

b. By adding new § 186.5450, to read as follows:

§ 186.5450 Tralomethrin.

(a) A time-limited feed additive regulation is established permitting residues of tralomethrin ((*S*)-*alpha*-cyano-3-phenoxybenzyl-(1*R*,3*S*)-2,2-dimethyl-3-[(*RS*)-1,2,2,2-tetrabromoethyl]-cyclopropanecarboxylate; CAS Reg. No. 66841-25-6) and its metabolites (*S*-*alpha*-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate and (*S*)-*alpha*-cyano-3-phenoxybenzyl(1*S*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate calculated as the parent in or on the following feed resulting from application of the insecticide to tomatoes in accordance with an experimental program (34147-EUP-2). The conditions set forth in this section shall be met.

Feed	Parts per million	Expiration date
Tomato pomace, wet.	1.50	June 1, 1997
Tomato pomace, dry.	4.00	June 1, 1997

(b) Residues in the feed not in excess of the established tolerance resulting from the use described in paragraph (a) of this section remaining after expiration of the experimental program will not be considered to be actionable if the insecticide is applied during the term of and in accordance with the provisions of the experimental use program and feed additive regulation.

(c) The company concerned shall immediately notify the Environmental Protection Agency of any findings from the experimental use that have a bearing on safety. The firm shall also keep records of production, distribution, and performance, and on request make the records available to any authorized officer or employee of the Environmental Protection Agency or the Food and Drug Administration.

[FR Doc. 95-18002 Filed 7-25-95; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Part 424

[BPD-709-FC]

RIN 0938-AF01

Medicare Program; Allowing Certifications and Recertification by Nurse Practitioners and Clinical Nurse Specialists for Certain Services

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period authorizes nurse practitioners and clinical nurse specialists, working in collaboration with a physician, to certify and recertify that extended care services are needed or continue to be needed. In addition, it sets forth the qualification requirements that a nurse practitioner or clinical nurse specialist must meet in order to sign certification or recertification statements. This final rule is necessary to implement section 6028 of the Omnibus Budget Reconciliation Act of 1989.

DATES: Effective Date: These regulations are effective on August 25, 1995.

Comment Date: Comments regarding the qualification requirements will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on September 25, 1995.

ADDRESSES: Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-709-FC, P.O. Box 7517, Baltimore, MD 21207.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201, or Room 132, East High Rise Building, 6325 Security Boulevard, Baltimore, MD 21207.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD-709-FC. 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). **FOR FURTHER INFORMATION CONTACT:** Jim Kenton, (410) 966-4607.

SUPPLEMENTARY INFORMATION:

I. Background

Section 1814(a) of the Social Security Act (the Act) requires specific certifications in order for Medicare payments to be made for certain services. Before the enactment of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101-239), section 1814(a)(2) of the Act required that, in the case of post-hospital extended care services, a physician certify that the services are or were required to be given because the individual needs or needed, on a daily basis, skilled nursing care (provided directly by or requiring the supervision of skilled nursing personnel) or other skilled rehabilitation services that, as a practical matter, can only be provided in a skilled nursing facility (SNF) on an inpatient basis.

The physician certification requirements were included in the law to ensure that patients require a level of care that is covered by the Medicare program and because the physician is a key figure in determining utilization of health services.

OBRA '89 was enacted on December 19, 1989. Section 6028 of OBRA '89 amended section 1814(a)(2) of the Act to allow, in the case of extended care services, a nurse practitioner or clinical nurse specialist who does not have a direct or indirect employment relationship with the facility, but is working in collaboration with a physician, to certify and recertify that extended care services are needed or continue to be needed. This provision took effect upon enactment.

Current regulations located at 42 CFR part 424, concerning conditions for Medicare payments, specify that a physician must certify and recertify the need for services. Regulations located at § 424.20 provide Medicare Part A coverage for post-hospital SNF care furnished by a SNF or a swing-bed hospital only if a physician certifies and recertifies the need for those services. Section 424.20(a)(2) contains certification requirements for certain swing-bed hospital patients under which a physician must certify that transfer to a SNF is not medically appropriate. Also, § 424.20(e) provides that certification and recertification statements may be signed by the physician responsible for the case or, with his or her authorization, by a

physician on the SNF staff or a physician who is available in case of an emergency and has knowledge of the case.

