ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 300

[FRL–6113–9]

National Oil and Hazardous Substances Contingency Plan; National Priorities List Update

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of deletion of the Berlin and Farro Liquid Incineration Superfund Site From the National Priorities List (NPL).

SUMMARY: The Environmental Protection Agency (EPA) announces the deletion of the Berlin and Farro Liquid Incineration Site in Michigan from the National Priorities List (NPL). The NPL is Appendix B of 40 CFR part 300 which is the National Oil and Hazardous Substances Contingency Plan (NCP), which EPA promulgated pursuant to section 105 of the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended. This action is being taken by EPA and the State of Michigan, because it has been determined that Responsible Parties have implemented all appropriate response actions required. Moreover, EPA and the State of Michigan have determined that remedial actions conducted at the site to date remain protective of public health, welfare, and the environment.

EFFECTIVE DATE: June 24, 1998.

FOR FURTHER INFORMATION CONTACT: Gladys Beard at (312) 886–7253, Associate Remedial Project Manager, Superfund Division, U.S. EPA—Region V, 77 West Jackson Blvd., Chicago, IL 60604. Information on the site is available at the local information repository located at: The Gaines Township Hall, 9255 W. Grand Blanc Rd., Gaines, Michigan 48436. Requests for comprehensive copies of documents should be directed formally to the Regional Docket Office. The contact for the Regional Docket Office is Jan Pfundheller (H–7J), U.S. EPA, Region V, 77 W. Jackson Blvd., Chicago, IL 60604, (312) 353–5821.

SUPPLEMENTARY INFORMATION: The site to be deleted from the NPL is: Berlin and Farro Site located in Gaines, Michigan. A Notice of Intent to Delete for this site was published January 19, 1998 (63 FR 3061). The closing date for comments on the Notice of Intent to Delete was February 20, 1998. EPA received comments during the public comment period requesting an extension to the comment period. EPA extended the comment period to April 20, 1998.

The EPA identifies sites which appear to present a significant risk to public health, welfare, or the environment and it maintains the NPL as the list of those sites. Sites on the NPL may be the subject of Hazardous Substance Response Trust Fund (Fund-) financed remedial actions. Any site deleted from the NPL remains eligible for Fund-financed remedial actions in the unlikely event that conditions at the site warrant such action. Section 300.425(e)(3) of the NCP states that Fund-financed actions may be taken at sites deleted from the NPL in the unlikely event that conditions at the site warrant such action. Deletion of a site from the NPL does not affect responsible party liability or impede agency efforts to recover costs associated with response efforts.

List of Subjects in 40 CFR Part 300

Environmental protection, Air pollution control, Chemicals, Hazardous substances, Hazardous waste, Intergovernmental relations, Penalties, Reporting and recordkeeping requirements, Superfund, Water pollution control, Water supply.

Dated: June 11, 1998.

David Ullrich,

Acting Regional Administrator, Region V.

40 CFR part 300 is amended as follows:

PART 300—[AMENDED]

1. The authority citation for Part 300 continues to read as follows:

Authority: 33 U.S.C. 1321(c)(2); 42 U.S.C. 9601–9657; E.O. 12777, 56 FR 54757, 3 CFR, 1991 Comp., p.351; E.O. 12580, 52 FR 2923, 3 CFR, 1987 Comp., p. 193.

Appendix B [Amended]

2. Table 1 of Appendix B to part 300 is amended by removing the Site ''Berlin & Farro, Swartz Creek, Michigan.''

[FR Doc. 98–16569 Filed 6–23–98; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 410

[HCFA–3004–IFC]

RIN 0938–AI89

Medicare Program; Medicare Coverage of and Payment for Bone Mass Measurements

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period provides for uniform coverage of, and payment for, bone mass measurements for certain Medicare beneficiaries for services furnished on or after July 1, 1998. It implements provisions in section 4106(a) of the Balanced Budget Act of 1997.

DATES: Effective date: These regulations are effective on July 1, 1998.

Comment date: Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on August 24, 1998.

ADDRESSES: Mail an original and 3 copies of written comments to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: HCFA–3004–IFC, P.O. Box 26585, Baltimore, MD 21207–0385.

If you prefer, you may deliver an original and 3 copies of your written comments to one of the following addresses: Room 309–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5–09–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Comments may also be submitted electronically to the following e-mail address: HCFA3004ifc@hcfa.gov. For e-mail and comment procedures, see the beginning of **SUPPLEMENTARY INFORMATION**. For information on ordering copies of the **Federal Register** containing this document and on electronic access, see the beginning of **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: William Larson, (410) 786–4639. (Conditions for Coverage, and Frequency Standards) William Morse, (410) 786–4520. (Physician Fee Schedule Payments)

SUPPLEMENTARY INFORMATION: E-mail comments must include the full name and address of the sender, and must be submitted to the referenced address in

order to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments. Electronically submitted comments will be available for public inspection at the Independence Avenue address, below. Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA–3004–IFC. Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, in Room 309–G of the Department's offices at 200 Independence Avenue, SW., Washington, D.C., on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690–7890).

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I. Background

A. Current Medicare Coverage

In general, bone mass measurements, using bone mineral densitometers and bone sonometers, are considered to be the most valuable objective indicator of the risk of fracture and/or osteoporosis. The clinical use of these devices is based on the assumption that bone mass is an important determinant of osteoporotic fractures, and that bone mass measurements may help reduce the number of fractures by identifying high-risk individuals, who can then receive appropriate preventive measures. Because osteoporosis is generally considered preventable, but not reversible, we believe that early detection of at-risk individuals is a desirable health outcome.

