

CoPs are intended to protect patient health and safety and to ensure that high quality care is provided to all patients. The State survey agencies (SAs), in accordance with section 1864 of the Social Security Act (the Act), survey hospitals to assess compliance with the CoPs. The SAs conduct surveys using the instructions in the State Operations Manual (SOM), (Health Care Financing Administration (HCFA) Publication No. 7). The SOM contains the regulatory language of the CoPs as well as interpretive guidelines and survey procedures and probes that elaborate on regulatory intent and give guidance on how to assess provider compliance. Under § 489.10(d), the SAs determine whether hospitals have met the CoPs and report their recommendations to us. The standards, procedures, and SA personnel involved in developing recommendations regarding EMTALA compliance are the same as those for recommendations regarding CoP compliance, since alleged violations of EMTALA are treated as allegations that a hospital has not complied with a requirement for Medicare participation.

Under the authority of section 1865 of the Act and the regulations at § 488.5, hospitals accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) or the American Osteopathic Association (AOA) are deemed to meet the requirements in the CoPs, and therefore, are not routinely surveyed for CoP compliance by the SAs. However, all Medicare and Medicaid participating hospitals are required to be in compliance with our CoPs regardless of their accreditation status.

Comment: Some commenters expressed general approval of the proposed revision to § 482.12(f), which is applicable to hospitals that provide emergency services but have departments off campuses that do not provide emergency services.

Response: We appreciate these commenters' support and have kept their views in mind in evaluating the other comments recommending specific changes in this final rule.

Comment: Some commenters stated that the proposed revision to § 482.12(f) seems to imply that hospitals must have staff trained in appraisal of emergencies on duty on a 24-hour per day, 7-day a week basis to comply with the requirement. The commenters believed that this would be an unreasonable requirement.

Response: We agree that such a requirement for off-campus departments would be unreasonably stringent. Therefore, we plan to clarify in the

interpretive guidelines or training materials used to implement this requirement that the policies and procedures in place for appraisal of emergencies and referral when appropriate must be implemented only within the hours of operation and normal staffing capability of the facility.

Comment: Some commenters opposed adding a specific CoP provision for off-campus departments of hospitals that have dedicated emergency departments but do not offer emergency services at their off-campus locations. The commenters believed this is an unnecessary burden on hospital governing bodies and medical staffs.

Response: We do not agree that adding this condition will impose an unnecessary burden on hospitals. First, the amount of burden will be minimal, because the regulation does not require that the facilities provide emergency care or add to their existing medical capabilities, but only that appropriate policies and procedures be in place. While developing and implementing these policies and procedures will require some effort from facilities that do not have them in place, the effort involved should be considerably less than that required to comply with current regulations at § 489.24(i) regarding EMTALA compliance by hospitals with off-campus nonemergency departments, which are being replaced by the condition. We also do not agree that any remaining burden associated with the revised requirement is unnecessary. On the contrary, the ability of such an off-campus facility to respond promptly and appropriately to an unexpected request for emergency care can be crucial to the health and safety of the individual with the emergency condition.

Because we believe that the burden of having a plan in place to deal with an occasional emergency is minimal and the potential benefit to the individual of having such a plan is considerable, we are not making changes to the proposed CoP in this final rule in response to this comment.

XIV. Other Issues

A. Editorial/Clarifying Changes

In addition to the changes to § 489.24 discussed in sections V. through XIII. of this preamble, we are revising § 489.24(d)(3) (Refusal to consent to treatment) to refer to an individual or a person acting on the individual's behalf who "does not consent to the examination or treatment," rather than referring to an individual or a person acting on the individual's behalf who

"refuses to consent to examination and treatment." We are making a parallel change in § 489.24(d)(5) (Refusal to consent to transfer). We are making these changes only for editorial reasons and in the interest of clarity; these revisions do not represent any change in policy.

B. Out-of-Scope Comments

We received a number of public comments on issues that were not addressed as part of the May 9, 2002 proposed rule. Because the issues addressed in the comments were not part of the proposed rule, we are not providing responses to them in this final rule. We will consider them in the future if we consider changes in related policy areas.

XV. Information Collection Requirements

Under the Paperwork Reduction Act (PRA) of 1995, we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

Therefore, we are soliciting public comments on each of these issues for the information collection requirements discussed below.

§ 482.12 Conditions of Participation: Governing Body

New § 482.12(f)(3) specifies that, if emergency services are provided at the hospital but are not provided at one or more off-campus departments of the hospital, the governing body of the hospital must assure that the medical staff have written policies and procedures in effect with respect to the off-campus department(s) for appraisal of emergencies and referral when appropriate.

While this information collection requirement is subject to the PRA, the fact that this requirement is a usual, customary, and prudent business and