when they are provided as physician services.

Comment: Two respondents expressed concern that their organizations were not included in discussions and meetings before publication of the April 2, 2003, proposed rule. One ''respectfully urges its inclusion whenever issues relating to hearing health are considered.'' The other ''* * * would like to request a meeting to discuss these issues, and any other speech, language, and hearing health care issues of interest to CMS.''

Response: It was not our intent to exclude any particular group or organization from participating in discussions and meetings before publication of the April 2, 2003, proposed rule. As we stated in the preamble, the intent of the contacts before publication was to gain an understanding of the implications change would have on Medicaid programs, providers, and beneficiaries. While we believe the information gained achieved that goal, we acknowledge and appreciate the commenters' interest in the Medicaid program and the formation of its rules and policies. As always, we wish to remain responsive to all concerns and welcome future opportunities to discuss issues of mutual interest.

Services Provided ''Under the Direction of''

Comment: Fourteen respondents commented positively on the guidance for providing services under the direction of a qualified audiologist. All urged us to strengthen the guidance to better ensure that Medicaid beneficiaries receive audiology services provided, or appropriately supervised, by a qualified audiologist. Three of the respondents suggested we establish what constitutes an appropriate supervisory ratio of Medicaid qualified providers v. ancillary support staff consistent with State laws and practices. They also believe we should set appropriate ratios of direct contact/supervisory time with the Medicaid recipient for both assessment and intervention. One commenter suggested strengthening our policy to advise audiologists in supervisory roles what recourse options they have if asked to supervise more ancillary support staff than is ethically reasonable, and to require States and school systems to provide ancillary support staff with the ability to reach the qualified audiologist by means of personal contact, telephone, pager, or other immediate means.

Response: We appreciate the commenters' concerns and suggestions on ways to strengthen the guidance for providing services under direction. In response to the suggestion that we establish staffing ratios, we are not establishing a ratio of providers to ancillary staff because we believe this is best done by States in a manner that addresses the unique circumstances within the State. In addition, we believe placing specific requirements on States may go beyond the authority of the guidance contained in this document and would require revisions to the regulatory requirements at § 440.110(c). We have, however, incorporated more general language offering our guidance with respect to staffing ratios by stating that we expect contractual agreements between providers to include requirements such as appropriate supervisory ratios and information on reporting instances of abuse of ethical practices. In response to the suggestion to require States and school systems to provide contact information, we revised the guidance to indicate our expectation that individuals working under the direction of a qualified audiologist be given contact information to enable them to directly contact the supervising audiologist as needed during treatment.

We also would like to say that our guidance in this area is evolving, particularly as it relates to speech-language and hearing services provided to Medicaid-eligible children in schools. We anticipate that we will continue to update and provide guidance as necessary to States and providers through various means such as *State Medicaid Manual* guidelines, letters to State Medicaid Directors, and educational documents, as well as direct technical assistance to State Medicaid agencies.

IV. Provisions of the Final Regulations

This final rule incorporates the provisions of the proposed rule. Thus, we are adopting the provider standards in the proposed rule as final.

Thus, this regulation creates a separate definition at § 440.110(c)(3) pertaining to qualified audiologists under the Medicaid program. We are making a minor technical revision to

§ 440.110(c)(2) to remove the reference to audiologists. Section 440.110(c)(1) remains unchanged and continues to require ''a patient be referred by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law'' to receive Medicaid audiology services.

In addition, although not part of the standards affected by this final rule, we are reiterating the guidance for providing services ''under the direction of.'' The guidance is intended as our interpretation of appropriate practice standards when providing audiology services under direction set forth § 440.110(c)(1). In response to public comments, we have made some revisions to clarify and eliminate confusion regarding an audiologist's scope of practice and to strengthen the guidance to ensure quality services are being provided in an appropriate and professional manner (specific responses to respondents' comments are addressed in section III).

''Under the Direction of''

Audiology services provided under § 440.110(c)(1) require that the ''services be provided by or under the direction of an audiologist for which a patient is referred by a physician or other licensed practitioner of the healing arts within the scope of his or her practice under State law.''