Before the enactment of the Balanced Budget Act of 1997 (BBA), Medicare coverage of bone mass measurements and the related physician interpretation of those procedures were available for some beneficiaries under sections 1861(s)(1) and (s)(3) of the Social Security Act (the Act). Section 1861(s)(1) of the Act provides for general Medicare coverage of physician services, including a physician's interpretation of the results of tests performed. Section 1861(s)(3) of the Act provides for general Medicare coverage of diagnostic x-ray, clinical laboratory and other diagnostic tests. Furthermore, section 1862(a)(1)(A) of the Act provides that Medicare cover only services that are reasonable and necessary for the diagnosis or treatment of illness or injury. In developing the current Medicare policy on bone mass measurements, we determined, based on the advice of our medical consultants, that certain measurements were consistent with the provisions of section 1862(a)(1)(A) of the Act.

Medicare coverage policy on bone mass measurements is described in section 50–44 of the Medicare Coverage Issues Manual (CIM). Specifically, the CIM provides for coverage of single-photon absorptiometry (SPA) if it is used in assessing changes in bone density of beneficiaries with osteodystrophy or osteoporosis. In addition, a bone biopsy, a physiological test that is a surgically, invasive procedure, is covered if used for the qualitative evaluation of bone. Finally, the CIM provides for coverage of photodensitometry, a noninvasive radiological procedure that attempts to assess bone mass. The CIM also states that dual-photon absorptiometry (DPA), is a noncovered service.

In recent years, various new bone mass measurements have been developed and gained acceptance in the medical community. Since they have not been excluded from coverage under section 50–44 of the CIM, most Medicare contractors have begun to pay for the medically necessary use of these measurements, but some Medicare contractors have not. As a result, Medicare coverage of bone mass measurements has been inconsistent in its application with regard to the types of (1) beneficiaries eligible, (many Medicare contractors have considered bone mass measurements of estrogen-deficient women to be screening services and not covered under Medicare) and (2) bone mass measurements considered to be clinically effective.

B. Recent Legislation

Section 4106(a)(1) of the BBA adds section 1861(s)(15) to provide for uniform coverage of bone mass measurements under the Part B program for services furnished on or after July 1, 1998. The law defines a ''bone mass measurement'' to mean (1) a radiologic, radioisotopic, or other procedure approved by the Food and Drug Administration (FDA) for the purpose of identifying bone mass, detecting bone loss, or interpreting bone quality, and (2) it includes a physician's interpretation of the results of those bone mass measurement procedures. The law also authorizes Medicare coverage of those medically necessary approved measurements that are performed for a ''qualified individual'' that fall into at least one of five diagnostic categories. These include (1) an estrogen-deficient woman at clinical risk for osteoporosis, (2) an individual with vertebral abnormalities, (3) an individual receiving long-term glucocorticoid (steroid) therapy, (4) an individual with primary hyperparathyroidism, and (5) an individual being monitored to assess the response to, or efficacy of, an approved osteoporosis drug therapy.

Section 4106(a)(2) of the BBA also requires the Secretary to establish frequency standards governing the time period when qualified individuals will be eligible to receive covered bone mass measurements.

Section 4106(b)(2) of the BBA amended section 1848(j)(3) of the Act, which defines ''physicians' services'' to include a bone mass measurement as a physician service. Physicians' services as defined in section 1848(j)(3) are paid for under the physician fee schedule (42 CFR part 414).

II. Rationale for Coverage of Bone Mass Measurements

We have consulted with appropriate Federal government organizations and reviewed medical literature regarding (1) the clinical efficacy of the various available bone mass measurement procedures that the FDA has approved or cleared for marketing for assessing bone density, (2) the medical indications for the five categories of Medicare beneficiary eligible to receive coverage under Medicare for the procedures, and (3) the frequency standards that the Secretary is required by law to establish under the new benefit. Based on review of the law and our research, we have reached the following conclusions on the various major issues raised by the coverage of bone mass measurements.

A. Clinically Effective Bone Mass Measurements

Section 1861(rr)(1) of the Act, as added by section 4106(a) of the BBA, defines the term ''bone mass measurement'' to mean, in part, ''a radiological, radioisotopic, or other procedure approved by the Food and Drug Administration'' that is ''performed on a qualified person . . . for the purpose of identifying bone mass or detecting bone loss or determining bone quality. * * *'' In addition, section 4106(b) of the BBA amended the law to provide that payment for bone mass measurements that are covered under this new benefit must be made under the Medicare physician fee schedule, as provided in section 1848(j)(3) of the Act. We have interpreted these provisions to mean that the scope of the bone mass measurement benefit includes bone densitometry or bone sonometry procedures that are performed with devices that have been approved or cleared for marketing by the FDA. We are not including payment for biochemical markers within this benefit at the present time. Even though biochemical markers have been approved for marketing by the FDA, they are, in fact, clinical laboratory tests that may be paid for under the Medicare clinical laboratory fee schedule (sections 1833(a)(1)(D) and 1833(h) of the Act), rather than under the Medicare physician fee schedule (many Medicare contractors currently pay for biochemical markers under the Medicare clinical laboratory fee schedule). We plan to raise the issue of coverage for biochemical markers used in measuring bone mass when we implement section 4554 of the BBA concerning national coverage and administrative policies for clinical laboratory tests. That section of the statute requires the use of a negotiated rulemaking process and was announced on June 3, 1998 (63 FR 30166).

The expansion of Medicare coverage to include additional preventive benefits for bone mass measurement reflects a Congressional intent to improve the overall health of qualified individuals that is consistent with medical science. There is a well-established causal relationship between reduced bone mass and the risk of fracture, particularly in the hip and spine. Although numerous risk factors exist for the development of fractures (Heaney, Robert P., M.D., ''Bone Mass, Bone Loss, and Osteoporosis Prophylaxis,'' Annals of Internal Medicine, Volume 128, Number 4, pages 313–314 (February 15, 1998)), bone mass is the most extensively-studied fragility factor, in tandem with considerable therapeutic options for restoration of bone mass. From a public health perspective, it has been noted in the medical literature that bone loss is highly prevalent among elders (Genant, H.K., Guglielmi, G., Jergas, M., (Eds) ''Bone Densitometry and Osteoporosis'' (Epidemiology of Osteoporosis) Ross, P.D., pgs 23–25 (1998)), and that only about ten percent of women in the United States over age 65 have ''normal'' bone mass.

At present, the FDA has approved or cleared for marketing a number of different types of bone densitometry or bone sonometry devices (or techniques) that can be used to perform bone mass measurements on the human skeleton. According to the information we have reviewed, the older densitometry x-ray techniques of single photon absorptiometry (SPA) and dual photon absorptiometry (DPA), which use isotope sources, have largely been replaced by the newer x-ray techniques of single X-ray absorptiometry (SEXA) and dual-X-ray absorptiometry (DEXA), which are superior in terms of accuracy, precision, and shorter exam time. We understand that the current FDA-recognized, and generally available, bone densitometry techniques for measuring the peripheral skeleton include SEXA, peripheral dual-X-ray absorptiometry (pDEXA), radiographic absorptiometry (RA), and peripheral quantitative computed tomography (pQCT), all of which are limited to measurement of the peripheral skeleton, principally the forearm, heel, or fingers. Recently, the FDA has approved for marketing a bone sonometry device that estimates bone mass or strength of the heel using ultrasound measurements. For measurement of the central skeleton, the currently FDA-approved or cleared, and available techniques are DEXA and quantitative computed tomography (QCT), both of which can measure the spine or hip, and the DEXA can measure the peripheral skeleton or whole body as well.

Based on the medical information we have reviewed, all of the FDA-approved or cleared bone densitometry and sonometry devices are currently being used actively in clinical practice, except for the SPA and the DPA devices. With respect to the last two devices, we considered not covering bone mass measurements performed on either one of these devices because they are generally considered to be obsolete and no longer of any clinical value.

Generally, coverage of medical items or services performed with FDA-approved or cleared devices is available to Medicare beneficiaries unless the item or service is precluded from payment by the reasonable and necessary exclusion in section 1862(a)(1)(A) of the Act, or is otherwise precluded from payment by one of the other Medicare statutory exclusions.

Based on our review of the medical information, we have decided to continue with our present policy of coverage of bone mass measurements performed on SPA devices and our noncoverage of measurements performed on DPA devices. Our noncoverage of the DPA procedure was established in 1983, and was based on medical advice received from the Public Health Service, indicating that it was not demonstrated to be medically effective, and, thus, should be excluded from coverage by the statutory ''reasonable and necessary'' exclusion of section 1862(a)(1)(A) of the Act.

Our review of available Medicare claims data for 1995 and 1996 shows that the use of the SPA procedure under the Medicare program has declined significantly in recent years. However, the claims data appears to indicate that Medicare beneficiaries may still benefit from the use of this procedure in some parts of the country. In view of this evidence, however, we have decided to request comments on the possibility of withdrawing coverage of the SPA. We expect that certain remote rural areas may not have bone densitometry or bone sonometry devices available at present for use in testing Medicare beneficiaries. Therefore, we are soliciting comments on whether this is, in fact, a problem that merits the continued coverage of SPA. In assessing this issue, we request specific examples of problems, within particular localities, such as remote and rural areas, and details regarding how such a regulation

may adversely affect bone mass measurement services.

In regard to the clinical utility of peripheral versus central bone density devices, there is a consensus that measurements of the central skeletal sites is the preferred method of assessment. The American College of Radiology reports that central techniques are associated with relatively higher predictive relative risk ratios for hip fractures than peripheral techniques, and allow for more frequent evaluations because of their intrinsic ability to better assess bone metabolic activity. Although either central or peripheral techniques may be used for most bone mass measurement indications, experts representing the National Osteoporosis Foundation have suggested clinical situations in which only central studies should be performed (that is, vertebral abnormalities, glucocorticoid maintenance, and monitoring the response to osteoporosis drug treatment).

Ultimately, however, it is essential that the physician treating the beneficiary be afforded flexibility in ordering those diagnostic measurements that are best suited to the beneficiaries in their special circumstances. For example, our consultation with the FDA indicated that peripheral bone mass measurements may be used for monitoring osteoporosis drug treatment in some cases. Our interim final policy allows physicians discretion to use peripheral bone mass measurements in this manner. Given the differential access and convenience of various bone mass measurement techniques available to Medicare beneficiaries, the attending physician must be given the option to order the most appropriate bone mass measurement for a beneficiary in a particular set of circumstances. Emerging literature on both existing and new technologies shows that bone mass measurement exists within a highly dynamic clinical setting, which can only be successfully approached with flexibility. In other words, there will be a continual need to reexamine which are the most pertinent bone mass measurement techniques for generating useful diagnostic information.

In view of these uncertainties about the clinical role of the peripheral measurement, we plan to monitor the Medicare use of these measurements. Based on data on the effectiveness of these measurements, we will reconsider our coverage policy in this regard if warranted. Although peripheral bone mass measurements have some apparent advantages in terms of access and convenience, if, over time, these parameters become more relatively favorable for central bone mass measurement, then our policies will be correspondingly updated.

