Federal Register when approval is obtained.

Organizations and individuals desiring to submit comments on the information collection and recordkeeping requirements should send them to the Health Care Financing Administration, Office of Financial and Human Resources, Management Planning and Analysis Staff, 7500 Security Boulevard, Baltimore, Maryland, 21244–1850 and to the Office of Management and Budget official whose name appears in the **ADDRESSES** section of this preamble.

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

V. Waiver of Prior Notice With Comment Period and of Delayed Effective Date

We ordinarily publish a notice of proposed rulemaking for a rule to provide a period of public comment prior to the effective date of the rule. This procedure can be waived, however, when an agency finds good cause that a notice and comment procedure is impracticable, unnecessary, or contrary to the public interest. Further, we generally provide for final rules to be effective no sooner than 30 days after the date of publication unless we find good cause to waive the delay.

In the case of this rule, we find good cause to implement this rule as a final rule because the delay involved in the prior notice and comment procedures for these DMEPOS supplier standards would be contrary to the public interest. In SSA '94, Congress enacted numerous substantive provisions designed to protect Medicare beneficiaries from abusive practices by DMEPOS suppliers. These provisions establish limitations on the information DMEPOS suppliers may include on a certificate of medical necessity (section 1834(j)(2)), establish restrictions on the methods DMEPOS suppliers may use to contact certain Medicare beneficiaries (section 1834(a)(17)), and limit the Medicare beneficiary's liability if the DMEPOS supplier does not comply with these statutory requirements (section 1834(j)(4)). Congress has also established significant penalties, including civil money penalties, if DMEPOS suppliers violate particular statutory provisions (section 1834(a)(18)(B)). Most importantly, for purposes of this regulation, Congress has indicated that beginning January 1, 1996, individuals or entities must meet at least three additional standards in order to obtain a Medicare supplier number.

When considered as a whole, these legislative changes demonstrate that Congress has serious concerns about the business practices employed by certain DMEPOS suppliers, and that Medicare beneficiaries require additional protection from these practices. It would, therefore, be contrary to the public interest to delay establishing the specific additional criteria that Congress has identified by adhering to the normal notice and comment procedures. In addition, as noted previously, the Secretary has already established certain regulatory standards for DMEPOS suppliers that were developed in accordance with the notice and comment procedures. These standards are familiar to the public and the regulated DMEPOS supplier community and provide a base level of protection for Medicare beneficiaries. Congress has not indicated any intention to reduce or eliminate these existing standards. It is necessary to maintain these existing regulatory standards in order to protect the public interest and to further our efforts to prevent fraud and abuse in the Medicare program through Operation Restore Trust.

As directed by statute, we have met with representatives of DMEPOS suppliers, the carriers, and consumers to consider whether additional standards are necessary. Although these meetings were productive, it was not possible to complete the full notice and comment procedure in order to have final rules in place before January 1, 1996. We are currently preparing a notice of proposed rulemaking reflecting our consultations with these entities and individuals and will publish that document in the near future. These final rules will be effective until altered by those regulations.

We believe that it would be contrary to public interest to delay implementation of the revised standards pending the process of publishing both a proposed rule and a final rule. The three new standards are required to be included in any new standards promulgated by the Secretary, and are not discretionary. Moreover, the existing DMEPOS standards had been promulgated in accordance with the notice and comment provisions of the Administrative Procedure Act. Therefore, we find good cause to waive proposed rulemaking for the revised requirements set forth in § 424.57 and to issue these regulations in final. However, we are providing a 60-day period for public comment, as indicated at the beginning of this rule, on the changes to § 424.57. For the above reasons, we also find good cause to waive the delay in effective date of this rule.

VI. Regulatory Impact Analysis

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless we certify that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all providers, physicians, and other suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 50 beds.

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

In accordance with the provisions of Executive Order 12866, this final rule was not reviewed by the Office of Management and Budget.

List of Subjects in 42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare.

42 CFR Part 424 is amended as set forth below:

PART 424—CONDITIONS FOR MEDICARE PAYMENT

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

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

2. Paragraph (c) of § 424.57 is revised to read as follows: