requirements of the Privacy Act. This rule adds a new paragraph to § 1014.12 to exempt the Inspector General's investigative files from certain requirements of the Privacy Act.

Pursuant to section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), the Commission certifies that the amendment to 16 CFR 1014.12, Specific Exemptions, will not have a significant impact on a substantial number of small entities.

List of Subjects in 16 CFR Part 1014

Privacy.

For the reason stated in the preamble, Chapter II, Title 16 of the Code of Federal Regulations is amended as follows:

PART 1014—POLICIES AND PROCEDURES IMPLEMENTING THE PRIVACY ACT OF 1974

1. The authority citation for part 1014 continues to read as follows:

Authority: Privacy Act of 1974 (5 U.S.C. 552a).

§ 1014.12 [Amended]

2. Section 1014.12, *Specific exemptions*, is amended by adding paragraph (b) to read as follows:

* * * * *

(b) *Inspector General Investigative Files—CPSC–6.* All portions of this system of records which fall within 5 U.S.C. 552a(k)(2) (investigatory materials compiled for law enforcement purposes) and 5 U.S.C. 552a(k)(5) (investigatory materials solely compiled for suitability determinations) are exempt from 5 U.S.C. 552a(c)(3) (mandatory accounting of disclosures); 5 U.S.C. 552a(d) (access by individuals to records that pertain to them); 5 U.S.C. 552a(e)(1) (requirement to maintain only such information as is relevant and necessary to accomplish an authorized agency purpose); 5 U.S.C. 552a(e)(4)(G) (mandatory procedures to notify individuals of the existence of records pertaining to them); 5 U.S.C. 552a(e)(4)(H) (mandatory procedures to notify individuals how they can obtain access to and contest records pertaining to them); 5 U.S.C. 552a(e)(4)(I) (mandatory disclosure of records source categories); and the Commission's regulations in 16 CFR part 1014 which implement these statutory provisions.

Dated: June 17, 1994.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 94–15177 Filed 6–21–94; 8:45 am]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 131

[Docket No. 91P–0090]

Evaporated Milk; Amendment of the Standard of Identity; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of June 13, 1994, for the final rule that amended the standard of identity for evaporated milk by revising the minimum milkfat and total milk solids content requirements and establishing a minimum milk solids-not-fat content requirement.

DATES: Effective date confirmed: June 13, 1994.

FOR FURTHER INFORMATION CONTACT: Nannie H. Rainey, Center for Food Safety and Applied Nutrition (HFS–158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–205–5099.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 14, 1994 (59 FR 17689), FDA published a final rule that amended the standard of identity for evaporated milk (21 CFR 131.130) to: (1) Reduce the minimum milkfat content requirement from 7.5 percent to 6.5 percent by weight; (2) reduce the minimum total milk solids content requirement from 25 percent to 23 percent by weight; and (3) add a minimum milk solids-not-fat content requirement of 16.5 percent by weight. This action was based on a petition from the American Dairy Products Institute, 130 North Franklin St., Chicago, IL 60606.

FDA gave interested persons until May 16, 1994, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the final rule published in the **Federal Register** of April 14, 1994, should be confirmed.

List of Subjects in 21 CFR Part 131

Cream, Food grades and standards, Milk, Yogurt.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201, 401, 403, 409, 701, 721 (21 U.S.C. 321, 341, 343, 348, 371, 379e)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), and redelegated to the Director, Center for Food Safety and Applied Nutrition (21 CFR 5.62), notice is given that the amendments of 21 CFR part 131 that were set forth in the **Federal Register** of April 14, 1994, final rule became effective June 13, 1994.

Dated: June 15, 1994.

Fred R. Shank,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 94–15186 Filed 6–21–94; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 8546]

RIN 1545–AL58

Limitations on Corporate Net Operating Loss

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final income tax regulations providing rules for allocating net operating loss or taxable income, and net capital loss or gain, within the taxable year in which a loss corporation has an ownership change under section 382 of the Internal Revenue Code of 1986. These regulations permit the loss corporation to elect to allocate these amounts between the period ending on the change date and the period beginning on the day after the change date as if its books were closed on the change date.

EFFECTIVE DATE: These regulations are effective June 22, 1994.

For dates of applicability of these regulations, see the **EFFECTIVE DATE** paragraph in the **SUPPLEMENTARY INFORMATION** portion of the preamble.

FOR FURTHER INFORMATION CONTACT: Roberta F. Mann of the Office of Assistant Chief Counsel (Corporate), Office of Chief Counsel, IRS, 1111 Constitution Avenue, NW, Washington, DC 20224 (Attention: CC:DOM:CORP:5) or telephone 202–622–7550 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in these final regulations has been reviewed and approved by the Office of Management and Budget in accordance with the Paperwork Reduction Act (44 U.S.C. 3504(h)) under

control number 1545–1381. The estimated annual burden per respondent is estimated to be 0.1 hour.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, PC:FP, Washington, DC 20224, and to the Office of Management and Budget, Attention: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503.

Background

This document contains final regulations to be added to the Income Tax Regulations (26 CFR part 1) under section 382 of the Internal Revenue Code. The final regulations provide rules for the allocation of net operating loss or taxable income and net capital loss or gain within the taxable year in which a loss corporation has an ownership change. Proposed regulations on this subject were set forth in a notice of proposed rulemaking published in the **Federal Register** on November 19, 1992 (57 FR 54535). The IRS received public comments on the proposed regulations. No public hearing was requested and none was held. Having considered the comments submitted, the IRS and the Treasury Department adopt the proposed regulations as revised by this Treasury decision.

Explanation of Provisions

Following an ownership change, section 382 limits the amount of post-change income that may be offset by a corporation's pre-change loss. Sections 382(b)(3)(A) and (d)(1) require that, except as provided in section 382(h)(5) (relating to certain built-in gains and losses) and in regulations, taxable income or net operating loss must be allocated ratably to each day in the change year for purposes of applying the section 382 limitation. Under section 383, similar rules apply with respect to pre-change capital losses and certain pre-change credits.

The proposed regulations provide rules for allocation of net operating loss or taxable income, and net capital loss or gain, within the change year. The proposed regulations generally provide that a loss corporation may allocate such items between the pre-change period and the post-change period (1) by ratably allocating an equal portion to each day in the change year, or (2) if it so elects, based on a closing of its books as of the change date. The final regulations adopt the proposed regulations with few changes. The most significant comments and changes are described below.

A. Consistency Rules for Consolidated and Controlled Groups

The proposed regulations provide consistency rules for corporations that are members of consolidated groups or controlled groups. These consistency rules are based on proposed regulations applying section 382 to consolidated and controlled groups. The consistency rules contained in the proposed regulations have been revised in the final regulations because the proposed consolidated and controlled group regulations have not been finalized yet. The final regulations provide that if a closing-of-the-books election is made with respect to an ownership change occurring during a consolidated return year, all allocations with respect to that ownership change must be consistent with the election. Further consideration will be given to consistency rules for consolidated groups in the development of final regulations applying section 382 to these groups.

B. Limitation Increase Rule

In Notice 87–79, 1987–2 C.B. 387, the IRS announced its intention to issue regulations that would allow taxpayers to make a closing-of-the-books election. The Notice stated that, prior to the issuance of regulations, taxpayers would be required to use the statutory ratable allocation method unless they obtained a private letter ruling allowing them to use a different method.

Pursuant to Notice 87–79, the IRS issued a number of private letter rulings that authorized allocations based on a closing of the taxpayers' books. Some of these rulings allowed taxpayers to increase in their section 382 limitation to the extent that any net pre-change income was offset by net post-change loss in computing taxable income or loss for the change year. The purpose of the increased limitation was to put the taxpayer in a position similar to the position it would have been in had its taxable year ended on the change date.

In the interest of simplicity, the proposed regulations do not include a rule providing for increases in the annual section 382 limitation in cases in which net post-change loss offsets net pre-change income. Several commentators questioned the failure to include a limitation increase rule.

The final regulations retain the approach of the proposed regulations, in which change year income and losses may be netted together without limitation. This approach may be either favorable or unfavorable to taxpayers, depending on the circumstances. This approach is disadvantageous when it results in the netting of a post-change loss against pre-change income. Conversely, the approach is advantageous to taxpayers that are able to net a pre-change loss against post-change income without limitation. In these cases, if the taxpayers' year had ended on the change date, the loss so used would have been subject to the section 382 limitation.

Adoption of a limitation increase rule would add significant complexity to the regulations. If taxpayers were protected from the disadvantages of netting a post-change loss against pre- change income, consistency would require that taxpayers not be allowed the benefit of netting pre-change loss against post-change income without limitation. In other words, detailed rules for applying the section 382 limitation within the change year to limit the use of a loss in the pre-change portion of the year against income in the post-change period would be necessary concomitants of a limitation increase rule. To avoid this complexity, the final regulations allow change year losses to offset change year income without limitation and do not include a limitation increase rule.