B. Medical Indications for Medicare Beneficiaries

As previously mentioned, section 1861(rr)(2) of the Act identifies five categories of ''qualified individuals'' who may receive Medicare coverage under the new bone mass measurement benefit. These include the following: (1) An estrogen-deficient woman at clinical risk for osteoporosis; (2) an individual with vertebral abnormalities; (3) an individual receiving long-term glucocorticoid (steroid) therapy; (4) an individual with primary hyperparathyroidism; or (5) an individual being monitored to assess the response to or efficacy of an approved osteoporosis drug therapy. (For purposes of this interim final rule, we refer to these ''qualified individuals'' as those categories of Medicare beneficiaries who may receive covered bone mass measurements.) In addition, section 1861(rr)(2) of the Act provides authority for further clarification of these categories to help ensure uniform national standards ''in accordance with regulations prescribed by the Secretary.''

We have interpreted this section of the statute, and are clarifying the five categories of Medicare beneficiaries who may receive these covered services as follows:

- An estrogen-deficient woman at clinical risk for osteoporosis means a woman who has been determined by the physician (or a qualified nonphysician practitioner) treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history or other findings.
- An individual with vertebral abnormalities as demonstrated by X-ray to be indicative of osteoporosis, low bone mass (osteopenia), or vertebral fracture.
- An individual receiving glucocorticoid (steroid) therapy equivalent to 7.5 mg of prednisone, or greater, per day for more than 3 months, or if the expected duration of such therapy is more than 3 months. (Review of medical literature has indicated that doses of steroid therapy lower than 7.5 mg of prednisone per day for periods shorter than 3 months usually do not result in significant bone loss.)
- An individual with primary hyperparathyroidism.
- An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.

In regard to the definition of estrogen-deficient women at clinical risk for osteoporosis, there is agreement among medical experts in the United States regarding the efficacy of the use of estrogen-replacement therapy (ERT) in preventing and treating post-menopausal bone loss and osteoporosis. According to the American Association of Clinical Endocrinologists ''Clinical Practice Guidelines for the Prevention and Treatment of Post-Menopausal Osteoporosis'' (March 1996), ERT ''is the standard of care for preventing and treating post-menopausal bone loss and should be considered for all estrogen-deficient women without contradictions.'' In addition, the guidelines provide that ''for maximal skeletal protection, therapy should begin at the time of menopause or oophorectomy, although therapy can be initiated at any time after menopause. Studies indicate that correction of estrogen deficiency at any age prevents or slows bone loss in post-menopausal women with osteoporosis.''

However, based on our review of the medical literature and other information, it appears that not every woman who has been prescribed ERT may be receiving an ''adequate'' dose of the therapy and, thus, may not be sufficiently protected against further bone loss. In view of the difficulty of trying to define the estrogen-deficient statutory category precisely, we have decided in this interim final rule to allow a woman's treating physician or other treating practitioner to determine whether she is estrogen-deficient and at clinical risk of osteoporosis, based on her medical history or other findings.

C. Frequency Standards

Section 1861(rr)(3) of the Act provides that ''the Secretary shall establish such standards regarding frequency with which a qualified individual shall be eligible to be provided benefits'' under the bone mass measurement provision. The American Association of Clinical Endocrinologists (AACE), the American College of Radiology, and National Osteoporosis Foundation appear to be generally in agreement with respect to the need to follow certain clinical guidelines for performing follow-up bone mass measurements to the initial bone mass measurement that is performed. In their 1996 clinical practice guidelines, the AACE indicated that with the use of the dual-x-ray absorptiometry, a change in bone mass ''of 5 percent is considered clinically significant and is usually not observed in less than 2 years.'' For patients taking long-term steroids, or other drug therapies that have been demonstrated

to cause a more rapid rate of bone loss, the AACE and others in the medical community have recommended that Medicare patients should have more frequent assessment (for example, baseline and after 6 months).

In determining the appropriate frequency interval for follow-up serial bone mass measurements, we also believe it is necessary to consider the clinical role that biochemical markers may play in monitoring the effectiveness of osteoporosis drug therapy. Bone mass measurement imaging provides one type of skeletal assessment, compared to assaying biochemical markers that provide a profile of bone turnover. With respect to quantifying bone loss, multiple collagen crosslink tests for pyridinoline, deoxypyridinoline, and the telopeptides can provide adjunct diagnostic information in concert with bone mass measurement (Siebel, Markus J. and Gangberg, Caren M., ''Basic Science and Clinical Utility of Biochemical Markers of Bone Turnover—A Congress Report'', Volume 107, pages 125–133, (1997)).

We have been informed by the FDA that the use of biochemical markers may be useful in assessing the effectiveness of osteoporosis treatment. Although we believe that bone mass measurement and biochemical markers have complementary roles to play in monitoring osteoporosis drug therapy, there are not yet specific, evidence-based guidelines for performing both in tandem. However, proper management of osteoporosis patients, who are on long-term therapeutic regimens, may require reliance upon such clinical laboratory testing (for example, at intervals of less than 1 year) after therapy is initiated.

We have decided to establish the following frequency standards for coverage of bone mass measurements:

- In general, coverage for follow-up bone mass measurements will be limited to only one measurement every 2 years for beneficiaries who receive coverage of bone mass measurements.
- Follow-up bone mass measurements performed more frequently than once every 2 years may be covered when medically necessary. Examples of situations where more frequent bone mass measurements procedures may be medically necessary include, but are not limited to, the following medical circumstances: (1) Monitoring beneficiaries on long-term glucocorticoid (steroid) therapy of more than 3 months; and (2) allowing for a confirmatory baseline bone mass measurement (either central or peripheral) to permit monitoring of beneficiaries in the future if the initial test was performed with a technique that is different from the proposed monitoring method, (for example, if the initial test was performed using bone sonometry and monitoring is anticipated using bone densitometry, we will allow coverage of baseline measurement using bone densitometry).