II. Provisions of the Proposed Rule

On June 28, 1991, we published a proposed rule (56 FR 29609) that would authorize nurse practitioners and clinical nurse specialists working in collaboration with a physician to certify and recertify that extended care services are needed or continue to be needed. In the preamble to that proposed rule, we described our policies concerning requirements for certification and recertification of need for extended care services, and proposed the following changes to the regulations:

- We proposed to revise §§ 424.1(b)(1) and 424.5(a)(4), concerning the general provisions of part 424, by deleting the statement that only a physician can certify and recertify the need for extended care services.
- We proposed to revise § 424.10(a), which specifies that certifications and recertifications must be made only by a physician, to permit a nurse practitioner or clinical nurse specialist to certify and recertify the need for services.
- We proposed to revise § 424.11(b), which specifies procedures for obtaining certifications and recertifications, to remove the requirement that only a physician can certify and recertify the need for services.
- We proposed to add a new § 424.11(e)(4) to specify that a nurse practitioner or clinical nurse specialist could certify and recertify that extended care services are needed or continue to be needed.
- We proposed to revise § 424.20(e), which pertains to the requirements for post-hospital SNF care, by adding a new provision to specify that the signer of the certification and recertification may be a nurse practitioner or clinical nurse specialist, provided that neither has a direct or indirect employment relationship with the facility, but is working in collaboration with a physician. In this section we also proposed that "collaboration" means a process whereby a nurse practitioner or clinical nurse specialist works with a doctor of medicine or osteopathy to deliver health care services. We further proposed that the services must be delivered within the scope of the practitioner's professional expertise as defined and as licensed by the State, with medical direction and appropriate supervision as provided for in guidelines jointly developed by the practitioner and the physician or other

mechanisms defined by Federal regulations and the law of the State in which the services are performed.

III. Analysis of and Response to Public Comments

In response to the June 28, 1991 proposed rule, we received 16 timely items of correspondence. The comments, submitted by or on behalf of long term care facilities, hospitals, providers of rehabilitative services, and nursing associations, and our responses, are presented below.

A. The Conditions and Scope of Practice Under Which a Nurse Practitioner or Clinical Nurse Specialist May Certify or Recertify the Need for Extended Care Services

Section 6028 of OBRA '89 amended section 1814(a)(2) of the Act to allow, in the case of extended care services, a nurse practitioner or clinical nurse specialist who does not have a direct or indirect employment relationship with the facility, but is working in collaboration with a physician, to certify and recertify that extended care services are needed or continue to be needed.

1. Comments and Responses

Comment: One commenter stated that before residents are certified or recertified for post-hospital SNF care for rehabilitation services only, the nurse practitioner or clinical nurse specialist should be required to consult with a rehabilitation professional in one or more of the relevant disciplines of physical therapy, occupational therapy, and speech-language pathology. The commenter believes that this should be made a requirement because assessment of the rehabilitative needs of the residents requires the input of professionals with specialized clinical training.

Response: Current law does not provide for the requirement of such a consultation. However, this type of consultation may result from the collaborative arrangements currently in place between the nurse practitioner or clinical nurse specialist and the physician. Collaborative arrangements provide for discussion of patient diagnosis and concerns related to case management to ensure the best care possible for the patient. The nurse practitioner or clinical nurse specialist, while working under clearly defined guidelines developed with the physician, may determine in certain instances that consultation with a rehabilitation professional is necessary.

In addition, under the SNF requirements for participation at § 483.20(b)(5), each resident must

receive a comprehensive assessment upon admission and a review of that assessment at least once every 3 months. The assessment must be conducted by a nurse and involve other practitioners as needed. A nurse practitioner or clinical nurse specialist who is performing a certification or recertification will have access to the assessment and will thus have the benefit of any assessment done by rehabilitation specialists.

Also, under the SNF requirements for participation at § 483.20(d), the SNF must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet the resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment. The care plan must be prepared by an interdisciplinary team that includes the attending physician, a registered nurse, and "other appropriate staff in disciplines as determined by the resident's needs." Accordingly, for a resident certified for SNF care for rehabilitation services, we expect that the interdisciplinary team that prepares a care plan would include a rehabilitation professional.

Comment: Three commenters stated that allowing nurse practitioners and clinical nurse specialists to certify and recertify that extended care services are needed or continue to be needed is an extremely narrow function when it is delegated only to those who work directly with attending physicians. The commenters believe that this provision should be expanded to include facility-employed nurse practitioners and clinical nurse specialists.