C. Additional Issues

The preamble to the proposed regulations requested comments on the interaction of the ratable allocation rules under the proposed regulations and the built-in gain and loss rules under section 382(h), particularly with respect to extraordinary items (*e.g.*, an asset sale not made in the ordinary course of business). A commentator recommended that the final regulations include both a rule for extraordinary items and the limitation increase rule (described in paragraph B above). After due consideration, the IRS and the Treasury Department decided that rules relating to extraordinary items would add unnecessary complexity to the final regulations. Thus, the final regulations do not contain special rules with respect to the allocation of extraordinary items. The IRS and the Treasury Department may give further consideration to the desirability of rules addressing extraordinary items.

D. Effective Date

The regulations apply to ownership changes occurring on or after June 22, 1994.

Special Analyses

It has been determined that this Treasury decision is not a significant regulatory action as defined in EO 12866. Therefore, a regulatory

assessment is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking preceding these regulations was submitted to the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal author of these regulations is Roberta F. Mann, Office of the Assistant Chief Counsel (Corporate), IRS. However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR parts 1 and 602 are amended as follows:

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding an entry in numerical order to read as follows:

Authority: 26 U.S.C. 7805 * * * § 1.382–6 also issued under 26 U.S.C. 382(b)(3)(A), 26 U.S.C. 382(d)(1), 26 U.S.C. 382(m), and 26 U.S.C. 383(d) * * *

Par 2. Section 1.382–1 is amended by revising the entry for § 1.382–6 and adding additional entries to read as follows:

§ 1.382–1 Table of contents.

* * * * *

§ 1.382–6 Allocation of income and loss to periods before and after the change date for purposes of section 382.

(a) General rule.
(b) Closing-of-the-books election.
(1) In general.
(2) Making the closing-of-the-books election.
(i) Time and manner.
(ii) Election irrevocable.
(3) Special rules relating to consolidated and controlled groups.
(i) Consolidated groups.
(ii) Controlled groups.
(c) Operating rules for determining net operating loss, taxable income, net capital loss, modified capital gain net income, and special allocations.
(1) In general.
(2) Adjustment to net operating loss.
(i) Determination of remaining capital gain.
(ii) Reduction of net operating loss by remaining capital gain.
(d) Coordination with rules relating to the allocation of income under § 1.1502–76(b).
(e) Allocation of certain credits.
(f) Examples.
(g) Definitions and nomenclature.
(1) Change year.
(2) Pre-change period.
(3) Post-change period.
(4) Modified capital gain net income.
(h) Effective date.

* * * * *

Par. 3. The heading of § 1.382–6 is revised, and the text of the section is added to read as follows:

§ 1.382–6 Allocation of income and loss to periods before and after the change date for purposes of section 382.

(a) *General rule.* Except as provided in paragraphs (b) and (d) of this section, a loss corporation must allocate its net operating loss or taxable income (see section 382(k)(4)), and its net capital loss (see section 1222(10)) or modified capital gain net income (as defined in paragraph (g)(4) of this section), for the change year between the pre-change period and the post-change period by ratably allocating an equal portion to each day in the year.

(b) *Closing-of-the-books election*—(1) *In general.* Subject to paragraphs (b)(3)(ii) and (d) of this section, a loss corporation may elect to allocate its net operating loss or taxable income and its net capital loss or modified capital gain net income for the change year between the pre-change period and the post-change period as if the loss corporation's books were closed on the change date. An election under this paragraph (b)(1) does not terminate the loss corporation's taxable year as of the change date (e.g., the change year is a single tax year for purposes of section 172).

(2) *Making the closing-of-the-books election*—(i) *Time and manner.* A loss corporation makes the closing-of-the-books election by including the following statement on the information statement required by § 1.382–2T(a)(2)(ii) for the change year: "THE CLOSING-OF-THE-BOOKS ELECTION UNDER § 1.382–6(b) IS HEREBY MADE WITH RESPECT TO THE OWNERSHIP CHANGE OCCURRING ON [INSERT DATE]." The election must be made on or before the due date (including extensions) of the loss corporation's income tax return for the change year.

(ii) *Election irrevocable.* An election under this paragraph (b) is irrevocable.

(3) *Special rules relating to consolidated and controlled groups*—(i) *Consolidated groups.* If an election under this paragraph (b) is made with respect to an ownership change occurring in a consolidated return year, all allocations under this section with respect to that ownership change must be consistent with the election.

(ii) *Controlled groups.* If paragraph (b)(3)(i) of this section does not apply, and if, as part of the same plan or arrangement, two or more members of a controlled group (as defined in section 1563(a), determined by substituting "50 percent" for "80 percent" each place that it appears, and without regard to section 1563(a)(4)), have ownership changes and continue to be members of the controlled group (or become members of the same other controlled group), a closing-of-the-books election applies only if the election is made by all members having the ownership changes.

(c) *Operating rules for determining net operating loss, taxable income, net capital loss, modified capital gain net income, and special allocations.* For purposes of this section, for the change year—

(1) *In general*—(i) Net operating loss or taxable income is determined without regard to gains or losses on the sale or exchange of capital assets; and

(ii) Net operating loss or taxable income and net capital loss or modified capital gain net income are determined without regard to the section 382 limitation and do not include the following items, which are allocated entirely to the post-change period—

(A) Any income, gain, loss, or deduction to which section 382(h)(5)(A) applies; and

(B) Any income or gain recognized on the disposition of assets transferred to the loss corporation during the post-change period for a principal purpose of ameliorating the section 382 limitation.

(2) *Adjustment to net operating loss*—(i) *Determination of remaining capital gain.* The amount of modified capital gain net income (defined in paragraph (g)(4) of this section) allocated to each period is offset by capital losses to which section 382(h)(5)(A) applies and capital loss carryovers, subject to the section 382 limitation (in the case of modified capital gain net income allocated to the post-change period).

(ii) *Reduction of net operating loss by remaining capital gain.* The amount of net operating loss allocated to each period is reduced (but not below zero)

without regard to the section 382 limitation, first by the modified capital gain net income remaining in the same period, and then by the modified capital gain net income remaining in the other period.

(d) *Coordination with rules relating to the allocation of income under § 1.1502–76(b).* If § 1.1502–76 applies (relating to the taxable year of members of a consolidated group), an allocation of items under paragraph (a) or (b) of this section is determined after applying § 1.1502–76. Thus, if a short taxable year under § 1.1502–76 is a change year for which an allocation under this section is to be made, the allocation under this section applies only to the items allocated to that short taxable year under § 1.1502–76.

(e) *Allocation of certain credits.* The principles of this section apply for purposes of allocating, under section 383, excess foreign taxes under section 904(c), current year business credits under section 38, and the minimum tax credit under section 53. The loss corporation must use the same method of allocation (ratable allocation or closing-of-the-books) for purposes of sections 382 and 383.

(f) *Examples.* The rules of this section are illustrated by the following examples:

Example 1. (i) Assume that the loss corporation, L, a calendar year taxpayer with a May 26, 1995, change date, determines a section 382 limitation under section 382(b)(1) of $100,000. Thus, for the change year, its section 382 limitation is $100,000 × (219/365)=$60,000. L makes the closing-of-the-books election under paragraph (b) of this section.

(ii) Assume that L has a $150,000 capital loss carryover (from its 1994 taxable year) and a $300,000 net operating loss carryover (from its 1994 taxable year) to the change year. L recognizes, in the pre-change period, $200,000 of ordinary loss, and, in the post-change period, $150,000 of capital gain and $100,000 of ordinary income. Assume that section 382(h) does not apply to the capital gain or the ordinary income.

(iii) L has a $100,000 net operating loss for the change year ($200,000 pre-change loss less $100,000 post-change income), as determined under paragraph (c)(1)(i) of this section. Because L has no current year capital losses, L's $150,000 capital gain recognized in the post-change period is its modified capital gain net income for the change year (as defined at paragraph (g)(4) of this section). L allocates $100,000 of net operating loss to the pre-change period and $150,000 of modified capital gain net income to the post-change period.

(iv) Under paragraph (c)(2)(i) of this section, L uses its capital loss carryover to offset its modified capital gain net income allocated to the post-change period, subject to its section 382 limitation. L's section 382 limitation is $60,000, so L uses $60,000 of its capital loss carryover to offset $60,000 of its $150,000 modified capital gain net income. L has absorbed its entire section 382 limitation for the change year and has $90,000 of modified capital gain net income remaining in the post-change period.

(v) Under paragraph (c)(2)(ii) of this section, L offsets its $100,000 net operating loss allocated to the pre-change period by the $90,000 of modified capital gain net income remaining in the post-change period, without regard to the section 382 limitation, thereby reducing its pre-change net operating loss to $10,000.

(vi) From its 1994 taxable year, L will carry over $90,000 of capital loss and $300,000 of net operating loss to its 1996 taxable year. From its 1995 taxable year, L will carry over $10,000 of net operating loss subject to the section 382 limitation to its 1996 taxable year.

Example 2. (i) Assume the facts of *Example 1*, except that L does not make the closing-of-the-books election under paragraph (b) of this section.

(ii) L ratably allocates its $100,000 net operating loss and its $150,000 of modified capital gain net income for the change year. $40,000 of net operating loss ($100,000 × (146/365)) and $60,000 of modified capital gain net income ($150,000 × (146/365)) are allocated to the pre-change period. $60,000 of net operating loss ($100,000 × (219/365)) and $90,000 of modified capital gain net income ($150,000 × (219/365)) are allocated to the post-change period.