III. Provisions of the Interim Final Rule

This interim final rule will implement section 4106 of the BBA by establishing conditions for coverage and frequency standards for bone mass measurements to ensure that they are paid for uniformly throughout the Medicare program and that they are reasonable and necessary for Medicare beneficiaries who are eligible to receive these measurements.

A. Coverage Conditions and Frequency Standards

We are establishing conditions for coverage and frequency standards for medically necessary bone mass measurements for five categories of Medicare beneficiaries in § 410.31.

We are defining ''bone mass measurement'' based on the statutory definition (§ 410.31(a)). We are setting forth conditions for coverage of all of the bone mass measurements that we will cover effective July 1, 1998. Under the ''reasonable and necessary'' provisions of section 1862(a)(1)(A) of the Act, we are establishing conditions under which we will cover bone mass measurements (§ 410.31(b)). Consistent with § 410.32 (Diagnostic x-ray tests, diagnostic laboratory tests, and diagnostic tests: Conditions), we are providing that coverage be available for the bone mass measurement only if it is ordered by the physician or a qualified nonphysician practitioner treating the beneficiary following an evaluation of the beneficiary's need for the test, including a determination as to the medically appropriate procedure to be used for the beneficiary. We believe that bone mass measurements are not demonstrably reasonable and necessary unless (among other things) they are ordered by the physician treating the beneficiary following a careful evaluation of the beneficiary's medical need, and they are employed to manage the beneficiary's care.

In addition, certain nonphysician practitioners who furnish services that would be physician services if furnished by a physician, and who are operating within the scope of the statutory benefit and their authority under State law or regulations, may also order bone mass measurements for their patients. Nonphysician practitioners who meet this definition are physician assistants (section 1861(s)(2)(K)(i) of the Act), nurse practitioners (section 1861(s)(2)(K)(ii) of the Act), clinical nurse specialists (section 1861(s)(2)(K)(iii) of the Act), and nurse-midwives (section 1861(s)(2)(L) and 1861(gg) of the Act).

To ensure that the bone mass measurement is performed as accurately and consistently in accordance with appropriate quality assurance guidelines as possible, we are requiring that it be performed under the appropriate supervision of a physician as defined in § 410.32(b)(3) of these regulations. To ensure that the bone mass measurement is medically appropriate for the five categories specified in the law, we are providing that it be reasonable and necessary for diagnosing, treating, or monitoring the condition of the beneficiary who meets the coverage requirements specified in § 410.31(d).

Furthermore, in § 410.31(c), we are setting forth limitations on the frequency for covering a bone mass measurement. Generally, we will cover a bone mass measurement for a beneficiary if at least 23 months have passed since the month the last bone mass measurement was performed. However, we will allow for coverage of follow-up bone mass measurements performed more frequently than once every 23 months when medically necessary. Examples of situations where more frequent bone mass measurements procedures may be medically necessary include, but are not limited to, the following medical circumstances: (1) Monitoring beneficiaries on long-term glucocorticoid (steroid) therapy of more than 3 months; and (2) allowing for a confirmatory baseline bone mass measurement (either central or peripheral) to permit monitoring of beneficiaries in the future if the initial test was performed with a technique that is different from the proposed monitoring method.

B. Beneficiaries Who May Be Covered

In § 410.31(d), we offer coverage for a bone mass measurement to the following Medicare beneficiaries:

- A woman who has been determined by the physician or a qualified nonphysician practitioner treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings.
- An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.
- An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to 7.5 mg of

prednisone, or greater, per day, for more than 3 months.

- An individual with primary hyperparthyroidism.
- An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.

C. Waiver of Liability

Under § 410.31(e), a beneficiary who did not know and could not reasonably have been expected to know that Medicare payment would be denied for a bone mass measurement under section 1862(a)(1)(A) of the Act receives protection from financial liability in accordance with §§ 411.400 through 411.406 under the limitation on liability provision of section 1879 of the Act. Existing regulations concerning limitation on liability in §§ 411.400 through 411.406 would apply to denial of bone mass measurements under §§ 410.31(b) through (d). Medicare payment may be made for certain claims for a bone mass measurement if the measurement was excluded from coverage in accordance with § 411.15(k) as not reasonable and necessary under section 1862(a)(1)(A) of the Act. Similarly, when the beneficiary is protected and the provider or supplier also did not know and could not reasonably have been expected to know that payment would be denied, the provider or supplier also receives protection from financial liability in accordance with the limitation on liability provision. Consequently, Medicare payment may be made to the provider or supplier.

D. Payments for Bone Mass Measurements

Medicare payments for covered bone mass measurements will be paid for under the physician fee schedule (42 CFR part 414) as required by statute. We are revising the definition of ''physician services'' in § 414.2 to include bone mass measurements. When bone mass measurement procedures are furnished to hospital inpatients and outpatients, the technical components of the procedures are payable under existing payment methods for hospital services. These methods include payments under the prospective payment system, on a reasonable cost basis, or under a special provision for determining pay rates for hospital outpatient radiology services.

The codes listed below are payable under this benefit.

