

these situations, the total minimum number of required lead NAMS is one.

* * * * *

6. References.

* * * * *

6. Lead Guideline Document, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-452/R-93-009.

7. Air Quality Criteria for Lead. Office of Research and Development, U.S. Environmental Protection Agency, Washington, DC. EPA-600/8-83-028 aF-dF, 1986, and supplements EPA-600/8-89/049F, August 1990. (NTIS document numbers PB87-142378 and PB91-138420.)

* * * * *

10. "Guidance for Conducting Ambient Air Monitoring for Lead Around Point Sources," Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC EPA-454/R-92-009, May 1997.

* * * * *

19. National Air Pollutant Emissions Trends, 1900-1995, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, Research Triangle Park, NC. EPA-454/R96-007, October 1996, updated annually.

* * * * *

6. Appendix E is amended by revising the first paragraph of section 7.1, adding a sentence at the beginning of section 7.3, revising section 7.4, and revising reference 18 in section 13 to read as follows:

Appendix E—Probe and Monitoring Path Siting Criteria for Ambient Air Quality Monitoring

* * * * *

7.1 *Vertical Placement.* Optimal placement of the sampler inlet for Pb monitoring should be at breathing height level. However, practical factors such as prevention of vandalism, security, and safety precautions must also be considered when siting a Pb monitor. Given these considerations, the sampler inlet for microscale Pb monitors must be 2-7 meters above ground level. The lower limit was based on a compromise between ease of servicing the sampler and the desire to avoid unrepresentative conditions due to re-entrainment from dusty surfaces. The upper limit represents a compromise between the desire to have measurements which are most representative of population exposures and a consideration of the practical factors noted above.

* * * * *

7.3. *Spacing from Roadways.* This criteria applies only to those Pb sites designed to assess lead concentrations from mobile sources. Numerous studies have shown that ambient Pb levels near mobile sources are a function of the traffic volume and are most pronounced at ADT >30,000 within the first 15 meters on the downwind side of the roadways. * * *

7.4. *Spacing from trees and other considerations.* Trees can provide surfaces for deposition or adsorption of Pb particles and obstruct normal wind flow patterns. For microscale and middle scale category (a) sites

there must not be any tree(s) between the source of the Pb and the sampler. For neighborhood scale category (b) sites, the sampler should be at least 20 meters from the drip line of trees. The sampler must, however, be placed at least 10 meters from the drip line of trees which could be classified as an obstruction, i.e., the distance between the tree(s) and the sampler is less than the height that the tree protrudes above the sampler.

* * * * *

13. References.

* * * * *

18. Air Quality Criteria for Lead. Office of Research and Development, U.S. Environmental Protection Agency, Washington, DC EPA-600/8-83-028 aF-dF, 1986, and supplements EPA-600/8-89/049F, August 1990. (NTIS document numbers PB87-142378 and PB91-138420.)

* * * * *

7. Section 1 and section 2b of Appendix G are revised to read as follows:

Appendix G—Uniform Air Quality Index and Daily Reporting

* * * * *

1. *General.* This appendix describes the uniform air quality index to be used by States in reporting the daily air quality index required by § 58.50.

2. *Definitions.*

* * * * *

b. Reporting Agency means the applicable State agency or a local air pollution control agency designated by the State, that will carry out the provisions of § 58.50.

* * * * *

[FR Doc. 97-29294 Filed 11-4-97; 8:45 am]

BILLING CODE 6560-50-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 424

[BPD-875-NC]

Medicare Program; Home Health Agency Physician Certification Regulations

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

ACTION: Decision to reexamine interpretations, with comment.

SUMMARY: This document with comment period announces our decision to reexamine our recent interpretations of the Medicare regulations pertaining to indirect compensation arrangements between home health agencies (HHAs) and physicians who certify or recertify the need for home health services or

establish or review the home health plan of care. We are withdrawing recent interpretations regarding indirect compensation arrangements where the physicians are salaried employees of, or have a contractual arrangement to provide services for, an entity that also owns the HHA. This will enable us to evaluate our recent interpretations of these regulations and related provisions of section 1877 of the Social Security Act to ensure consistent application of Medicare policy among providers of services.

DATES: Effective Date: This document is effective on December 5, 1997.

Comment Date: Written comments will be considered if we receive them at the appropriate address, as provided below, no later than 5:00 p.m. on January 5, 1998.

ADDRESSES: Mail written comments (an original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-875-NC, P.O. Box 7517, Baltimore, MD 21244-0517.

If you prefer, you may deliver your written comments (an original and three copies) to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW, Washington, DC 20201 or C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD-875-NC. 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, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250-7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also placed by calling the order desk at (202) 512-1800 or by faxing to (202) 512-2250. The cost of each copy is \$8.00. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated

as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

FOR FURTHER INFORMATION CONTACT:
Jennifer Carter, (410) 786-4615.