We interpret the authority to provide services ''under the direction of'' an audiologist to mean that a federally qualified audiologist who is directing audiology services must supervise each beneficiary's care. To meet this requirement, the qualified audiologist must see the beneficiary at the beginning of and periodically during treatment, be familiar with the treatment plan as recommended by the referring physician or other licensed practitioner of the healing arts practicing under State law, have continued involvement in the care provided, and review the need for continued services throughout treatment. The supervising audiologist must assume professional responsibility for the services provided under his or her direction and monitor the need for continued services. The concept of professional responsibility implicitly supports face-to-face contact by the qualified audiologist at least at the beginning of treatment and periodically thereafter. Thus, audiologists must spend as much time as necessary directly supervising services to ensure beneficiaries are receiving services in a safe and efficient manner in accordance with accepted standards of practice. To ensure the availability of adequate supervisory direction, supervising audiologists must ensure that individuals working under their direction have contact information to permit them direct contact with the supervising audiologist as necessary during the course of treatment.

In many cases, qualified audiologists are employed by entities such as a Medicaid agency, clinic, or school. In such instances, the terms of the audiologist's employment must ensure that the audiologist is adequately supervising any individual providing audiology services. In addition to the supervisory requirements described above, employment terms should provide for supervisory ratios that are reasonable and ethical and in keeping with professional practice acts in order to permit the supervising audiologist to adequately fulfill his or her supervisory obligations and ensure quality care.

In all cases, documentation must be kept supporting the qualified audiologist's supervision of services and ongoing involvement in the treatment services. Because Medicaid law requires that documentation be kept supporting the provision and proper claiming of services, appropriate documentation of services provided by supervising audiologists, as well as services performed by individuals working under the direction of a qualified audiologist, are necessary. Absent appropriate service documentation, Medicaid payment for services may be denied providers.

Where appropriate, audiology services must adhere to all State requirements and State practice acts governing the provision of services under the direction of a qualified audiologist. As with all Medicaid benefits that permit services furnished under direction, both Federal and State requirements must be met at the time services are furnished for the Medicaid program to appropriately provide Federal financial participation for services furnished on behalf of Medicaid eligible individuals.

V. Collection of Information Requirements

This document does not impose any information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993), Regulatory Planning and Review, the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives, and if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

We are unable to provide a specific dollar estimate of the economic impact this final regulation will have on State and local governments and participating providers. Because the flexibility permitted under Medicaid allows States to provide audiology under various Medicaid benefits, it is not possible to capture accurate expenditure data.

We have determined, however, that this rule is not a major rule under Executive Order 12866, and that this rule will not have a significant economic impact on a substantial number of small entities. We have made this determination because while we believe this rule will permit States to have more flexibility in determining who is qualified to provide audiology services, we do not anticipate any increase in States' use of audiology services due to this regulation. Section 804(2) of title 5, United States Code (as added by section 251 of Pub. L. 104–121), specifies that a ''major rule'' is any rule that the Office of Management and Budget finds is likely to result in—

- An annual effect on the economy of $100 million or more;
- A major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; or
- Significant adverse effects on competition, employment, investment productivity, innovation, or on the ability of United States-based enterprises in domestic and export markets.

In addition, consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare and publish an initial regulatory flexibility analysis for proposed regulations unless we have determined that the regulations would not have a significant impact on a substantial number of small entities. For purposes of the RFA, we do not consider States or individuals to be small entities.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. For purposes of the RFA, audiologists that generate total revenues of $6 million or less in any 1 year are considered to be small entities. The Small Business Administration (SBA) categorizes small businesses for audiologists along with physical, occupational, and speech therapists. The total number of providers within this category that have total revenues of between $5 million and $7.5 million or less in any 1 year is 23,823 that they consider small businesses. Those firms and establishments with total revenue above $7.5 million are not considered small businesses according to the SBA. Therefore, approximately 0.92 percent of audiologists are considered small businesses. (For further information on the SBA size standards, *see* 65 FR 69432.)

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside a Metropolitan Statistical Area and has fewer than 100 beds. This rule will not have a significant impact on small rural hospitals. The Medicaid program permits States the flexibility to provide audiology services under a variety of benefits. The majority of States do so under the home health benefit, the therapies benefit, and the rehabilitation benefit serving a variety of Medicaid beneficiaries. In addition, current Medicaid rules permit States the flexibility to provide audiology services by, or under the direction of, a qualified audiologist. This provider flexibility is recognized by States and is widely used to provide audiology services to children through school-based services programs. Because this rule retains the ability for audiology services to be provided ''under the direction of,'' the rule will not have an impact on how States currently provide services to their Medicaid populations. Therefore, small rural hospitals are not affected.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. We do not anticipate this rule will have an effect on the States, local, or tribal governments, or on private sector costs. As we stated earlier, this regulation gives States more flexibility in determining qualified audiologists thereby giving them the ability to choose from a larger provider pool of ''qualified'' individuals. However, because we expect the primary users of Medicaid audiology services, such as children and seniors, to remain fairly constant, we do not anticipate any significant increase in the use of audiology services due to this rule. In addition, because Medicaid audiology services are optional for States to provide to their Medicaid populations, many States choosing to do so limit utilization in some manner. In addition, many States limit the use of optional services such as audiology in favor of mandatory Medicaid benefits. States providing audiology services to children under the EPSDT program primarily do so as part of their school based services program under IDEA. Since all 50 States currently have a school-based services program in operation, we do not anticipate this rule to have any significant effect on audiology services provided to Medicaid children.

Additionally, recognizing that States currently use the flexibility permitted in the Medicaid law to provide audiology services ''under the direction of'' a qualified audiologist, we expect States will continue to do so by providing audiology services using individuals working under the supervision of qualified audiologists.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts a State law, or otherwise has Federalism implications. We do not believe this rule in any way will impose substantial direct compliance costs on State and local governments or preempts or supersedes State or local law. This rule permits States to use State-licensed audiologists to provide Medicaid audiology services, thereby giving them increased flexibility in providing Medicaid audiology services. In addition, after researching national audiology usage and reviewing States' currently approved Medicaid State Plans, we anticipate that most, if not all, qualified audiologists currently enrolled in the Medicaid program will continue to be qualified as a result of the continued flexibility established in this rule. For this reason, we do not believe that the change in requirements for audiologists included in this rule will result in reduced access to services, or otherwise result in fewer audiology services available through the Medicaid program. We also anticipate that States will continue to provide audiology services by using the additional flexibility already granted under the Medicaid program to provide audiology services using individuals meeting State provider qualifications and working within State practice acts ''under the direction of'' a qualified Medicaid audiologist. We believe the additional flexibility set forth in this rule to recognize State licensure will serve to enhance States' ability to provide services. We do not, however, anticipate this rule will have a significant effect on the actual provision of audiology services in State Medicaid programs, and, therefore, the rule does not have Federalism implications.

B. Anticipated Effects

We anticipate this rule will give States increased flexibility in determining who is a Medicaid-qualified audiologist. We also anticipate that the quality care standards established in this rule will help ensure that Medicaid audiology services continue to be provided by, or under the direction of, highly qualified and trained individuals. Additionally, we believe conforming the Medicare and Medicaid provider requirements will help eliminate any confusion providers may experience in complying with Federal rules and help reduce or eliminate conflict where audiologists provide services to both the Medicaid and Medicare populations (such as in nursing facilities or through home health care agency providers). Additionally, this final rule also serves to eliminate inconsistencies in Medicaid provider standards by no longer recognizing equivalency rulings. Under the current Medicaid rules, States can seek equivalency rulings from their State Attorney General in instances where they believe State licensure is equivalent to ASHA certification. Since this rule recognizes State licensure that meets Medicare-equivalent standards, equivalency rulings are no longer necessary or required. We believe States will look favorably on the elimination of equivalency rulings since they proved administratively burdensome and time-consuming to obtain.

C. Alternatives Considered

In developing the policies set forth in this rule, we met with professional organizations and interested parties to solicit their ideas and concerns. We also worked with our national regional office staffs to review currently approved Medicaid State Plans for information on the provision of audiology services in States' Medicaid programs. We considered the role of audiology services in the Medicaid program and the potential impact changes in the standards for audiology providers will have overall. We considered several options that suggested we— (1) make no change to the current Medicaid audiology requirements; (2) retain current requirements but issue updated policy guidance on issues such as provider equivalency authority; (3) rewrite the current Medicaid regulations to adopt the current Medicare requirements; and (4) rewrite the current Medicaid regulations to adopt the Medicare standards, but with minimum standards that apply in States that license as well as those that do not license or that exempt some practitioners from State licensure requirements.

After much research and consideration of the impact of each of the options, we concluded that option 4—the standards contained in this rule—best satisfies the Secretary's intention, and addresses the request raised by interested parties, to conform the definition of a qualified audiologist under the Medicare and Medicaid programs by recognizing the role of State licensure as a Medicaid provider requirement. We also concluded that the standards in this rule best continue to recognize the broad program discretion granted States under Medicaid by retaining program flexibility while at the same time also building in quality standards that continue to ensure Medicaid services are provided to all Medicaid-eligible individuals by recognized, highly trained professionals.

D. Conclusion

For the reasons stated above, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects Affected in 42 CFR Part 440

Grant programs—Health, Medicaid.

■ For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 440—SERVICES: GENERAL PROVISIONS

Subpart A—Definitions

■ 1. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

■ 2. In § 440.110, paragraph (c)(2) is revised, and a new paragraph (c)(3) is added to read as follows:

§ 440.110 Physical therapy, occupational therapy, and services for individuals with speech, hearing, and language disorders.

* * * * *

(c) * * *

(2) A ''speech pathologist'' is an individual who meets one of the following conditions:

(i) Has a certificate of clinical competence from the American Speech and Hearing Association.

(ii) Has completed the equivalent educational requirements and work experience necessary for the certificate.

(iii) Has completed the academic program and is acquiring supervised work experience to qualify for the certificate.

(3) A ''qualified audiologist'' means an individual with a master's or doctoral degree in audiology that maintains documentation to demonstrate that he or she meets one of the following conditions:

(i) The State in which the individual furnishes audiology services meets or exceeds State licensure requirements in paragraph (c)(3)(ii)(A) or (c)(3)(ii)(B) of this section, and the individual is licensed by the State as an audiologist to furnish audiology services.

(ii) In the case of an individual who furnishes audiology services in a State that does not license audiologists, or an individual exempted from State licensure based on practice in a specific institution or setting, the individual must meet one of the following conditions:

(A) Have a Certificate of Clinical Competence in Audiology granted by the American Speech-Language-Hearing Association.

(B) Have successfully completed a minimum of 350 clock-hours of supervised clinical practicum (or is in the process of accumulating that supervised clinical experience under the supervision of a qualified master or doctoral-level audiologist); performed at least 9 months of full-time audiology services under the supervision of a qualified master or doctoral-level audiologist after obtaining a master's or doctoral degree in audiology, or a related field; and successfully completed a national examination in audiology approved by the Secretary.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program)

Dated: January 23, 2004.

Dennis G. Smith,

Acting Administrator, Centers for Medicare & Medicaid Services.

Approved: February 23, 2004.

Tommy G. Thompson,

Secretary.

Editorial Note: This document was received at the Office of the Federal Register on May 25, 2004.

[FR Doc. 04–12096 Filed 5–27–04; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[WT Docket No. 99–217; FCC 04–41]

Promotion of Competitive Networks in Local Telecommunications Markets

AGENCY: Federal Communications Commission.

ACTION: Final rule, petition for reconsideration.

SUMMARY: In this document the Commission addresses four petitions seeking Reconsideration and/or Clarification of the Commission's determination to extend to users of fixed-wireless telecommunications antennas the same OTARD (Over-the-Air-Reception Devices) protections previously available to customers of multi-channel video service.

DATES: Effective July 27, 2004.

FOR FURTHER INFORMATION CONTACT: Cara Voth, Broadband Division, Wireless Telecommunications Bureau, at (202) 418–0025.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Order on Reconsideration, (Order) released on March 24, 2004 (FCC 04–41). The full text of the Order is available for inspection and copying during normal business hours in the FCC Reference Center, Room CY–A257, 445 12th Street, SW., Washington, DC 20554. The complete text may also be purchased