Response: Facility-employed nurse practitioners and clinical nurse specialists are prohibited by section 1814(a)(2) of the Act from providing certification and recertification services for a facility; therefore, we cannot adopt the commenter's suggestion. However, the requirements for certification and recertification authorizations are not limited to those individuals who work directly with attending physicians. The nurse practitioner or clinical nurse specialist is free to engage in independent practice (if allowed by State law) so long as he or she works in collaboration with a physician. This process allows each professional to retain responsibility for his or her respective services and engage in those services independently.

Comment: One commenter expressed concern that the prohibition that the nurse practitioner or clinical nurse specialist cannot work for the facility will have adverse effects on small rural hospitals. The commenter noted that, in rural areas, skilled nursing facilities are

often faced with dual problems. First, facilities in rural areas have a difficult time recruiting physicians. Since not many physicians live near the facility, it is difficult to find a physician who will make the long-distance visits to certify (or supervise) the care of residents in SNFs. Second, a nurse practitioner or clinical nurse specialist who lives close enough to the SNF is likely to already be employed by the SNF, since that is likely the only employment that would be available in that area. Thus, not only are nurse practitioners and clinical nurse specialists a less costly alternative for the facility to employ, but they generally must be an employee if the facility wishes to retain their services. The commenter suggested that a waiver be considered to allow nurse practitioners and clinical nurse specialists who are employed by rural facilities to certify and recertify the need or continued need for extended care services.

Response: The statute does not authorize us to grant a waiver to allow nurse practitioners and clinical nurse specialists who are employed by rural facilities to perform certification and recertification. However, those who are authorized by section 1861(s)(2)(K)(iii) of the Act to engage in independent practice, and are working in collaboration with a physician, can provide the service of certifying and recertifying extended care services in a high quality, cost-effective manner. Similarly, nurse practitioners and clinical nurse specialists who work directly for a physician who is not an employee of the facility can also provide this service. These types of arrangements will reduce the need for visits to the nursing facility by a physician solely for the purpose of meeting the signature requirements, and thus free physicians to deliver medical care that only they can furnish. We believe that such arrangements can provide some relief to those rural areas where it is often difficult to recruit and retain physicians.

Comment: One commenter noted that many smaller facilities would have to pay an outside nurse to certify and recertify patients, which would result in a direct or indirect employment relationship with the facility.

Response: When nurse practitioners or clinical nurse specialists are employees of qualified legal entities, under the common law test of section 210(j) of the Act (more fully set forth in 20 CFR 404.1005, 404.1007, and 404.1009, which set forth definitions of employers and employees for purposes of social security benefits), they are considered for the purposes of this

provision to have a direct or indirect employment relationship. Qualified legal entities may include the facility or someone working on the medical staff of the facility. These provisions set forth a number of factors that indicate whether a nurse practitioner or clinical nurse specialist has a direct or indirect employment relationship including, but not limited to the following:

- The facility or someone on its medical staff has the authority to hire or fire the nurse;
- The facility or someone on its medical staff furnishes the equipment and the place to work, sets the hours, and pays the nurse by the hour, week or month;
- The facility or someone on its medical staff restricts the nurse's ability to work for someone else or provides training and requires the nurse to follow instructions.

However, even though a facility may make direct payment to an independent practice nurse practitioner or clinical nurse specialist for the certification and recertification of extended care services, that individual is not considered to have a direct or indirect relationship with the facility as long as he or she does not perform other duties for the facility or someone on its staff, or is not under the control of the facility or someone on its staff.

Comment: One commenter stated that nurse practitioners and clinical nurse specialists should be given a wider scope of practice by the Federal Government in a manner similar to that in which States have used their services, that is, permit them to replace physician visits in the nursing home and have prescriptive authority within the nursing home.

Response: We understand the commenter's concerns, but note that the sole purpose of this rule is to implement section 1814(a)(2) of the Act, as amended by section 6028 of OBRA '89, which is relatively narrow in focus. Therefore, we do not have present legal authority to increase the scope of practice of nurse practitioners or clinical nurse specialists. However, it also should be noted that, in recent years, the Congress has continued to expand Medicare coverage of services furnished by nurse practitioners and clinical nurse specialists, which helps improve beneficiary access to medical services. For example, section 4155(a)(3) of the Omnibus Budget Reconciliation Act of 1990 (Pub. L. 101-508) amended section 1861(s)(2)(K) of the Act to authorize Medicare coverage for certain services performed by a nurse practitioner or a clinical nurse specialist working in a rural area. Those services

were previously covered only if performed by a physician. In addition, § 483.40 permits a physician to delegate certain tasks, including some physician visits, to nurse practitioners or clinical nurse specialists (as well as to physician assistants) with certain limitations, providing they are within the scope of State law. In these cases, however, the expansion in coverage was the direct result of a change in law, not an administrative decision.

Comment: Another commenter believes that HCFA should extend the signature authority to certification and recertification of specific types of health services within the extended care setting. This could include the plan of treatment requirements for outpatient physical therapy and speech language pathology, and the certification and recertification of the comprehensive outpatient rehabilitation facility benefit.

Response: Again, section 1814(a)(2) of the Act, as amended by section 6028 of OBRA '89, applies only to the certification and recertification of extended care services, which is the only subject of this final rule. The certification and recertification signature requirements for the various outpatient services mentioned in the above comment are addressed in other sections of the law and regulations.

2. Weight Given to Physician's Opinions

Subsequent to the June 28, 1991 proposed rule concerning certifications by nurse practitioners and clinical nurse specialists, we published a HCFA Ruling (No. 93-1, May 1993) that clarified HCFA's position regarding the weight to be given to a treating physician's opinion in determining Medicare coverage of inpatient hospital and SNF care. Although this ruling focused on certifications by physicians, it has significant implications for certifications by nurse practitioners and clinical nurse specialists. Therefore, although no commenter explicitly raised this issue, we believe it is appropriate to make an additional clarification regarding the scope of authority of a nurse practitioner and clinical nurse specialist. Specifically, we wish to clarify that although completion of the required certification or recertification is a prerequisite for Medicare SNF coverage, it does not absolutely ensure coverage. In order to qualify for coverage, the care must also meet Medicare's overall requirement of being reasonable and necessary for diagnosing or treating the beneficiary's condition (section 1862(a)(1) of the Act). This aspect of the certification and recertification requirement is discussed in detail in HCFA Ruling No. 93-1. As

the ruling indicates, the treating physician's certification or recertification of the need for care is to be given great weight in determining SNF coverage, but coverage decisions are not made solely based on this certification: "* * *if the attending physician's certification of the medical need for services is consistent with other records submitted in support of the claim for payment, the claim is paid. However, if the medical evidence is inconsistent with the physician's certification, the medical review entity considers the attending physician's certification only on a par with the other pertinent medical evidence" (HCFAR 93-1-8).

Thus, although an attending physician's certification or recertification that care is needed is to be given great weight in determining SNF coverage, we do not consider a certification or recertification irrefutable in the face of medical evidence to the contrary. We do not believe that a certification or recertification should be considered more binding when completed by a nurse practitioner or clinical nurse specialist than it would have been if completed by the attending physician. Therefore, it is possible for a nurse practitioner or clinical nurse specialist's certification of the need for care to be superseded by medical evidence to the contrary, which can include the opinion of the attending physician. We do not anticipate that such a certification or recertification would be completed in direct contradiction to the attending physician's opinion. For example, if the attending physician disagrees with a nurse practitioner's or clinical nurse specialist's certification of the need for care, the medical review entity can deny coverage, provided that the attending physician's opinion is consistent with the medical evidence in the file.

B. The Definition of "Collaboration"

In the proposed rule of June 28, 1991, we defined "collaboration" as a process whereby a nurse practitioner or clinical nurse specialist works with a doctor of medicine or osteopathy to deliver health care services. The services are delivered within the scope of the practitioner's professional expertise with medical direction and appropriate supervision as provided for in guidelines jointly developed by the practitioner and the physician, or other mechanisms defined by Federal regulations and the law of the State in which the services are performed.

Comment: One commenter maintained that HCFA's proposed definition of "collaboration," which

provides that appropriate supervision should be provided, implies that a physician should be physically present. The commenter believes this implication is overreaching and does not reflect the professional practice of these practitioners. The commenter contends that physicians are not physically present in the facility at the same time the services are performed.

Response: We do not believe that our proposed definition is overreaching. The requirement that collaboration entail medical direction and supervision does not imply that the physician be physically present in the facility or even that the physician be consulted on each patient. Our definition is meant to apply to the overall relationship between the physician and the nurse practitioner or clinical nurse specialist. Thus, we envision that collaboration would involve some systematic formal planning, assessment, and a practice arrangement that reflects and demonstrates evidence of consultation, recognition of statutory limits, clinical authority, and accountability for patient care, according to some mutual agreement that allows each professional to function independently.

C. The Limitation on Authorization To Sign Certification and Recertification Statements

In the June 28, 1991, proposed rule, we proposed to revise § 424.11(e) to specify that nurse practitioners and clinical nurse specialists be authorized to sign certifications and recertifications for extended care services. We defined these entities as individuals, licensed by the State, who meet the requirements in § 424.20(e).

Comment: One commenter suggested that regulations should provide that the physician assistant, as well as the nurse practitioner and clinical nurse specialist, be allowed to certify and recertify residents for Medicare benefits.

Response: Under current law, physician assistants are not allowed to perform these certifications and recertifications. Section 6028 of OBRA '89 extended the signature authorization for certification and recertification to nurse practitioners and clinical nurse specialists only.

Comment: One commenter indicated that the criteria in the proposed rule that require State licensure for the nurse practitioner and clinical nurse specialist to meet the signature authorization requirements place restraints on many of the nurse practitioners and clinical nurse specialists who are not formally recognized through their State practice acts (that is, formal licensure requirements), but who are not

prevented from practicing in those same States. The commenter believes that the lack of a formal licensure program should not prevent this provision from being implemented in a State.

Response: We agree that the proposed qualifications requiring State licensure are unduly restrictive on those nurse practitioners and clinical nurse specialists who are in States that currently authorize them to practice under State law, even though no formal licensure exists. Therefore, we are revising proposed § 424.11(e) to eliminate the requirement for State licensure. Instead, we are setting forth the necessary qualifications that nurse practitioners and clinical nurse specialists must meet for purposes of this provision. As detailed below, these qualification requirements will ensure that the signature authority is extended to nurse practitioners and clinical nurse specialists who are currently authorized under State law to perform such services, even if no formal licensure exists.

Nurse practitioners and clinical nurse specialists are primary health care providers. As a primary health care provider, the nurse practitioner and/or clinical nurse specialist manages care under a framework that includes assessment of health status, diagnosis, development of a treatment plan, implementation of that plan, follow up, and patient education. The autonomous nature of advanced practice nursing requires accountability for outcomes in health care.

In the early years, many of the nurse practitioner and clinical nurse specialist programs were hospital based certificate programs that provided basic education and clinical requirements that were very similar to the requirements that Medicare established in regulations for rural health clinics in § 491.2. In the late 1970's, post-basic advanced practice programs began to evolve in response to societal and health care needs and are rapidly being phased out in favor of master's programs. Most of the educational preparation now required is defined by guidelines established by the profession to assure appropriate knowledge and clinical competency necessary for the delivery of primary health care.

A formal, graduate educational program provides the nurse practitioner and clinical nurse specialist the theoretical knowledge and clinical skills appropriate for their scope of practice that includes clinical, technical and ethical learning experiences for delivery of care and role development in advanced nursing practice. Formal graduate education also enables nurse

practitioners and clinical nurse specialists to achieve and maintain national certification and recognition. Currently, for the nurse practitioner, 47 States require at least national certification or a master's degree and/or completion of an advanced practice program. For the clinical nurse specialist, 29 States specify a graduate degree and/or national certification. For the remaining States, advanced practice nursing is not recognized, the authority to practice is covered under a broad Nurse Practice Act, or, in still others, the scope of practice is based on the registered nurse's own determination of education, experience and amount of physician supervision necessary to conduct practice safely.

The completion of a formal, graduate education program ensures that the nurse practitioner and clinical nurse specialist acquire and maintain the theoretical knowledge and clinical skills appropriate for the certification and recertification of extended care services. Therefore, in this final rule we are requiring master's preparation for entry level nurse practitioners and clinical nurse specialists who certify and recertify SNF residents. We believe that this requirement is consistent with the training requirement currently associated with advanced practice nursing specialties.

We also intend to allow nurse practitioners and clinical nurse specialists who are currently practicing under previously set standards, which may be less restrictive (for example, not requiring a master's degree in nursing), to certify and recertify SNF services. Consequently, we are providing that an individual may certify and recertify SNF residents if the individual: is a registered professional nurse currently licensed to practice nursing in the State where he or she practices; is authorized to perform the services of a nurse practitioner or clinical nurse specialist; and has received, within 36 months from the effective date of this final rule, a certificate of completion from a formal advanced practice program that prepares registered nurses to perform an expanded role in the delivery of primary care.