SUPPLEMENTARY INFORMATION:

I. Background

Section 903 of the Omnibus Reconciliation Act of 1980 amended sections 1814(a) and 1835(a) of the Social Security Act (the Act) to prohibit the certification of need for home health services under Medicare, and the establishment and review of a home health plan of care for those services, by a physician who has a significant interest in, or a significant contractual or significant financial relationship with, the HHA that provides those services. These amendments were incorporated into the regulations at 42 CFR 405.1633(d) (which was redesignated as § 424.22(d)), by an interim final rule with comment period that was published in the **Federal Register** on October 26, 1982 (47 FR 47388), and was made effective on November 26, 1992.

On June 30, 1986, we published a final rule in the **Federal Register** (51 FR 23541) that confirmed the provisions of the October 1982 rule, and clarified that under the term, "significant interest or a significant financial or contractual relationship" with the HHA, we intended to include salaried employment. This clarification was made effective on August 29, 1986.

The only exceptions to the home health regulations were uncompensated officers or directors of an HHA, HHAs operated by Federal, State, or local governmental authority, and sole community HHAs. The home health physician certification restrictions of sections 1814(a) and 1835(a) of the Act and § 424.22(d) of the regulations have not been revised or updated since 1986.

On December 19, 1989, section 6204 of the Omnibus Budget Reconciliation Act of 1989 added section 1877, "Limitation on Certain Physician Referrals," to the Act. In general, section 1877 of the Act prohibits a physician who has a financial relationship with an entity that furnishes clinical laboratory services (or a physician with an immediate family member who had such a relationship) from making referrals to the entity for clinical laboratory services for which Medicare may otherwise pay.

On August 10, 1993, section 13562 of the Omnibus Budget Reconciliation Act of 1993 (OBRA '93) revised section 1877 of the Act to cover 10 additional

designated health services, including home health services, beginning with referrals made after December 31, 1994. The statute was also revised to provide for certain exceptions to the prohibition, including a bona fide employment exception subject to certain conditions. Additionally, referrals are defined in part to include the request or establishment of a plan of care by a physician which includes the provision of a plan of care by a physician which includes the provision of a designated health service. On August 14, 1995, we published a final rule with comment in the **Federal Register** (60 FR 41914) to implement the amendments of OBRA '93 that apply to referrals for clinical laboratory services and which were effective retroactively to January 1, 1992. In this final rule we indicated our intention to rely on the language and interpretations of the final rule when reviewing referrals in appropriate cases for the 10 designated health services. Appropriate cases were defined as those in which our interpretation of the statute clearly applied equally to clinical laboratory services and other designated health services. We are currently developing a proposed rule to implement the provisions of section 1877 of the Act which were effective January 1, 1995, and relate to the additional designated health services.

It is our intention to reconcile the statutory prohibitions in sections 1814(a) and 1835(a) of the Act concerning physician certification of home health services with the related section 1877 prohibitions as part of the proposed regulations implementing the OBR '93 changes to section 1877. This proposed regulation is in the final stages of development and should be published in the very near future.

In the meantime, we have received numerous inquiries about the applicability of the current home health prohibitions at § 424.22 regarding hospital-employed physicians certifying and recertifying the need for home health services provided by the hospital-owned HHA. We recently released an interpretation of § 424.22(d)(3)(ii) and indirect compensation in the case where a physician is employed by the hospital that also owns the HHA. In that interpretation of § 424.22, we stated that hospital-employed physicians are prohibited from certifying or recertifying the need for home health services for the hospital-owned HHA. Furthermore, we stated that if the HHA is separately incorporated and not included on the hospital's cost report, the hospital-employed physicians are permitted to certify or recertify the need

for home health services for the hospital-owned HHA. We also released an interpretation that indicated that payment of compensation to a physician by the HHA's parent or related organization would very likely be considered to be paid by the HHA.

As we begin to reconcile the home health prohibitions with the section 1877 prohibitions, we have concluded that our recent interpretations of this regulation have brought about unintended consequences affecting rural areas, integrated delivery systems, and current medical practice and may be inconsistent with the provisions of section 1877. Therefore, we are going to address "indirect compensation" and the relationship between the HHA regulations and the section 1877 provisions in the separate proposed rule that is in the final stages of development and should be published in the very near future. We will address the scope of an indirect compensation arrangement where the physicians are salaried employees of, or have a contractual arrangement to provide services for, the entity that owns the HHA in that proposed regulation. In the meantime, we withdraw these recent interpretations concerning indirect compensation under § 424.22(d).

II. Purpose of This Notice

We have decided to reexamine appropriate provisions of section 1877 of the Act and the home health regulations as they pertain to indirect compensation arrangements between physicians and home health agencies. We are concerned with the situation in which the physician receives compensation from the same entity that also owns the home health agency. Pending that evaluation, we have decided to withdraw recent interpretations of § 424.22(d)(3)(ii) as it applies to certification and recertification or establishment and review of plans of care by physicians who are salaried employees of, or have a contractual arrangement to provide services for, an entity that also owns the HHA. Instead, we will address the issue of indirect compensation, applicable to the health services specified in section 1877 of the Act, in the proposed rule that is in the final stages of development and should be published in the **Federal Register** in the very near future. In the meantime, we withdraw these recent interpretations concerning indirect compensation under 424.22(d).

