

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);

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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:

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(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.

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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.