Accordingly, we are revising § 424.11(e)(5) to specify that, in order to qualify as a nurse practitioner, an individual must:

(1) Be a registered professional nurse who is currently licensed to practice nursing in the State where he or she practices; be legally authorized to perform the services of a nurse practitioner in accordance with State law; and have a master's degree in nursing;

(2) Be certified as a nurse practitioner by a duly recognized professional association that has, at a minimum, eligibility requirements that meet the standards in § 424.11(e)(5)(i) (that is, in item (1) immediately above); or

(3) Meet the requirements for a nurse practitioner set forth in § 424.11(e)(5)(i), except for the master's degree requirement, and have received before August 25, 1998 a certificate of completion from a formal advanced practice program that prepares registered nurses to perform an expanded role in the delivery of primary care.

We have chosen a 36-month period for two reasons. First, we note that most advanced nursing programs are from one to two years in length, and we want to be sure that students currently or soon to be enrolled in existing non-master's programs would be able to complete their training and be eligible for Medicare participation without the need to change programs. Secondly, we want to provide the institutions operating the programs with enough time to react to these regulations. Our research to date leads us to believe that non-master's advanced programs are steadily being converted to master's degree programs and we therefore believe that this requirement may well affect the timing of institutional decisions for conversion, rather than the nature of those decisions. We welcome comments on this particular issue.

In addition, under revised § 424.11(e)(6), in order to qualify as a clinical nurse specialist the individual must:

(1) Be a registered professional nurse who is currently licensed to practice nursing in the State where he or she practices; be legally authorized to perform the services of a clinical nurse specialist in accordance with State law; and have a master's degree in a defined clinical area of nursing;

(2) Be certified as a clinical nurse specialist by a duly recognized professional association that has, at a minimum, eligibility requirements that meet the standards in § 424.11(e)(6)(i) (that is, item (1)); or

(3) Meet the requirements for a clinical nurse specialist set forth in § 424.11(e)(6)(i), except for the master's degree requirement, and have received before August 25, 1998, a certificate of completion from a formal advanced practice program that prepares registered nurses to perform an expanded role in the delivery of primary care.

As noted above, we are adding the above provisions as a result of a public comment on our June 28, 1991 proposed

rule. However, since it would have been difficult for readers to anticipate the changes that are necessary in this final rule, we are accepting public comments on the qualification requirements set forth in new § 424.11(e)(5) and (6).

D. Timing of the Recertification

Neither OBRA '89 nor the June 28, 1991 proposed rule addressed the timing of the recertification statements. However, current regulations in § 424.20(d) specify that the first recertification is required no later than the 14th day of post-hospital SNF care, and subsequent recertifications are required at least every 30 days after the first recertification.

Comment: One commenter suggested that HCFA change the requirement of recertification for medical and health services, from every 30 days to monthly.

Response: The timing requirements for certification and recertification were not addressed in the proposed rule and thus are not the subject of this regulation. We note, however, that the requirements are stated in regulations (§ 424.20(d)) in terms of days because they must relate to an admission, which may occur any time during a month. We do not believe that it would be appropriate to restate these requirements in terms of months. Such a change could result in extending the period between recertifications to 60 days if a recertification took place on the 1st day of one month and on the last day of the next month.

IV. Provisions of the Final Rule With Comment Period

For the most part, the final rule adopts the provisions of the proposed rule. Those provisions of the final rule that differ from the proposed rule follow.

In the proposed rule, we added a new § 424.11(e)(4) to extend to nurse practitioners and clinical nurse specialists the authority to sign statements that would certify and recertify that extended care services are needed or continue to be needed. We proposed that nurse practitioners and clinical nurse specialists must be licensed by the State in order to be authorized to sign these statements. As a result of public comment, in this final rule we are revising § 424.11(e)(4) of the proposed rule to delete the licensure requirement. Instead, as discussed above in section III.C. of this preamble, we are adding paragraphs (e)(5) and (e)(6) to § 424.11(e) to set forth specific qualification requirements for nurse practitioners and clinical nurse specialists, respectively, for purposes of the certification provisions. We are

accepting public comments on these provisions.

V. Impact Statement

Unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities, we generally prepare a regulatory flexibility analysis that is consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612). For purposes of the RFA, physicians are considered to be small entities. We also consider nurses who work on a consulting basis or who are self-employed to be small entities.

Section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any rule that 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. With the exception of hospitals located in certain rural counties adjacent to urban areas, for purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

As discussed in preceding sections of this preamble, this final rule implements section 6028 of OBRA '89 concerning the expansion of the certification and recertification authority for extended services to nurse practitioners and certified nurse specialists. In view of the specificity of the statutory provisions, we considered no alternatives beyond those raised by commenters. Any economic effects of this rule stem directly from the OBRA '89 provisions. However, we believe that economic effects of this rule are minimal. We do anticipate that the implementation of the provision to allow nurse practitioners and clinical nurse specialists to certify and recertify that extended care services are needed will be beneficial to physicians since this will free physicians to perform other procedures that require their professional expertise.