(iii) Under paragraph (c)(2)(i) of this section, L uses its capital loss carryovers to offset modified capital gain net income. The capital loss carryovers offset the $60,000 modified capital gain net income allocated to the pre-change period without limitation. Subject to the section 382 limitation, the remaining $90,000 of capital loss carryovers offset the modified capital gain net income allocated to the post-change period. Accordingly, L uses $60,000 of its capital loss carryovers to offset $60,000 of its $90,000 modified capital gain net income allocated to the post-change period. L has absorbed its entire section 382 limitation for the change year.

(iv) Under paragraph (c)(2)(ii) of this section, L's $60,000 net operating loss allocated to the post-change period is offset by its remaining $30,000 of post-change modified capital gain net income, reducing its post-change net operating loss to $30,000.

(v) From its 1994 taxable year, L will carry over $30,000 of capital loss and $300,000 of net operating loss to its 1996 taxable year. From its 1995 taxable year, L will carry over $70,000 of net operating loss ($40,000 pre-change +$30,000 post-change) to its 1996 taxable year. The $40,000 pre-change portion of that carryover is subject to the section 382 limitation.

(g) *Definitions and nomenclature.* The terms and nomenclature used in this section and not otherwise defined herein have the same meanings as in sections 382 and 383 and the regulations thereunder. For purposes of this section:

(1) *Change year.* A loss corporation's taxable year that includes the change date is its *change year.*

(2) *Pre-change period.* The *pre-change period* is the portion of the change year ending on the close of the change date.

(3) *Post-change period.* The *post-change period* is the portion of the change year beginning with the day after the change date.

(4) *Modified capital gain net income.* A loss corporation's *modified capital gain net income* is the excess of the gains from sales or exchanges of capital assets over the losses from such sales or exchanges for the change year, determined by excluding any short-term capital losses under section 1212.

(h) *Effective date.* This section applies to ownership changes occurring on or after June 22, 1994.

PART 602—OMB CONTROL NUMBERS UNDER THE PAPERWORK REDUCTION ACT

Par. 4. The authority citation for part 602 continues to read as follows:

Authority: 26 U.S.C. 7805.

§ 602.101 [Amended]

Par. 5. Section 602.101(c) is amended by adding the entry "1.382–6. . . .1545–1381" in numerical order to the table.

Dated: June 2, 1994.

Margaret Milner Richardson,

Commissioner of Internal Revenue.

Approved:

Leslie Samuels,

Assistant Secretary of the Treasury.

[FR Doc. 94–14970 Filed 6–21–94; 8:45 am]

BILLING CODE 4830–01–U

DEPARTMENT OF EDUCATION

34 CFR Part 600

RIN 1840–AB87

Institutional Eligibility Under the Higher Education Act of 1965, As Amended

AGENCY: Department of Education.

ACTION: Final regulations; Correction.

SUMMARY: This document corrects errors in the final regulations published in the **Federal Register** on April 29, 1994 for Institutional Eligibility Under the Higher Education Act of 1965, as Amended (59 FR 22324). These regulations implement statutory changes in the programs authorized by the Higher Education Act of 1965, as amended by the Higher Education Amendments of 1992, and the Higher Education Technical Amendments of 1993.

EFFECTIVE DATE: July 1, 1994.

FOR FURTHER INFORMATION CONTACT: Cheryl Leibovitz, U.S. Department of Education, 400 Maryland Avenue SW. (Room 4318, ROB–3), Washington, DC 20202. Telephone (202) 708–7888. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday.

Dated: June 14, 1994.

David A. Longanecker,

Assistant Secretary for Postsecondary Education.

The following corrections are made in FR Doc. 94–10139, published on April 29, 1994 (59 FR 22324):

1. On page 22324, column 3, remove the third full paragraph beginning "Institutions may choose . . .", and insert in its place "An institution substantiates its compliance with this standard by having either the auditor who prepares its financial statement audit or the auditor who prepares its title IV, HEA program compliance audit report on the accuracy of its compliance determination. The auditor's report must be based on performing an "attestation engagement" in accordance with the American Institute of Certified Public Accountants (AICPA's) Statement on Standards for Attestation Engagements. The auditor must submit his or her report with the appropriate audit report. In the attestation report, the auditor must indicate whether the institution's determination that the percentage of its revenues derived from title IV, HEA program funds is not more than 85 percent of its revenues is accurate; *i.e.*, fairly presented in all material respects."

2. On page 22325, in column 2, before heading "Section 600.9 Written Arguments", add the paragraph "An institution substantiates its compliance with the provisions of this section in the same manner as a proprietary institution of higher education substantiates its compliance with the 85 percent rule."

§ 600.5 [Corrected]

3. On page 22338, in column 2, § 600.5 (e)(1) is corrected by removing the remainder of the sentence following the words "accuracy of", and adding in its place "its determination that the percentage of its revenue derived from title IV, HEA program funds is not more that 85 percent of its revenue."; and by correcting paragraphs (e)(2) and (e)(3) to read as follows:

(2) The certified public accountant's report must be based on performing an "attestation engagement" in accordance with the American Institute of Certified Public Accountants (AICPA's) Statement on Standards for Attestation Engagements. The certified public accountant shall include that attestation report with the audit report referenced in paragraph (e)(1) of this section.

(3) The certified public accountant's attestation report must indicate whether the institution's determination that the percentage of its revenues derived from title IV, HEA program funds is not more than 85 percent of its revenues is accurate; *i.e.*, fairly presented in all material respects.

4. On page 22340, in paragraph (e)(2) introductory text, in column 3, the cross-reference to paragraph "(e)(3)(ii)" is corrected to read "(c)(3)(ii)".

§ 600.7 [Amended]

5. On page 22340, column 3, § 600.7 (g)(1) is corrected by removing the remainder of the sentence following the words "accuracy of", and adding in its place "those determinations."; and by correcting paragraphs (g)(2) and (g)(3) on pages 22340, column 3, and 22341, column 1 to read as follows:

(2) The certified public accountant's report must be based on performing an "attestation engagement" in accordance with the American Institute of Certified Public Accountants (AICPA's) Statement on Standards for Attestation Engagements. The certified public accountant shall include that attestation report with or as part of the audit report referenced in paragraph (g)(1) of this section.

(3) The certified public accountant's attestation report must indicate whether the institution's determinations regarding paragraph (a)(1) of this section and any relevant waiver or exception under paragraphs (b), (c), and (d) of this section are accurate; *i.e.*, fairly presented in all material respects.

[FR Doc. 94–14993 Filed 6–21–94; 8:45 am]

BILLING CODE 4000–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 9

[FRL–5001–9]

OMB Approval Numbers Under the Paperwork Reduction Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Technical amendment.

SUMMARY: The Environmental Protection Agency is amending a table to display Office of Management and Budget (OMB) control numbers issued under the Paperwork Reduction Act (PRA) to the consolidated table at 40 CFR Part 9.

EFFECTIVE DATE: This final rule is effective July 22, 1994.

FOR FURTHER INFORMATION CONTACT: Sandy Farmer on (202) 260–2740.

SUPPLEMENTARY INFORMATION: EPA is today amending the table of currently approved information collection request (ICR) control numbers issued by OMB for various regulations. Today's amendment updates the table to accurately display those information requirements promulgated under the Federal Grant and Cooperative Agreement Act. The affected regulations are codified at 40 CFR parts 30, 31 and 33. EPA will continue to present OMB control numbers in a consolidated table format to be codified in 48 CFR Part 1501 of EPA's Acquisition Regulations, in 40 CFR Part 9 of the Agency's regulations, and in each 40 CFR volume containing EPA regulations. The table lists the part and section numbers with reporting and recordkeeping requirements, and the current OMB control numbers. This display of the OMB control numbers and their subsequent codification in the Code of Federal Regulations satisfies the requirements of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) and OMB's implementing regulations at 5 CFR Part 1320.

The ICR(s) were previously subject to public notice and comment prior to OMB approval. As a result, EPA finds that there is "good cause" under section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553(b)(B)) to amend this table without prior notice and comment. Due to the technical nature of the table, further notice and comment would be unnecessary.

List of Subjects in 40 CFR Part 9

Reporting and recordkeeping requirements.

Dated: June 14, 1994.

Carol M. Browner,

Administrator.

For the reasons set out in the preamble 40 CFR part 9 is amended as follows:

PART 9—[AMENDED]

1. The authority citation for part 9 continues to read as follows:

Authority: 7 U.S.C. 135 *et seq.*, 136–136y; 15 U.S.C. 2001, 2003, 2005, 2006, 2601–2671; 21 U.S.C. 331j, 346a, 348; 31 U.S.C. 9701; 33 U.S.C. 1251 *et seq.*, 1311, 1313d, 1314, 1321, 1326, 1330, 1344, 1345 (d) and (e), 1361; E.O. 11735, 38 FR 21243, 3 CFR, 1971–1975 Comp. p. 973; 42 U.S.C. 241, 242b, 243, 246, 300f, 300g, 300g–1, 300g–2, 300g–3, 300g–4.

300g–5, 300g–6, 300j–1, 300j–2, 300j–3, 300j–4, 300j–9, 1857 *et seq.*, 6901–6992k, 7401–7671q, 7542, 9601–9657, 11023, 11048.