76075—Dual energy x-ray absorptiometry (DEXA), bone density study, one or more sites; axial skeleton (e.g., hips, pelvis, spine)

76076—Dual energy x-ray absorptiometry (DEXA), bone density study, one or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)

76078—Radiographic absorptiometry (photodensitometry), one or more sites

78350—Bone density (bone mineral content) study, one or more sites; single photon absorptiometry

G0130—Single energy x-ray (SEXA) absorptiometry bone density study, one or more sites, appendicular skeleton (peripheral) (e.g., radius, wrist, heel)

G0131—Computerized tomography bone mineral density study, one or more sites; axial skeleton (e.g., hips, pelvis, spine)

G0132—Computerized tomography bone mineral density study, one or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)

G0133—Ultrasound bone mineral density study, one or more sites, appendicular skeleton (peripheral) (e.g., radius, wrist, heel)

The relative value units and payment amounts for CPT codes 76075, 76076, 76078, and 78350, including their component parts (professional component (PC) identified by a -26 modifier and technical component (TC) identified by a -TC modifier), are the same as published in the Medicare physician fee schedule final rule of October 31, 1997 (62 FR 59048). The payment amounts for G0130, G0132, and G0133 and their component parts are the same as determined for CPT 78350 and its components parts under that final rule. The amounts payable for G0131 and its component parts is the same as listed for CPT 76070 and its component parts under that final rule.

We are revising § 414.50(a), regarding physician billing for purchased diagnostic tests, to clarify that section does not apply to payment for bone mass measurements.

E. Conforming Changes

To allow for appropriate placement in the CFR of the bone mass measurement coverage requirements, we are redesignating § 410.31 (Prescription drugs used in immunosuppressive therapy) as § 410.30.

F. Manual Instructions

Currently, section 50–44 of the Coverage Issues Manual sets forth instructions for Medicare carriers concerning coverage of bone mass measurements. The provisions of this interim final rule supersede the current manual instructions. We intend to revise the instructions to conform them to this final rule.

IV. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the major comments in the preamble to that document.

V. Waiver of Proposed Rulemaking and Delayed Effective Date

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms of the proposed rule or a description of the subjects and issues involved (5 U.S.C. 555(b)). This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued. In addition, we ordinarily publish a rule not less than 30 days before the rule's effective date in order to afford persons affected a reasonable time to prepare for the effective date of the rule. The 30-day delay in the effective date can be waived for good cause found and published within the rule.

We find good cause to waive the notice and comment procedure for these rules implementing section 4106 of the BBA. This rule involves little exercise of agency discretion, but rather conforms the regulations to the revisions contained in section 4106 of the BBA. Notice-and-comment rulemaking is generally considered ''unnecessary'' so far as the public is concerned for such technical, conforming changes. Indeed, under both the Administrative Procedure Act and the Social Security Act, interpretative rules are generally exempt from notice and comment rulemaking (5 U.S.C. 553(b); 42 U.S.C. 1395hh(b)(2)(C)). While this rule interprets the statute, publication in the **Federal Register** is necessary to identify the categories of Medicare beneficiaries who may receive covered bone mass measurements under section 1861(rr)(2) of the Act and to promote uniform Medicare coverage of bone mass

measurements under section 1861(s)(15) of the Act.

We also find good cause to waive the notice and comment procedures and to waive the 30 day-delay in the effective date because those procedures would be contrary to the public interest. Section 4106 of the BBA of 1997 expands Medicare coverage to a larger group of beneficiaries, and it will enable these individuals to obtain timely treatment to prevent irreversible bone loss. The explicit provision of benefits in section 4106 that are implemented by these rules will provide a broader range of bone mass measurement procedures to a broader set of beneficiaries. The statute, however, requires the Secretary to issue regulations in order to implement this benefit. Thus, any delay in this rule's effective date to permit additional public participation in the rulemaking process would harm the intended beneficiaries of this statute. Moreover, although these rules expand Medicare coverage, the rules do not impose additional documentation requirements or alter the existing procedures for submitting Medicare claims. Because many individuals or entities affected by these rules are already familiar with these procedures, it is expected that the public would not require 30 days in order to prepare for changes necessitated by these rules. We will, of course, consider any public comments received on this interim final rule, and to the extent necessary, we will issue a final rule with additional clarifications or expansions.

We also note that in this preamble, we identify a number of interim 1998 codes for bone densitometry and bone sonometry procedures. Since technology in the bone mass measurement area is changing rapidly, as new techniques are being approved or cleared for marketing by the FDA, and as these techniques are being phased into clinical practice in the United States, there is a need to adopt new codes (or changes in existing codes) so that the new procedures performed with these techniques can be billed under Medicare.

For the above reasons, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day comment period for public comment. Since we have referenced existing physician fee schedule relative value units (RVUs) to establish RVUs on bone mass measurement procedures, we are inviting comments on these linkages. We will consider comments when we establish the final RVUs that will be used to compute Medicare payments for the bone mass measurement codes in 1999. These final RVUs will be established by the physician fee schedule final rule scheduled for publication later this year.

VI. Collection of Information Requirements

This document does not impose 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.

VII. Regulatory Impact Statement

We have examined the impacts of this interim final rule under Executive Order (E.O.) 12866, the Unfunded Mandates Act of 1995, and the Regulatory Flexibility Act. E.O. 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when 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 annually). The benefit changes in this interim final rule due to section 4106 of BBA 1997 will result in additional expenditures of $10 million and $100 million for fiscal years 1998 and 1999, respectively.

Because the expenditures resulting from this interim final rule are expected to reach $100 million in FY 1999, it is considered a major rule, and, as required by law, this final rule is subject to congressional review. Therefore, this interim final rule is being forwarded to the Congress for a 60-day review period.

The Unfunded Mandates Reform Act of 1995 also requires (in section 202) that agencies prepare an assessment of anticipated costs and benefits for any rule that may result in annual expenditures by State, local, or tribal governments, in the aggregate, or by the private sector, of $100 million. The final rule has no consequential effect on State, local, or tribal governments. We believe the private sector costs of this rule fall below these thresholds, as well.

