

medical practice exempts the burden associated with this requirement from the PRA as stipulated under 5 CFR 1320.3(b)(2). It is standard for medical facilities to have written policies and procedures pertaining to medical emergencies. Having written policies and procedures saves time deciding what to do and thus benefits the patient; it also gives the provider liability protection.

In the May 9, 2002 proposed rule (67 FR 31496), we solicited, public comment on this information collection requirement. However, we did not receive any public comments on this information collection requirement.

§ 489.24 Special responsibilities of Medicare hospitals in emergency cases.

Paragraph (d) of this section requires that, if the hospital offers an individual the further medical examination and treatment described in that paragraph and informs the individual (or a person acting on the individual's behalf) of the risks and benefits to the individual of the examination and treatment, but the individual (or a person acting on the individual's behalf) does not consent to the examination or treatment: (1) The medical record must contain a description of the examination, treatment, or both if applicable, that was refused by or on behalf of the individual; (2) the hospital must take all reasonable steps to secure the individual's written informed refusal (or that of the person acting on his or her behalf); and (3) the written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.

Paragraph (d) of this section also requires that, if the hospital offers to transfer the individual to another medical facility in accordance with paragraph (e) of this section and informs the individual (or a person acting on his or her behalf) of the risks and benefits to the individual of the transfer, but the individual (or a person acting on the individual's behalf) does not consent to the transfer: (1) The hospital must take all reasonable steps to secure the individual's written informed refusal (or that of a person acting on his or her behalf); (2) the written document must indicate the person has been informed of the risks and benefits of the transfer and state the reasons for the individual's refusal; and (3) the medical record must contain a description of the proposed transfer that was refused by or on behalf of the individual.

The burdens associated with these requirements is the time it will take a hospital to secure a written refusal, create a written document containing

the information the patient has been given, and describing in the patient's record what was refused. These information collection requirements are currently approved under 0938-0667.

Paragraph (j) of this section requires that each hospital must maintain an on-call list of physicians on its medical staff in a manner that best meets the needs of the hospital's patients who are receiving services required under this section in accordance with the resources available to the hospital, including the availability of on-call physicians. It also requires that the hospital have written policies and procedures in place to respond to situations in which a particular specialty is not available or the on-call physician cannot respond because of circumstances beyond the physician's control and to provide that emergency services are available to meet the needs of patients with emergency medical conditions if it elects to permit on-call physicians to schedule elective surgery during the time that they are on call or to permit on-call physicians to have simultaneous on-call duties.

The burden associated with these requirements is the time it will take to create the list and write down the policies and procedures. We believe that these actions reflect usual, customary, and prudent medical and business practices; the burden is exempt from the PRA under 5 CFR 1320.3(b)(2). We believe that the providers have the necessary written information available to the staff in times of emergencies to reduce the time it takes to contact a doctor or to decide what to do if the doctor is unavailable. These actions benefit the patient and give the provider liability protection.

We note that these requirements in paragraph (j) are revisions of provisions that were included in the May 9, 2002 proposed rule.

We have submitted a copy of this final rule to OMB for its review of the information collection requirements described above. These requirements are not effective until they have been approved by OMB.

If you comment on any of these information collection and record keeping requirements, please mail copies directly to the following:

Centers for Medicare & Medicaid Services, Office of Strategic Operations and Regulatory Affairs, Regulations Development and Issuances Group, Attn: Julie Brown, CMS-1063-F Room C5-16-03, 7500 Security Boulevard, Baltimore, MD 21244-1850; and
Office of Information and Regulatory Affairs, Office of Management and

Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Brenda Aguilar, CMS Desk Officer.

Comments submitted to OMB may also be e-mailed to the following address: e-mail: baguilar@omb.eop.gov; or faxed to OMB at (202) 395-6974.

XVI. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 16, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

B. Executive Order 12866

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if 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 in any 1 year).

We have determined that this final rule is not a major rule as defined in 5 U.S.C. 804(2). As explained below, we do not have sufficient information to estimate the precise economic impact of this final rule. However, in general, this final rule diminishes rather than increases the EMTALA compliance burden on hospitals and physicians as this burden exists under current regulations. In both the previous EMTALA rules, the proposed EMTALA rule published on June 16, 1988 (53 FR 22513) and the preamble to the interim final rule published on June 22, 1994 (59 FR 32120), we explained, and the Secretary certified, that those regulations would not have a significant impact on a substantial number of small entities and would not have a significant impact on the operations of a substantial number of small rural hospitals. As explained above, this final rule further reduces compliance burden and cost. Therefore, we estimate that the total impact of these changes will be less than the threshold for a major rule (\$100 million or more in any 1 year).