2. Section 9.1 is amended by revising under the heading "Procurement Under Assistance Agreements" the OMB control number "2030–0013" to read "2030–0020" wherever it appears and by adding new entries and new headings in numerical order to read as follows:

§ 9.1 OMB approvals under the Paperwork Reduction Act.

* * * * *

40 CFR citation	OMB control No.
General Regulation for Assistance Programs for Other than State and Local Governments	
30.400	2030–0020
30.500	2030–0020
30.501	2030–0020
30.503	2030–0020
30.505	2030–0020
30.510	2030–0020
30.520	2030–0020
30.530	2030–0020
30.531	2030–0020
30.532	2030–0020
30.535	2030–0020
30.1002	2030–0020
30.1003	2030–0020
30.1200	2030–0020
Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments	
31.10	2030–0020
31.20–31.21	2030–0020
31.31–31.32	2030–0020
31.36(g)–31.36(h)	2030–0020
31.40	2030–0020
31.42	2030–0020
31.6	2030–0020

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[FR Doc. 94–15071 Filed 6–21–94; 8:45 am]
BILLING CODE 6560–50–P

40 CFR Part 180

[OPP–300349; FRL–4871–4]

RIN 2070–AC18

N-(n-Octyl)-2-Pyrrolidone and N-(n-Dodecyl)-2-Pyrrolidone; Tolerance Exemptions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document establishes tolerance exemptions for residues of *N*-(*n*-octyl)-2-pyrrolidone and *N*-(*n*-dodecyl)-2-pyrrolidone as inert ingredients (solvents) applied to growing crops. These exemptions were requested by NOR-AM Chemical Co.

EFFECTIVE DATE: This regulation becomes effective June 22, 1994.

ADDRESSES: Written objections, identified by the document control number, [OPP-300349], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St. SW., Washington, DC 20460.

In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

FOR FURTHER INFORMATION CONTACT: By mail: Tina Levine, Registration Support Branch, Registration Division (7505W), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Westfield Building North, 6th floor, 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8393

SUPPLEMENTARY INFORMATION: NOR-AM Chemical Co., Little Falls Centre One, 2711 Centerville Rd., Wilmington, DE 19808, submitted pesticide petitions (PPs) proposing to amend 40 CFR part 180 to establish a tolerance exemption for residues of *N*-(*n*-octyl)-2-pyrrolidone (PP 1E3959) and *N*-(*n*-dodecyl)-2-pyrrolidone (PP 1E3960) as inert ingredients (solvents) applied to growing crops. EPA issued a notice, published in the **Federal Register** of March 23, 1994 (57 FR 13720), announcing receipt of these petitions. No comments were received in response to the notice.

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 162.3(c), and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting and spreading agents; propellants in aerosol dispensers; and emulsifiers. The term "inert" is not intended to imply to nontoxicity; the ingredient may or may not be chemically active.

As part of the EPA policy statement on inert ingredients published in the **Federal Register** of April 22, 1987 (52 FR 13305), the Agency set forth a list of studies which would generally be used to evaluate the risks posed by the presence of an inert ingredient in a pesticide formulation. The data submitted in the petitions and other relevant material have been evaluated. This inert ingredient is considered useful for the purpose for which the tolerance is sought. Toxicological, ecological, and environmental fate data were considered in evaluating this inert ingredient for use in pesticides. The data considered in support of these exemptions from tolerance include:

1. A 90-day oral toxicity study in the rat using *N*-(*n*-octyl)-2-pyrrolidone with a no-observed-adverse-effect level (NOAEL) of 600 ppm (53 mg/kg) and a lowest-observed-adverse-effect level (LOAEL) of 8,460 ppm. Effects observed include significantly increased absolute and relative liver weights and mild hepatocellular hypertrophy.

2. A 90-day oral toxicity study in the dog using *N*-(*n*-octyl)-2-pyrrolidone with a NOAEL of 30 mg/kg and a LOAEL of 90 mg/kg. Effects observed include increased absolute and relative liver weights, hepatocellular hypertrophy, and altered blood levels of liver enzymes.

3. A developmental toxicity study in the rat using *N*-(*n*-octyl)-2-pyrrolidone with a maternal NOAEL of 50 mg/kg and a developmental NOAEL of 200 mg/kg. At the developmental LOAEL of 800 mg/kg there was altered growth and an increased incidence of wavy ribs.

4. A negative mutagenicity battery for *N*-(*n*-octyl)-2-pyrrolidone including an Ames Test, Micronucleus Test, and TK Locus Test and negative Ames and Micronucleus Tests for *N*-(*n*-dodecyl)-2-pyrrolidone.

5. An oncogenicity study on *N*-methyl pyrrolidone, a related compound, was judged negative by reviewers in the Office of Pollution Prevention and Toxics, EPA.

Residue data is generally not required for inert ingredient exemptions from tolerance. In this case, worst-case residue calculations were done based on the proposed uses. These calculations indicated that a broad exemption could not be granted without additional residue information because of the potential for high dietary exposure. The petitioner therefore requested that the exemption be modified to include only the use of these solvents in cotton defoliant formulations containing

thidiazuron and diuron as active ingrdients. This yielded worstcase residue estimates of 735 ppm in cotton seed, concentrating to 4,630 ppm in cottonseed oil. Consumption of cottonseed oil in children, the subgroup with the highest exposure, is .036355 gms/kg/day. This leads to an exposure of .18 mg/kg/day, with a margin of exposure of 166 from the NOAEL in the 90 day dog study. Residue information from thidiazuron as a cotton defoliant indicates that actual residues for these inerts are expected to be orders of magnitude below this worst-case estimate.

Based upon the above information and review of its use, EPA has found that, when used in accordance with good agricultural practice, these ingredients are useful and a tolerance is not necessary to protect the public health. Therefore, EPA proposes that the exemptions from the requirement of a tolerance be established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the Federal Register, file written objections and/or request a hearing with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations or recipients thereof, or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive order.

Pursuant to the terms of the Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review. Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the Federal Register of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Recording and recordkeeping requirements.

Dated: June 2, 1994.

Daniel M. Barolo,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. In subpart D, by adding new § 180.1130, to read as follows:

§ 180.1130 N-(n-octyl)-2-pyrrolidone and N-(n-dodecyl)-2-pyrrolidone; exemptions from the requirement of a tolerance.

N-(*n*-octyl)-2-pyrrolidone and *N*-(*n*-dodecyl)-2-pyrrolidone are exempt from the requirement of a tolerance when used as solvents in cotton defoliant formulations containing thidiazuron and diuron as active ingredients.

[FR Doc. 94-15081 Filed 6-21-94; 8:45 am]
BILLING CODE 6560-50-F

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40 CFR Part 180

[PP 1F3961 and 1F3962/R2065; FRL-4868-8]

RIN 2070-AB78

Pesticide Tolerances for Thifensulfuron Methyl and Tribenuron Methyl

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This document sets tolerances for residues of the herbicides thifensulfuron methyl and tribenuron methyl on the raw agricultural commodities (RAC) oat grain at 0.05 part per million (ppm) and oat straw at 0.1 ppm. E.I. DuPont de Nemours & Co., Inc., requested this regulation.

EFFECTIVE DATE: This regulation becomes effective June 22, 1994.

ADDRESSES: Written objections and hearing requests, identified by the document control number, [PP 1F3961 and 1F3962/R2065], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing requests to: Rm. 1132, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

FOR FURTHER INFORMATION CONTACT: By mail: Joanne I. Miller, Product Manager (PM) 23, Registration Division (7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 237, 1921 Jefferson Davis Hwy., Arlington, VA 22202, (703)-305-7830.

SUPPLEMENTARY INFORMATION: In the Federal Register of April 14, 1994 (59 FR 17751), EPA issued a proposed rule that gave notice that E.I. DuPont de

Nemours & Co., Inc., Barley Mill Plaza, P.O. Box 80038, Wilmington, DE 19880-0038, had submitted pesticide petitions (PP) 1F3961 and 1F3962 to EPA proposing that 40 CFR part 180 be amended under section 408 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 346a, by establishing tolerances for the herbicides thifensulfuron methyl (methyl-3-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino]carbonyl]amino]sulfonyl]-2-thiophene carboxylate) and tribenuron methyl (methyl-2-[[[[*N*- (4-methoxy-6-methyl-1,3,5-triazin-2-yl) methylamino] carbonyl] amino]sulfonyl] benzoate), each on the raw agricultural commodities (RAC) oat grain at 0.05 part per million (ppm) and oat straw at 0.1 ppm.

There were no comments or requests for referral to an advisory committee received in response to the proposed rule.

The data submitted on the proposal and other relevant material have been evaluated and discussed in the proposed rule. Based on the data and information considered, the Agency concludes that the tolerances will protect the public health. Therefore, the tolerances are established as set forth below.