Consistent with the provisions of the Regulatory Flexibility Act, we analyze options for regulatory relief for small businesses and other small entities. We prepare a Regulatory Flexibility Analysis (RFA) unless we certify that rule will not have a significant economic impact on a substantial number of small entities. The RFA must include a justification of why action is being taken, the kinds and number of small entities the interim final rule will affect, and an explanation of any considered meaningful options that achieve the objectives and will lesson any significant adverse economic impact on the small entities.

For purposes of the Act, all physicians are considered to be small entities. Thus, we have prepared the following analysis, which, together with the rest of this preamble, meets all three assessment requirements. It explains the rationale for the purposes of this rule, details the costs of the rule, analyzes alternatives, and presents the measures to minimize the burden on small entities.

Section 4106 of the BBA 1997 provides for uniform coverage of certain bone mass measurements, effective July 1, 1998, subject to certain frequency and payment limits. Specifically, the revised coverage will allow periodic coverage of medically necessary bone mass measurements performed with (1) all of the FDA approved or cleared devices that are currently in clinical use in the United States, and for (2) five mandated categories of eligible Medicare beneficiaries, who meet certain medical indications, including estrogen-deficient women at clinical risk for osteoporosis. Before enactment of the BBA, periodic coverage of bone mass measurements was available to certain beneficiaries in at least four of the five categories in most parts of the country, but not uniformly throughout the Medicare program. In addition, coverage of some of the bone mass measurements—particularly several of the peripheral techniques—has not been available throughout the United States for imaging Medicare beneficiaries, even though these techniques have been approved or cleared for marketing by the FDA. In the case of the fifth category (estrogen-deficient women at clinical risk of osteoporosis), coverage of bone mass measurements has not been available in many parts of the country. We estimate that these changes in the coverage of bone mass measurements will result in an increase in Medicare payments. These payments will be made to a large number of physicians, mostly medical specialists such as gynecologists, radiologists, rheumatologists, and clinical endocrinologists, but also to certain primary care physicians and hospital outpatient departments who perform these services.

PROJECTED BUDGET IMPACT OF NEW BENEFIT

[In millions]

FY 1998	FY 1999	FY 2000	FY 2001	FY 2002
$10	$100	$140	$180	$190

We believe that the effect of this rule on beneficiaries will be a very positive one. Medical experts agree that early detection and management of disease can lead to substantial reductions in life-threatening and serious illness. The National Osteoporosis Foundation estimates that there are over 10 million people in the United States who have osteoporosis and that another 18 million are at risk for the disease. Through earlier detection of low bone mass made possible under the new benefit and the use of appropriate prevention and treatment measures, our expectation is that the ravaging effects of this disease among the Medicare population will be reduced in the future.

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

VIII. Effect of the Contract With America Advancement Act of 1996 (Pub. L. 104–121)

This rule has been determined to be a major rule as defined in Title 5, United States Code, section 804(2). Ordinarily under 5 U.S.C. 801, as added by section 251 of Pub. L. 104–121, a major rule shall take effect 60 days after the later of (1) the date a report on the rule is submitted to the Congress, or (2) the date the rule is published in the **Federal Register**. However, section 808(2) of Title 5, United States Code, provides that, notwithstanding 5 U.S.C. 801, a major rule shall take effect at such time as the Federal agency determines if for good cause the agency finds that notice and comment procedures are impracticable, unnecessary, or contrary to the public interest. As explained above, for good cause we find that it was impracticable, unnecessary, or contrary to the public interest to complete notice and comment procedures before publication of this rule. Accordingly, pursuant to 5 U.S.C. 808(2), these regulations are effective on July 1, 1998.

List of Subjects

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set out in the preamble, 42 CFR Chapter IV is amended as follows:

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

A. Part 410 is amended to read as follows:

1. The authority citation for part 410 continues to read as follows:

Authority: Sections 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh), unless otherwise indicated.

2. Section 410.31 is redesignated as § 410.30.

3. New § 410.31 is added to read as follows:

§ 410.31 Bone mass measurement: Conditions for coverage and frequency standards.

(a) *Definition*. As used in this section unless specified otherwise, the following definition applies:

Bone mass measurement means a radiologic, radioisotopic, or other procedure that meets the following conditions:

(1) Is performed for the purpose of identifying bone mass, detecting bone loss, or determining bone quality.

(2) Is performed with either a bone densitometer (other than dual-photon absorptiometry) or with a bone sonometer system that has been cleared for marketing for this use by the FDA under 21 CFR part 807, or approved for marketing by the FDA for this use under 21 CFR part 814.

(3) Includes a physician's interpretation of the results of the procedure.

(b) *Conditions for coverage*. Medicare covers a medically necessary bone mass measurement if the following conditions are met:

(1) Following an evaluation of the beneficiary's need for the measurement, including a determination as to the medically appropriate procedure to be used for the beneficiary, it is ordered by the physician or a qualified nonphysician practitioner (as these terms are defined in § 410.32(a)) treating the beneficiary.

(2) It is performed under the appropriate level of supervision of a physician (as set forth in § 410.32(b)).

(3) It is reasonable and necessary for diagnosing, treating, or monitoring the condition of a beneficiary who meets the conditions described in paragraph (d) of this section.

(c) *Standards on frequency of coverage*—(1) *General rule*. Except as allowed under paragraph (c)(2) of this section, Medicare may cover a bone mass measurement for a beneficiary if at least 23 months have passed since the month the last bone mass measurement was performed.

(2) *Exception*. If medically necessary, Medicare may cover a bone mass measurement for a beneficiary more frequently than allowed under paragraph (c)(1) of this section. Examples of situations where more frequent bone mass measurement procedures may be medically necessary include, but are not limited to, the following medical circumstances:

(i) Monitoring beneficiaries on long-term glucocorticoid (steroid) therapy of more than 3 months.

(ii) Allowing for a confirmatory baseline bone mass measurement (either central or peripheral) to permit monitoring of beneficiaries in the future if the initial test was performed with a technique that is different from the proposed monitoring method.

(d) *Beneficiaries who may be covered*. The following categories of beneficiaries may receive Medicare coverage for a medically necessary bone mass measurement:

(1) A woman who has been determined by the physician (or a qualified nonphysician practitioner) treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings.

(2) An individual with vertebral abnormalities as demonstrated by an x-ray to be indicative of osteoporosis, osteopenia, or vertebral fracture.

(3) An individual receiving (or expecting to receive) glucocorticoid (steroid) therapy equivalent to 7.5 mg of prednisone, or greater, per day for more than 3 months.

(4) An individual with primary hyperparathyroidism.

(5) An individual being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy.

(e) *Denial as not reasonable and necessary*. If HCFA determines that a bone mass measurement does not meet the conditions for coverage in paragraphs (b) or (d) of this section, or the standards on frequency of coverage in paragraph (c) of this section, it is excluded from Medicare coverage as not ''reasonable'' and ''necessary'' under section 1862(a)(1)(A) of the Act and § 411.15(k) of this chapter.

PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

B. Part 414 is amended to read as follows:

1. The authority citation for part 414 continues to read as follows:

Authority: Sections 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, and 1395rr(b)(1)).

2. In § 414.2, in the definition of ''Physician services'', a new paragraph (7) is added to read as follows:

§ 414.2 Definitions.

* * * * *

Physician services * * *

(7) Bone mass measurement.

* * * * *

§ 414.50 [Amended]

3. In § 414.50(a), in the first sentence, revise ''If a'' to read ''For services covered under section 1861(s)(3) of the Act and paid for under this part 414 subpart A, if a''.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: June 3, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: June 9, 1998.

Donna E. Shalala,

Secretary.

[FR Doc. 98–16783 Filed 6–19–98; 3:00 pm]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

45 CFR Part 1302

RIN 0970–AB52

Head Start Program

AGENCY: Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF), HHS.

ACTION: Final rule.

SUMMARY: The Administration on Children, Youth and Families is issuing this final rule to amend its procedures regarding replacement of Indian tribal grantees. The change would add provisions to implement a new statutory provision that allows Indian tribes which are Head Start grantees to identify an agency, and request that the agency be designated by the Department as an alternative grantee, when the grantee is terminated or denied refunding.

EFFECTIVE DATES: The effective date of this final rule is July 24, 1998.

FOR FURTHER INFORMATION CONTACT: Douglas Klafehn, Deputy Associate Commissioner, Head Start Bureau, Administration for Children, Youth and Families, P.O. Box 1182, Washington, D.C. 20013; (202) 205–8572.

SUPPLEMENTARY INFORMATION:

I. Program Purpose

Head Start is authorized under the Head Start Act (42 U.S.C. 9801 *et seq.*). It is a national program providing comprehensive developmental services primarily to low-income preschool children, age three to the age of compulsory school attendance, and their families. In addition, Section 645A of the Head Start Act provides authority to fund programs for families with infants and toddlers, known as Early Head Start programs. To help enrolled children achieve their full potential, Head Start programs provide comprehensive health, nutritional, educational, social and other services. Additionally, Head Start programs are required to provide for the direct participation of the parents of enrolled children in the development, conduct, and direction of local programs. Parents also receive training and education to foster their understanding of and involvement in the development of their children. In fiscal year 1997, Head Start served 793,809 children through a network of over 2,000 grantees and delegate agencies.

While Head Start is intended to serve primarily children whose families have incomes at or below the poverty line, or who receive public assistance, the Head Start Act and implementing regulations permit up to 10 percent (and more for Indian tribes under certain circumstances) of the children in local programs to be from families who do not meet these low-income criteria. The Act also requires that a minimum of 10 percent of the enrollment opportunities in each program be made available to children with disabilities. Such children are expected to participate in the full range of Head Start services and activities with their non-disabled peers and to receive needed special education and related services.

II. Summary of the Final Rule

This final rule was published as a Notice of Proposed Rulemaking on December 16, 1997, in the **Federal Register** (62 FR 65778). We received no comments on the rule and therefore are issuing it as final with no changes.

The authority for this final rule is section 646 of the Head Start Act (42 U.S.C. 9841), as amended by Public Law 103–252, Title I of the Human Service Amendments of 1994. Section 646(e) directs the Secretary to specify a process by which an Indian tribe may identify an agency, and request that the agency identified be designated as the Head Start agency providing services to the tribe, if (a) financial assistance to the tribal grantee is terminated, and (b) the tribe would otherwise be precluded from providing Head Start services to its members because of the termination. The Act specifies that the regulation must prohibit the designation as Head Start grantee of an agency that includes an employee who served on the administrative or program staff of the terminated agency when that employee was responsible for a deficiency that was the basis for the termination.

The final rule:

- Adds a new definition for Indian tribe;
- Provides that an Indian tribe may identify an agency to serve as the alternative grantee at the time that it receives a notice of termination or a notice of denial of refunding;
- Allows the tribe to participate in the selection of the replacement grantee; and
- Allows the tribe a second opportunity to identify an alternative agency if the Department finds the first agency identified by the tribe is not an eligible agency capable of operating a Head Start program. If the second agency identified by the tribe is not selected as a Head Start grantee, a