In the proposed rule (56 FR 29611), we stated that the proposed changes to the regulations would not produce any effects that would have a significant effect on the economy or on a substantial number of small entities. We received no comments on this assertion. The only change that we are making in this final rule is to clarify that these provisions will apply to nurse practitioners and clinical nurse specialists when they are authorized under State law to perform services even if no formal licensure exists. This

change will have no significant economic effect.

We have determined, and the Secretary certifies, that this final rule will not have a significant effect on the operations of a substantial number of small entities or on small rural hospitals. Therefore, we have not prepared a regulatory flexibility analysis or an analysis of the effects of this rule on small rural hospitals.

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

VI. Collection of Information Requirements

Section 424.20 of the regulations contains information collection requirements. The information collection requirements concern the signatures for certification and recertification statements for extended care services. The respondents who will be responsible are physicians, nurse practitioners or clinical nurse specialists working in collaboration with a physician. Public reporting burden for this collection of information is estimated to be 1 hour per response.

The requirements contained in § 424.20 were approved by OMB on May 3, 1991, in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). The OMB approval number is 0938-0454, and the expiration date is March 31, 1998.

VII. Response to Comments

Because of the large number of items of correspondence we normally receive on FR documents published for comment, we are not able to acknowledge or respond to them individually. We will consider all comments we receive about the qualification requirements for nurse practitioners or clinical nurse specialists by the date and time specified in the DATES section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

List of Subjects in 42 CFR Part 424

Assignment of benefits, Physician certification, Claims for payment, Emergency services, Plan of treatment.

42 CFR chapter IV, part 424, is amended as follows:

PART 424—CONDITIONS FOR MEDICARE PAYMENT

1. The authority citation for part 424 is revised to read as follows:

Authority: Secs. 216(j), 1102, 1814, 1815(c), 1835, 1842(b), 1861, 1866(d), 1870(e) and (f), 1871, 1872 and 1883(d) of the Social Security Act (42 U.S.C. 416(j), 1302, 1395f, 1395g(c), 1395n, 1395u(b), 1395x, 1395cc(d), 1395gg(e) and (f), 1395hh, 1395ii and 1395tt(d)).

2. In § 424.1, the introductory text of paragraph (b) is republished and paragraph (b)(1) is revised to read as follows:

§ 424.1 Basis and scope.

* * * * *

(b) *Scope.* This part sets forth certain specific conditions and limitations applicable to Medicare payments and cites other conditions and limitations set forth elsewhere in this chapter. This subpart A provides a general overview. Other subparts deal specifically with—

(1) The requirement that the need for services be certified and that a physician establish a plan of treatment (subpart B);

* * * * *

3. In § 424.5, the introductory text of paragraph (a) is republished and paragraph (a)(4) is revised to read as follows:

§ 424.5 Basic conditions.

(a) As a basis for Medicare payment, the following conditions must be met:

* * * * *

(4) *Certification of need for services.* When required, the provider must obtain certification and recertification of the need for the services in accordance with subpart B of this part.

* * * * *

4. The heading for subpart B is revised to read:

Subpart B—Certification and Plan of Treatment Requirements

5. Section 424.10 is revised to read as follows:

§ 424.10 Purpose and scope.

(a) *Purpose.* The physician has a major role in determining utilization of health services furnished by providers. The physician decides upon admissions, orders tests, drugs, and treatments, and determines the length of stay. Accordingly, sections 1814(a)(2) and 1835(a)(2) of the Act establish as a condition for Medicare payment that a physician certify the necessity of the services and, in some instances, recertify the continued need for those services.

Section 1814(a)(2) of the Act also permits nurse practitioners or clinical nurse specialists to certify and recertify the need for post-hospital extended care services.

(b) *Scope.* This subpart sets forth the timing, content, and signature requirements for certification and recertification with respect to certain Medicare services furnished by providers.

6. In § 424.11, paragraph (b) is revised, the introductory text of paragraph (e) is revised, and new paragraphs (e)(4), (e)(5), and (e)(6) are added to read as follows:

§ 424.11 General procedures.