Any person adversely affected by this regulation may, within 30 days after publication of this document in the **Federal Register**, file written objections and/or request a hearing with the Hearing Clerk, at the address given above (40 CFR 178.20). A copy of the objections and/or hearing requests filed with the Hearing Clerk should be submitted to the OPP docket for this rulemaking. The objections submitted must specify the provisions of the regulation deemed objectionable and the grounds for the objections (40 CFR 178.25). Each objection must be accompanied by the fee prescribed by 40 CFR 180.33(i). If a hearing is requested, the objections must include a statement of the factual issue(s) on which a hearing is requested, the requestor's contentions on such issues, and a summary of any evidence relied upon by the objector (40 CFR 178.27). A request for a hearing will be granted if the Administrator determines that the material submitted shows the following: There is a genuine and substantial issue of fact; there is a reasonable possibility that available evidence identified by the requestor would, if established, resolve one or more of such issues in favor of the requestor, taking into account uncontested claims or facts to the contrary; and resolution of the factual issue(s) in the manner sought by the requestor would be adequate to justify the action requested (40 CFR 178.32).

Under Executive Order 12866 (58 FR 51735, Oct. 4, 1993), the Agency must determine whether the regulatory action is "significant" and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. Under section 3(f), the order defines a "significant regulatory action" as an action that is likely to result in a rule (1) having an annual effect on the economy of $100 million or more, or adversely and materially affecting a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities (also referred to as "economically significant"); (2) creating serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raising novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

Pursuant to the terms of the Executive Order, EPA has determined that this rule is not "significant" and is therefore not subject to OMB review.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 7, 1994.

Daniel M. Barolo,

Acting Director, Office of Pesticide Programs.

Therefore, 40 CFR part 180 is amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. By revising § 180.439, to read as follows:

§ 180.439 Thifensulfuron methyl (methy-3-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl) amino]carbonyl]amino]sulfonyl]-2-thiophene carboxylate); tolerances for residues.

Tolerances are established for residues of the herbicide thifensulfuron methyl (methyl-3-[[[[(4-methoxy-6-methyl-1,3,5-triazin-2-yl)amino] carbonyl] amino] sulfonyl]-2-thiophene carboxylate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.05
Barley, straw	0.1
Oat, grain	0.05
Oat, straw	0.10
Soybeans	0.1
Wheat, grain	0.05
Wheat, straw	0.1

2. By revising § 180.451, to read as follows:

§ 180.451 Tribenuron methyl (methy-2-[[[[N-(4-methoxy-6-methyl-1,3,5-triazin-2- yl) methylamino] carbonyl]amino]sulfonyl]benzoate); tolerances for residues.

Tolerances are established for the residues of the herbicide tribenuron methyl (methyl-2-[[[[*N*-(4-methoxy-6-methyl-1,3,5-triazin-2-yl) methylamino] carbonyl]amino]sulfonyl] benzoate) in or on the following raw agricultural commodities:

Commodity	Parts per million
Barley, grain	0.05
Barley, straw	0.10
Oat, grain	0.05
Oat, straw	0.10
Wheat, grain	0.05
Wheat, straw	0.10

[FR Doc. 94–15079 Filed 6–21–94; 8:45 am]

BILLING CODE 6560–50–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405 and 489

Office of Inspector General

42 CFR Part 1003

[BPD–393–IFC]
RIN 0938–AC58

Medicare Program; Participation in CHAMPUS and CHAMPVA, Hospital Admissions for Veterans, Discharge Rights Notice, and Hospital Responsibility for Emergency Care

AGENCIES: Health Care Financing Administration (HCFA) and Office of Inspector General (OIG).

ACTION: Interim final rule with comment period.

SUMMARY: We are revising requirements for Medicare participating hospitals by adding the following:

A hospital must provide inpatient hospital services to individuals who have health coverage provided by either the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS) or the Civilian Health and Medical Program of the Veterans Administration (CHAMPVA), subject to limitations provided by regulations that require the hospital to collect the beneficiary's cost-share and accept payment from the CHAMPUS/CHAMPVA programs as payment in full.

A hospital must provide inpatient hospital services to military veterans (subject to the limitations provided in 38 CFR 17.50 ff.) and accept payment from the Department of Veterans Affairs as payment in full.

A hospital must give each Medicare beneficiary (or his or her representative) at or about the time of admission, a written statement of his or her rights concerning discharge from the hospital.

A hospital (including a rural primary care hospital) with an emergency department must provide, upon request and within the capabilities of the hospital or rural primary care hospital, an appropriate medical screening examination, stabilizing treatment and/or an appropriate transfer to another medical facility to any individual with an emergency medical condition, regardless of the individual's eligibility for Medicare.

The statute provides for the termination of a provider's agreement for violation of any of these provisions.

These revisions implement sections 9121 and 9122 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (as amended by section 4009 of the Omnibus Budget Reconciliation Act of 1987), section 233 of the Veteran's Benefit Improvement and Health Care Authorization Act of 1986, sections 9305(b)(1) and 9307 of the Omnibus Budget Reconciliation Act of 1986, sections 6003(g)(3)(D)(xiv), 6018 and 6211 of the Omnibus Budget Reconciliation Act of 1989, and sections 4008(b), 4027(a), and 4027(k)(3) of the Omnibus Budget Reconciliation Act of 1990.

DATES: *Effective date:* This interim final rule with comment period is effective July 22, 1994, with the exception of the new information collection and recordkeeping requirements contained in § 488.18, § 489.20(m), § 489.20(r)(2) and (3), and § 489.24(d) and (g), which are not yet approved by OMB under the Paperwork Reduction Act of 1980. Following OMB approval, a document will be published in the **Federal Register** announcing the effective date for those sections.

Comment date: Comments on changes to the June 16, 1988 proposed rule resulting from provisions of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89) or the Omnibus Budget Reconciliation Act of 1990 (OBRA 90) will be considered if we receive them at the appropriate address as provided below, no later than 5:00 p.m. on August 22, 1994. These changes generally concern the responsibility of Medicare participating hospitals in emergency cases. The specific new provisions in this area from OBRA 89 and OBRA 90 are discussed in section II.D.2 of this preamble. We will also accept comments on Appendix II to this interim final rule. Appendix II instructs hospitals with emergency departments on their responsibilities concerning the posting of signs specifying rights of individuals under section 1867 of the Act with respect to examination and treatment for emergency medical conditions. We will not consider comments on provisions that remain unchanged from the June 16, 1988 proposed rule or on provisions that were changed based on public comments.

ADDRESSES: Mail comments (an original and three copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD–393–FC, P.O. Box 7517 Baltimore, MD 21207–0517.

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

Room 309–G, Hubert H. Humphrey Building, 200 Independence Ave., 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–393–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 5:00 P.M. (Phone: 202–690–7890).

If you wish to submit comments on the information collection requirements contained in this interim final rule with comment period, you may submit comments to: Allison Herron Eydt, HCFA Desk Officer, Office of Information and Regulatory Affairs, Room 3002, New Executive Office Building, Washington, DC 20503.

Copies: To order copies of the **Federal Register** containing this document, send your request to: New Orders, Superintendent of Documents, P.O. Box 371954, Pittsburgh, PA 15250–7954. Specify the date of the issue requested and enclose a check or money order payable to the Superintendent of Documents, or enclose your Visa or Master Card number and expiration date. Credit card orders can also be placed by calling the order desk at (202) 783–3238 or by faxing to (202) 275–6802. The cost for each copy is $6.00. As an alternative, you may view and photocopy the **Federal Register** document at most libraries designated as U.S. Government Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

FOR FURTHER INFORMATION, CONTACT:

Arlene Ford, 410–966–4617—For provisions relating to the beneficiary statement of discharge rights.

Tom Hoyer, 410–966–4607—For provisions relating to individuals with emergency medical conditions.

Lindsey Bramwell, 410–966–6747—For PRO provisions relating to responsibilities to determine whether the individual involved had an emergency medical condition that had not been stabilized.

Joel Schaer, 202–619–0089—For OIG civil monetary penalty and physicia exclusion provisions relating to

individuals with emergency medical conditions.

Beverly Christian, 410–966–4616—For provisions relating to participation in the CHAMPUS/CHAMPVA and VA health care programs.

Rose Sabo, 303–361–1178—For questions regarding CHAMPUS and CHAMPVA programs.

Wanda Elam, 202–535–7434—For questions regarding the Department of Veterans Affairs health care program.

SUPPLEMENTARY INFORMATION:

I. Background

On June 16, 1988, we published a proposed rule concerning participation in the CHAMPUS and CHAMPVA programs, hospital admissions for veterans, a requirement for a discharge rights notice, and hospital responsibility for emergency care (53 FR 22513). Below is a discussion of the issues for which we proposed regulations.

A. Participation in the CHAMPUS and CHAMPVA Programs

CHAMPUS (Civilian Health and Medical Program of the Uniformed Services) and CHAMPVA (Civilian Health and Medical Program of the Veterans Administration) programs pay for health care services furnished to dependents and survivors of military personnel, to retirees and their dependents, and to veterans. Generally, the programs have paid hospitals based on the hospital's charges. Section 931 of the Department of Defense Authorization Act, 1984 (Pub. L. 98–94), authorized these programs to pay (to the extent practicable) for inpatient hospital services using Medicare payment procedures. Because the Medicare prospective payment system (the system whereby we pay a hospital a predetermined amount based on the patient's diagnosis and any surgical procedures performed, rather than by the number of days hospitalized) results in Medicare cost savings, the Department of Defense (DoD) expected to realize similar savings if it were to use a model similar to Medicare's prospective payment system. Paying on the basis of a fixed rate appropriate to the particular diagnosis involved has been shown to be an equitable method of paying for hospital care. Therefore, the Office of Civilian Health and Medical Program of the Uniformed Services (OCHAMPUS) published a final rule on September 1, 1987, that included provisions for the implementation of a DRG-based payment system modeled after Medicare's prospective payment system for CHAMPUS inpatient hospital admissions occurring on or after October 1, 1987 (52 FR 32992).