We remain concerned about inappropriate physician certification for home health services. However, we are also concerned about the effect that the recent interpretations of the home

health regulation at § 424.22(d)(3)(ii), as it applies to indirect salaried employment or contractual arrangements, may have on rural areas where the hospital or other entity is so pervasive a presence in the community that, in addition to owning the home health agency, it also employs the majority of the physicians.

We have asked the Medicare fiscal intermediaries to cooperate with the Office of Inspector General to look into the referral patterns of hospitals that own facilities providing ancillary services, including home health services.

III. Other Required Information

A. Executive Order 12866 Review

In accordance with provisions of Executive Order 12866, this notice with comment period was received by the Office of Management and Budget.

B. Collection of Information Requirements

This notice with comment period does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget for purposes of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

C. 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 notice, and, if we proceed with a subsequent document, we will respond to the comments in that document.

(Authority: Secs. 1102, 1814(a), 1835(a), 1871, and 1877 of the Social Security Act (42 U.S.C. 1302, 1395f(a), 1395(a), 1395hh, and 1395nn))

(Catalog of Federal Domestic Assistance Program No. 93.773 Medicare—Hospitals Insurance Program; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: October 17, 1997.

Nancy-Ann Min DeParle,

Deputy Administrator, Health Care Financing Administration.

Dated: October 23, 1997.

Donna E. Shalala,

Secretary.

[FR Doc. 97-29071 Filed 11-4-97; 8:45 am]

BILLING CODE 4120-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

43 CFR Part 1860

[WO-350-1220-00-24 1A]

RIN 1004-AC-88

Patent Preparation and Issuance

AGENCY: Bureau of Land Management, Interior.

ACTION: Final rulemaking.

SUMMARY: This final rule amends part 1860 of Title 43 of the Code of Federal Regulations (CFR) to completely remove subpart 1862, which contains internal instructions on preparing and issuing patents. The Bureau of Land Management (BLM) plans to place these procedures in an existing BLM Manual/Handbook, a more appropriate location than the CFR. The public will have access to the material.

EFFECTIVE DATE: December 5, 1997.

FOR FURTHER INFORMATION CONTACT: Vanessa Engle, Lands and Realty Group, Bureau of Land Management, 1849 C Street, N.W., Washington, DC 20240; Telephone (202) 452-7776 (Commercial or FTS).

SUPPLEMENTARY INFORMATION:

- I. Background
- II. Response to Comments
- III. Discussion of Final Rule
- IV. Procedural Matters

I. Background

The existing regulation at 43 CFR part 1862 has no requirements with which the public must comply. Instead, it contains internal instructions on preparing and issuing patents, which properly should be in manuals and handbooks. For this reason, BLM published a Notice of Proposed Rulemaking in the August 16, 1996, **Federal Register** (61 FR 42579), to advise the public of its plans to completely remove subpart 1862 from 43 CFR and place the material in the BLM Manual/Handbook. We invited public comments for 30 days and received comments from a mining association. We have considered the association's comments in preparing the final rule.

II. Response to Comments

The commenter opposed the proposed rule because it neither indicated where in BLM's policy manuals and handbooks the regulation would reside nor whether the instructions would remain the same or change.

Changes to the proposed rule, based on this comment, are not necessary.

BLM will not make any substantive alterations to the instructions but will update them before they are placed in the existing BLM Manual/Handbook, which currently is being updated to ensure continuity of the subpart 1862 instructions. Under the heading of subpart 1862, the manual/handbook will go into considerable detail on the requirements for preparing and issuing patents. In addition to the information previously contained in subpart 1862, the manual will include sections on different types of patents, specific language to be included in patents, directions on how to correctly format and number patents and other particulars. BLM will not remove any of the requirements previously found in 43 CFR part 1862.

III. Discussion of Final Rule

This final rule completely removes Subpart 1862 of Title 43 CFR, which provides internal instructions on preparing and issuing patents. BLM is issuing the rule without change from the August 16, 1996, Notice of Proposed Rulemaking. This action meets one of the objectives of President Clinton's Government-wide regulatory reform initiative—to eliminate unnecessary regulations from the CFR.

IV. Procedural Matters

National Environmental Policy Act of 1969

BLM has prepared an environmental assessment (EA), and has found that the final rule would not constitute a major Federal action significantly affecting the quality of the human environment under section 102(2)(C) of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 432(2)(C). BLM has placed the EA and the Finding of No Significant Impact (FONSI) on file in the BLM Administrative Record, 1620 L Street, NW, Room 401, Washington, DC, during regular business hours, 7:45 a.m. to 4:15 p.m. Monday through Friday.

Paperwork Reduction Act

This final rule does not contain information collection requirements that the Office of Management and Budget must approve under the Paperwork Reduction Act, 44 U.S.C. 3501.

Regulatory Flexibility Act

BLM has determined that the final rule, which merely removes unnecessary regulations, will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*)