* * * * *

(b) *Obtaining the certification and recertification statements.* No specific procedures or forms are required for certification and recertification statements. The provider may adopt any method that permits verification. The certification and recertification statements may be entered on forms, notes, or records that the appropriate individual signs, or on a special separate form. Except as provided in paragraph (d) of this section for delayed certifications, there must be a separate signed statement for each certification or recertification.

* * * * *

(e) *Limitation on authorization to sign statements.* A certification or recertification statement may be signed only by one of the following:

* * * * *

(4) A nurse practitioner or clinical nurse specialist, as defined in paragraph (e)(5) or (e)(6) of this section, in the circumstances specified in § 424.20(e).

(5) For purposes of this section, to qualify as a nurse practitioner, an individual must—

(i) Be a registered professional nurse who is currently licensed to practice nursing in the State where he or she practices; be authorized to perform the services of a nurse practitioner in accordance with State law; and have a master's degree in nursing;

(ii) Be certified as a nurse practitioner by a professional association recognized by HCFA that has, at a minimum, eligibility requirements that meet the standards in paragraph (e)(5)(i) of this section; or

(iii) Meet the requirements for a nurse practitioner set forth in paragraph (e)(5)(i) of this section, except for the master's degree requirement, and have received before August 25, 1998 a certificate of completion from a formal advanced practice program that prepares registered nurses to perform an expanded role in the delivery of primary care.

(6) For purposes of this section, to qualify as a clinical nurse specialist, an individual must—

(i) Be a registered professional nurse who is currently licensed to practice nursing in the State where he or she practices; be authorized to perform the services of a clinical nurse specialist in accordance with State law; and have a master's degree in a defined clinical area of nursing;

(ii) Be certified as a clinical nurse specialist by a professional association recognized by HCFA that has at a minimum, eligibility requirements that meet the standards in paragraph (e)(6)(i) of this section; or

(iii) Meet the requirements for a clinical nurse specialist set forth in paragraph (e)(6)(i) of this section, except for the master's degree requirement, and have received before August 25, 1998 a certificate of completion from a formal advanced practice program that prepares registered nurses to perform an expanded role in the delivery of primary care.

7. In § 424.20, the introductory text and paragraph (e) are revised to read as follows:

§ 424.20 Requirements for posthospital SNF care.

Medicare Part A pays for posthospital SNF care furnished by a SNF, or a hospital or RPCH with a swing-bed approval, only if the certification and recertification for services are consistent with the content of paragraph (a) or (c) of this section, as appropriate.

* * * * *

(e) *Signature.* Certification and recertification statements may be signed by—

(1) The physician responsible for the case or, with his or her authorization, by a physician on the SNF staff or a physician who is available in case of an emergency and has knowledge of the case; or

(2) A nurse practitioner or clinical nurse specialist, neither of whom has a direct or indirect employment relationship with the facility but who is working in collaboration with a physician. For purposes of this section, *collaboration* means a process whereby a nurse practitioner or clinical nurse specialist works with a doctor of medicine or osteopathy to deliver health care services. The services are delivered within the scope of the nurse's professional expertise, with medical direction and appropriate supervision as provided for in guidelines jointly developed by the nurse and the physician or other mechanisms defined by Federal regulations and the law of the State in which the services are performed.

* * * * *

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

Dated: April 4, 1994.

Bruce C. Vladeck,
Administrator, Health Care Financing Administration.

Dated: February 18, 1995.

Donna E. Shalala,
Secretary.

[FR Doc. 95-18282 Filed 7-25-95; 8:45 am]

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FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 64

[Docket No. FEMA-7621]

List of Communities Eligible for the Sale of Flood Insurance

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: This rule identifies communities participating in the National Flood Insurance Program (NFIP). These communities have applied to the program and have agreed to enact certain floodplain management measures. The communities' participation in the program authorizes the sale of flood insurance to owners of property located in the communities listed.

EFFECTIVE DATES: The dates listed in the third column of the table.

ADDRESSES: Flood insurance policies for property located in the communities listed can be obtained from any licensed property insurance agent or broker serving the eligible community, or from the NFIP at: Post Office Box 6464, Rockville, MD 20849, (800) 638-6620.

FOR FURTHER INFORMATION CONTACT: Robert F. Shea, Jr., Division Director, Program Implementation Division, Mitigation Directorate, 500 C Street, SW., room 417, Washington, DC 20472, (202) 646-3619.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase flood insurance which is generally not otherwise available. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Since the communities on the attached list have recently entered the NFIP, subsidized flood insurance is now available for property in the community.

In addition, the Director of the Federal Emergency Management Agency