Hospitals that furnish services to CHAMPUS and CHAMPVA beneficiaries are authorized to provide services to these beneficiaries following an approval process similar to that used for Medicare participation. Generally, that means the hospital is licensed and accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and otherwise meets CHAMPUS requirements. A hospital certified and participating under Medicare may be deemed to meet CHAMPUS requirements.

"Participation" has a different meaning for CHAMPUS and CHAMPVA than for Medicare. Providers have been able to decide on a claim-by-claim basis whether to "participate" in the program and thus accept the CHAMPUS/CHAMPVA-determined allowable amount, plus the patient cost-share, as payment in full. Beneficiaries are required to pay a cost-share for each hospital admission. The CHAMPUS/CHAMPVA payment, plus the beneficiary's cost-share, constitute payment in full for the covered services when the provider signs and submits an appropriately completed program claim form that indicates participation. Under Medicare, hospitals must agree to bill the program for all beneficiaries and accept the CHAMPUS/CHAMPVA payment as payment in full (less applicable deductibles, coinsurance amounts, and noncovered items).

As indicated above, Medicare hospitals also may be authorized providers in CHAMPUS and CHAMPVA on the basis of their JCAHO-approved status or may be deemed authorized providers based on their Medicare-approved status. The benefits to the DoD of requiring the providers to be paid either under a DRG-based payment system or based on reasonable cost are lost, however, if the hospitals can selectively participate in the CHAMPUS and CHAMPVA programs.

Under section 9122 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA), Pub. L. 99–272, all Medicare hospitals are now required, beginning January 1987, to participate in CHAMPUS or CHAMPVA as authorized providers (that is, they must bill CHAMPUS or CHAMPVA and accept the CHAMPVA/CHAMPUS-determined allowable amount as payment in full, less applicable deductible, patient cost-share, and noncovered items).

B. Participation in the Department of Veterans Affairs (VA) Health Care Program

Broadly speaking, a veteran can only receive services from a non-VA hospital for a service-connected disability when there is a medical emergency or when a VA facility is not available. In such cases, the VA in the past paid for the services based on usual and customary charges.

As this type of payment is more expensive than payment made on a prospective basis or based on reasonable costs, the VA has implemented a national prospective payment system.

To alleviate hospital expenses for the VA, Congress passed section 233 of the Veterans' Benefit Improvement and Health-Care Authorization Act of 1986 (Pub. L. 99–576). This section requires Medicare hospitals to be participating providers of medical care to veterans eligible to receive care at the hospital. The hospital then receives payment for the services under the applicable VA payment system, in accord with the recent regulations concerning the payment methodology and amounts that the VA provides for those hospitals that furnish inpatient hospital care to veterans whose care has been authorized or will be sponsored by the VA (55 FR 42848). This rule was developed jointly by VA and HHS, and the VA payment system conforms to Medicare's hospital inpatient prospective payment system in most cases.

C. Statement of Beneficiary Rights

After the prospective payment system became effective for the Medicare program, we began to hear allegations that Medicare beneficiaries were discharged too early from the hospital. We also began to receive complaints that patients did not understand their rights as Medicare beneficiaries in cases in which they were advised that discharge was appropriate but they disagreed. On April 17, 1985, we revised 42 CFR 466.78(b)(3) to require all hospitals to provide Medicare beneficiaries with information about Utilization and Quality Control Peer Review Organization (PRO) review, including beneficiary appeal rights (50 FR 15331). In further response to concerns about early discharges and lack of adequate appeal information, we began requiring all hospitals to furnish each Medicare beneficiary upon admission a specific statement developed by HCFA (that is, "An Important Message from Medicare" (see Appendix I)) telling a beneficiary of his or her rights to be fully informed about

decisions affecting Medicare coverage or payment and about his or her appeal rights in response to any hospital's notice to the effect that Medicare will no longer cover the care. The "Message" we developed also advises the patient of what to do when he or she receives such a hospital statement and how to elicit more information. The requirements relating to "An Important Message from Medicare" were incorporated into the program's operating instructions.

Congress subsequently passed section 9305(b) of the Omnibus Budget Reconciliation Act of 1986 (OBRA 86). Now, as part of its participation agreement with Medicare, each hospital (including those not paid under the prospective payment system) must agree to furnish each Medicare beneficiary with a notice, at or about the time of admission, that explains the patient's rights in detail.

D. Responsibilities of Medicare Participating Hospitals in Emergency Cases

Hospitals that choose to participate in the Medicare program agree in writing to meet various requirements included in section 1866 of the Social Security Act (the Act). Before enactment of COBRA on April 7, 1986, the Act did not specifically address the issue of how hospitals with emergency medical departments must handle individuals who have emergency medical conditions or who are in labor.

In its Report accompanying H.R. 3128, the House Ways and Means Committee indicated that Congress was concerned about the increasing number of reports that hospital emergency rooms were refusing to accept or treat individuals with emergency conditions if the patients did not have medical insurance.

In addition, the Report stated that there were reports that individuals in an unstable condition were transferred improperly, sometimes without the consent of the receiving hospital. Because Congress believed that this situation may have worsened since the Medicare prospective payment system for hospitals became effective, the Report stated that the Committee "wants to provide a strong assurance that pressures for greater hospital efficiency are not to be construed as license to ignore traditional community responsibilities and loosen historic standards." (H.R. Rep. No. 99–241, 99th Cong., 1st Sess. 27 (1985).)

Subsequently, section 9121 of COBRA, sections 6003(g)(3)(D)(XIV), 6018, and 6211 of the Omnibus Budget Reconciliation Act of 1989 (OBRA 89), Pub. L. 101–239, and sections 4008(b), 4027(a), and 4027(k)(3) of the Omnibus Budget Reconciliation Act of 1990 (OBRA 90), Pub. L. 101–508, have all addressed this concern.

II. Legislation

A. Participation in CHAMPUS and CHAMPVA Programs

Section 9122 of COBRA amended section 1866(a)(1) of the Act by adding a new paragraph (J), which requires hospitals in the Medicare program to be participating providers of medical care, for inpatient services only, under any health plan contracted for under 10 U.S.C. 1079 or 1086 (CHAMPUS) or under 38 U.S.C. 613 (CHAMPVA), in accordance with admission practices and payment methodology and amounts as prescribed under joint regulations issued by the Secretaries of Health and Human Services, Defense, and Transportation. This requirement applies to services furnished to CHAMPUS and CHAMPVA beneficiaries admitted on or after January 1, 1987.

(Section 9122 of COBRA also required that the legislation apply to all agreements entered into on or after April 7, 1986, but this requirement was deleted by section 1895(b)(6) of the Tax Reform Act of 1986 (Pub. L. 99–514), enacted October 22, 1986.)

B. Participation in the Veterans Administration Health Care Program

Section 233 of the Veterans' Benefit Improvement and Health-Care Authorization Act of 1986 (Pub. L. 99–576) was enacted on October 28, 1986. It added a new paragraph (L) to section 1866 (a)(1) of the Act. It requires hospitals that participate in Medicare to be participating providers under 38 U.S.C. 603, in accordance with the admissions practices, and payment methodology and amounts, prescribed under joint regulations issued to implement this section by the Secretary of HHS and the Administrator of the VA. This provision applies to services furnished to veterans admitted on or after July 1, 1987.

C. Statement of Beneficiary Rights

Section 9305(b)(1) of OBRA 86, which was enacted on October 21, 1986, added a new paragraph (M) to section 1866(a)(1) of the Act. That paragraph requires a hospital that is eligible to participate in the Medicare program to agree to furnish a beneficiary, or an individual acting on his or her behalf, at or about the time of admission, with a written statement of the beneficiary's discharge rights. The statement must explain:

(a) The individual's rights to benefits for inpatient hospital services and for posthospital services under Medicare;

(b) The circumstances under which the individual will and will not be liable for charges for continued stay in the hospital;

(c) The individual's right to appeal denials of benefits for continued inpatient hospital services, including the practical steps to initiate the appeal;

(d) The individual's liability for services if the denial of benefits is upheld on appeal; and

(e) Additional information that the Secretary specifies.

Section 9305(b)(2) of OBRA 86 requires that we prescribe the language to be used in the statement not later than 6 months after the effective date of OBRA 86. After development of the revised language for the statement required under OBRA 86, the hospitals must comply with the requirement to give the revised statement to beneficiaries upon admission.

D. Responsibilities of Medicare Participating Hospitals in Emergency Cases

Set forth below is a summary of the current legislative provisions concerning the responsibilities of Medicare participating hospitals (including rural primary care hospitals) in emergency cases. This legislative summary first sets forth the major provisions of section 1867 of the Act, as originally enacted by COBRA on April 7, 1986, and including all amendments that have occurred since that time. The summary then describes separately the amendments made by OBRA 89 and OBRA 90, which were enacted after the publication of the June 16, 1988, notice of proposed rulemaking.

1. Current Provisions

Section 9121 of COBRA added a paragraph (I) to section 1866(a)(1) of the Act and added a new section 1867 to the Act. As amended, these sections prohibit hospitals (including rural primary care hospitals) with emergency medical departments from refusing to treat individuals with unstable emergency medical conditions and also contain provisions designed to halt the inappropriate transfers of these individuals to other medical facilities.

(**Note:** For purposes of this preamble, all further references to "hospital" in the context of a "Hospital's Responsibility for Emergency Care" include rural primary care hospitals.)

Section 1866(a)(1)(I) of the Act requires that a hospital participating in the Medicare program must agree to comply with the requirements of section

1867 of the Act to the extent applicable. Section 1867 of the Act currently provides the following:

• A hospital with an emergency department must, within the capabilities of its emergency department (including ancillary services routinely available to the emergency department), provide an appropriate medical screening examination to any individual who comes to the emergency department for examination or treatment of a medical condition and on whose behalf the examination or treatment is requested; the purpose of the examination is to determine whether the individual has an emergency medical condition. This requirement applies regardless of the individual's eligibility for Medicare benefits.

• If an individual, regardless of eligibility for Medicare benefits, has an emergency medical condition, the hospital must either provide for further examination and treatment (within its capabilities) to stabilize the medical condition or make an appropriate transfer, with a proper certification, of the individual to another medical facility, unless the treatment or transfer is refused.

• A hospital may not transfer an individual unless—

+ —The individual, or a legally responsible person acting on his or her behalf, requests the transfer, or

—A physician, or other qualified medical personnel, after consulting with a physician (who later countersigns the certification because a physician is not physically present in the emergency department), has certified that the medical benefits expected from the treatment at the receiving facility outweigh the increased risks to the individual and, in the case of labor, to the unborn child, from effecting the transfer; and

+ The transfer is an "appropriate transfer", that is, a transfer—

—Where the transferring hospital provides the medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;

—In which the receiving facility has available space and qualified personnel for the treatment of the individual and has agreed to accept the transfer and to provide appropriate medical treatment;

—In which the transferring hospital sends to the receiving facility all appropriate medical records (or copies) available at the time of transfer that are related to the emergency condition for which the individual has presented including records related to the individual's emergency medical condition, observation of signs or symptoms, preliminary diagnosis, treatment provided, results of any tests and informal written consent or certification (or copies), and the name and address of any on-call physician who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment;

—In which the transfer is effected through qualified personnel and transportation equipment, as required, including the use of necessary and medically appropriate life support measures during the transfer; and

—That meets other requirements as the Secretary may find necessary in the interest of the health and safety of the patient.

• A hospital that fails to meet the requirements of section 1867 of the Act—

+ Is subject to termination of its Medicare provider agreement if it fails to comply with section 1867; and

+ Is subject to civil monetary penalties if it negligently violates section 1867 of the Act. The penalty cannot exceed $25,000 for each violation committed between August 1, 1986 (the effective date of the statute) and December 21, 1987, or $50,000 for violations on or after December 22, 1987. (The amount was raised by section 4009(a)(1) of the Omnibus Budget Reconciliation Act of 1987 (OBRA 87), Pub. L. 100–203, effective December 22, 1987.)

(Exception: If the hospital has fewer than 100 State-licensed, Medicare-certified beds, then the maximum civil monetary penalty is $25,000. See discussion of section 4008 of OBRA 90 below.)

• Each physician who is responsible for the examination, treatment or transfer of an individual (including a physician who is on-call for the care of such individual) is also subject to a civil money penalty of not more than $25,000 for each violation ($50,000 for violations on or after December 22, 1987), including—

+ The signing of transfer certifications if the physician knew or should have known that the benefits of transfer did not outweigh the risks, and

+ Misrepresenting an individual's condition or other information, including a hospital's obligations under this section.

A physician may also be excluded from participation in the Medicare and State health care programs for a violation that is gross and flagrant or repeated.

• If a hospital violates the requirements of section 1867 of the Act and a patient suffers personal harm as a direct result, he or she may, in a civil action against the participating hospital, obtain damages for personal injury under the law of the State in which the hospital is located and may obtain such equitable relief as is appropriate.

• Any medical facility that suffers a financial loss as a direct result of a participating hospital's violation of section 1867 of the Act may obtain damages available in a civil action against the participating hospital, under the law of the State in which the hospital is located, and may obtain such equitable relief as is appropriate.

• No civil action to obtain damages, as described above, may be brought more than 2 years after the date of the violation with respect to which the action is brought.

• The following terms are defined for purposes of section 1867 of the Act: "emergency medical condition," "hospital," "participating hospital," "to stabilize," "stabilized," and "transfer."

• The provisions of section 1867 of the Act do not preempt any State or local law except where they directly conflict.

• Participating hospitals are not to delay a medical screening examination or treatment to ask about an individual's status or method of payment.

• Participating hospitals with specialized capabilities or facilities are obligated to accept the appropriate transfer of an individual requiring such services if the hospital has the capacity to treat them.

• Except when a delay would jeopardize the health and safety of individuals, or when there was no screening examination, the appropriate PRO will assess whether the individual had an emergency condition that had not been stabilized before the Office of Inspector General (OIG) imposes a civil monetary penalty or exclusion.

• Hospitals are required, among other things, to maintain medical and other records related to individuals transferred to and from a hospital for a period of 5 years from the transfer date. Each hospital must maintain a list of on-call physicians available to provide stabilizing treatment. Each hospital must also post a conspicuously placed sign in its emergency department that lists the individuals' rights regarding their examination and treatment.

• Hospitals are not to penalize or take an adverse action against a physician or a qualified medical person who refused to authorize the transfer of an

unstabilized individual with an emergency medical condition or against a hospital employee because the employee reported a violation.

2. Summary of the Related OBRA 89 and OBRA 90 Provisions

Set forth below is a brief summary of the new and revised provisions from OBRA 89 (enacted December 19, 1989) and OBRA 90 (enacted November 5, 1990) that were added to strengthen and clarify the requirements concerning the examination, treatment and transfer of individuals with emergency medical conditions.

a. OBRA 89 Provisions

• Rural primary care hospitals. A new category of provider, rural primary care hospitals, was established (section 6003(g)(3) of OBRA 89). Only facilities currently certified as hospitals and not in violation of any conditions of participation (42 CFR part 482) could be designated by the Secretary as rural primary care hospitals.

• Compliance requirements (section 6018 of OBRA 89). Hospitals are required to—

+ Adopt and enforce a policy to ensure compliance with section 1867 of the Act;

+ Maintain medical and other records related to individuals transferred to or from a hospital for a period of 5 years from the transfer date; and

+ Maintain a list of on-call physicians available for duty to provide treatment needed to stabilize an individual with an emergency medical condition.

• Posted information (section 6018 of OBRA 89). Participating hospitals must post conspicuously in their emergency departments—

+ A sign listing the rights of individuals under section 1867 of the Act regarding examination and treatment for emergency medical conditions; and

+ Information indicating whether the facility participates in the Medicaid program under a State plan approved under title XIX of the Act.

Both posted items are to be in a form specified by the Secretary.

• Additional requirements for Medicare participating hospitals with emergency departments (section 6211 of OBRA 89).

+ The medical screening requirement was changed to indicate that the capability of the facility's emergency department includes "ancillary services routinely available to the emergency department."

+ Participating facilities are now required to inform each individual (or a person acting on his or her behalf) of the risks and benefits to the individual of examination and treatment and/or transfer, and to "take all reasonable steps to secure the individual's (or person's) written informed consent to refuse such examination and treatment" and/or transfer.

+ Changes were made relating to the restrictions on transfers to include—

—A requirement that participating facilities obtain written requests for transfer to another medical facility after informing individuals (or legally responsible persons acting on their behalf) of the hospital's obligations and the risk of transfer;

—An explicit statement that there should be consideration of the risks and benefits to unborn children of women in labor in determining whether the physician should certify that the benefits outweigh the risks of transfer;

—A requirement that transfer certifications by participating facilities include a summary of the risks and benefits upon which the certification is based;

—A requirement that when a qualified medical person signs the certification, it be done in consultation with a physician and that the physician later countersign the certification;

—A requirement that the hospital provide medical treatment within its capacity to minimize the risks of transfer; and

—A requirement that the transferring hospital include specified documents in the medical records sent to receiving hospitals.

• Civil monetary penalties (section 6211(e) of OBRA 89).

+ Physicians, including on-call physicians, are subject to civil monetary penalties and exclusion from Medicare and the State health care programs for violations of section 1867 of the Act, including—

—The signing of transfer certifications if the physician knew or should have known that the benefits of transfer did not outweigh the risks; or

—Misrepresenting an individual's condition or other information on the transfer certification.

+ A participating facility or an on-call physician is subject to a penalty if the on-call physician fails or refuses to appear within a reasonable period of time when notified by an emergency department physician that his or her services are needed and the emergency physician orders a transfer because he or she determines that without the services of the on-call physician the benefits of transfer outweigh the risks of transfer.

• Specialty hospitals (section 6211(f) of OBRA 89). Participating hospitals with special capabilities or facilities are obligated to accept the appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual.

• No delay in examination or treatment (section 6211(f) of OBRA 89). Participating hospitals are not to delay the provision of a medical screening examination, treatment, or both, to inquire about the individual's method of payment or insurance status.

• Whistleblower protections (section 6211(f) of OBRA 89). Participating hospitals may not take action against a physician because he or she refused to authorize the transfer of an unstabilized individual with an emergency medical condition.

• Definitions.

+ The term "responsible physician" is no longer used in section 1867(d) of the statute. It was changed to "a physician who is responsible for the examination, treatment or transfer of an individual" under section 1867(d)(1)(B) of the Act. (Section 6211(e)(1) of OBRA 89.)

+ The term "patient" was replaced with the term "individual." (Section 6211(g) of OBRA 89.)

+ The term "emergency medical condition" now includes a pregnant woman who is having contractions, either when there is inadequate time to effect safe transfer, or when the transfer may pose a threat to the health or safety of a pregnant woman or her unborn child. The term "active labor" was deleted. (Section 6211(h) of OBRA 89.)

+ The terms "to stabilize" and "stabilized" now take into account what might occur during a transfer and explicitly extend the protection of section 1867 of the Act to a pregnant woman until delivery (including the delivery of the placenta). (Section 6211(h) of OBRA 89.)

All of the provisions described above were effective beginning July 1, 1990, with the exception of the definition of the term "rural primary care hospital", which was effective upon enactment.

b. OBRA 90 Provisions

• Civil monetary penalties.

+ The standard for liability for imposing civil monetary penalties against hospitals and physicians was changed from "knowingly" to "negligently." (Sections 4008(b)(1) and 4027(a)(2) of OBRA 90.)

+ Hospitals with fewer than 100 State-licensed, Medicare-certified beds are subject to a civil monetary penalty of not more than $25,000, while all

other hospitals remain subject to a maximum CMP of $50,000. (Section 4008(b)(2) of OBRA 90.)

• Termination of hospital provider agreements (section 4008(b)(3) of OBRA 90).

+ The provision in section 1867(d)(1) of the Act that subjected violating hospitals to termination or suspension of their Medicare provider agreements was deleted.

+ Hospitals are now required, under section 1866(a)(1)(I)(i), to adopt and enforce a policy to ensure compliance with the requirements of section 1867 in order to participate in and receive payments under the Medicare program.

• PRO assessment (section 4027(a)(1) of OBRA 90).

+ In considering allegations of violations, before the OIG imposes a sanction, HCFA is required to request the appropriate PRO (with a contract under part B of title XI) to assess whether the individual involved had an emergency medical condition that had not been stabilized, except when a delay would jeopardize the health and safety of individuals.

+ The PRO must provide—

—An assessment of the alleged violation to determine whether the individual involved had an emergency medical condition that had not been stabilized and a report of the violation to the Secretary;

—Reasonable notice of the review to the physician and hospital involved;

—Within the time allotted by the Secretary, reasonable opportunity for the affected physician and the hospital to discuss the case with the PRO and to submit additional information before the PRO issues its report. The Secretary will request such a review, except when delay would jeopardize the health or safety of individuals or when there was no screening examination, before effectuating a sanction. When a delay would not jeopardize the health or safety of individuals, the PRO will have at least 60 calendar days to complete its review.

• Standard for excluding physicians (section 4027(a)(3) of OBRA 90). The standard for excluding physicians, including on-call physicians, from participation in the Medicare and State health care programs was changed from "knowing and willful or negligent" to "gross and flagrant or is repeated."

• Revised whistleblower protections (section 4027(k)(3) of OBRA 90). The prohibition of a hospital from penalizing or taking adverse action against a physician because he or she refused to authorize the transfer of an unstabilized individual with an emergency medical condition was extended to protect a qualified medical person. Also, a hospital is prohibited from taking action against a hospital employee because the employee reported a violation of these requirements.

• Drafting errors. We note that the drafters of OBRA 90 misnumbered the section following section 4206, calling it section 4027. The drafters also misnumbered the subsections of section 4027, so that what should have been section 4027(k) was misnumbered as section 4027(m). The error in misnumbering the subsections was corrected between the submission of the conference report and the enrolled bill, Pub. L. 101–508. The error in misnumbering the section was not corrected, however. Therefore, the correct section numbers at present for the relevant sections of OBRA 90 are 4008(b), 4027(a) and 4027(k)(3). The above provisions were effective May 1, 1991, with the exception of the provisions of section 4027(a)(1), which were effective February 1, 1991, and the provisions of section 4027(k)(3), which were effective upon enactment.

III. Proposed Regulations

As noted earlier, on June 16, 1988 (53 FR 22513), we published a notice of proposed rulemaking to implement the legislative changes enacted before that date. Following is a summary of that proposal.

A. Participation in CHAMPUS and CHAMPVA Programs

We proposed to revise § 489.20, Basic commitments, to show that a participating Medicare hospital must agree to participate in the CHAMPUS and CHAMPVA programs and accept payment from the CHAMPUS/CHAMPVA program as payment in full in accordance with a new § 489.25, which incorporates statutory provisions.

In new § 489.25, we would require Medicare participating hospitals to be participating providers in the CHAMPUS and CHAMPVA programs. We proposed to require the hospitals to comply with DoD regulations governing admissions practices and payment methodology and amounts for such services. As noted above, CHAMPUS published a final rule on September 1, 1987, that contains provisions for the implementation of a DRG-based payment system. We would continue the policy that hospitals participating in CHAMPUS and CHAMPVA that also participate in Medicare must meet all Medicare conditions of participation. Thus, if CHAMPUS or CHAMPVA have requirements for participating that differ from Medicare's, Medicare's requirements also would have to be met.

We proposed to require hospitals to accept payment from CHAMPUS/CHAMPVA programs as payment in full for the services provided to these beneficiaries (less applicable deductible, patient cost-share, and noncovered items).

In addition, we intended to add a new paragraph (11) to § 489.53, Terminations by HHS, to show that a hospital that does not meet the requirements of § 489.25 would be subject to possible termination.

The proposed changes would apply only to inpatient hospital services furnished to beneficiaries admitted on or after January 1, 1987.

B. Participation in the Department of Veterans Affairs (VA) Health Care Program

To implement section 233 of Pub. L. 99–576, we proposed to add a new § 489.26. Hospitals do not enter into participation agreements with the Department of Veterans Affairs program as they do if they choose to participate in the Medicare program or the CHAMPUS or CHAMPVA programs. Instead, the VA authorizes payment for the treatment, usually on a preadmission basis at a designated hospital that furnishes the service. We proposed to require a Medicare participating hospital to admit any veteran whose hospitalization is authorized by the VA under 38 U.S.C. 603 (this includes emergency cases, which may be authorized after admission). The hospital would have to meet the requirements of 38 CFR Part 17 regarding admission practices and payment methodology and amounts published October 24, 1990 (55 FR 42848). This arrangement would not affect the hospital's need to meet all Medicare hospital conditions of participation.

We also proposed to revise § 489.20, Basic commitments, to require hospitals to admit veterans whose admission is authorized under 38 U.S.C. 603 and to meet the requirements of § 489.26.

We also proposed to revise § 489.53, Termination by HCFA, to show that HHS may terminate any hospital that fails to meet the requirements of § 489.26.

The proposed regulations would apply to inpatient services furnished to veterans admitted on or after July 1, 1987.

C. Statement of Beneficiary Rights

We proposed to add a new § 489.27, to require participating hospitals that

furnish inpatient hospital services to Medicare beneficiaries to give every beneficiary (or individual acting on his or her behalf) at or about the time of admission the publication "An Important Message from Medicare." We did not specify the contents of the "Message" in the proposed rule, as hospitals are not responsible for writing it. We have distributed and will continue to distribute to hospitals the language of the "Message" that they are to use. A copy of the "Message" is included as Appendix I to this interim final rule.

We proposed to require hospitals to obtain a separate signed acknowledgment from the beneficiary attesting to the receipt of "An Important Message from Medicare" and to retain a copy of the acknowledgment. Effective with admissions on and after March 24, 1986, PROs were required to monitor each hospital to assure that the hospital distributes "An Important Message from Medicare" to all Medicare beneficiaries. Therefore, we proposed to require the hospital to obtain the beneficiary's separate, signed acknowledgment attesting to the receipt of the "Message" and to retain a copy of the acknowledgment.

We also proposed to revise § 489.20, Basic commitments, to show that a hospital must distribute "An Important Message from Medicare".

We planned to add a new paragraph (12) to § 489.53, Terminations by HHS, to show that a hospital failing to meet the requirements of § 489.27 may be terminated. Whether or not HHS would terminate a provider would depend on HCFA's judgment as to the scope of the failure and the hospital's correction or plan for correction of the failure. We did not anticipate any hospital opposition to the requirement that the "Message" be distributed. We believe we already have full cooperation from hospitals.

The revisions were to apply only to Medicare admissions beginning after we distributed "An Important Message from Medicare".

D. Hospital Emergency Care

The revisions to the regulations we proposed on June 16, 1988 would have been revisions and additions to 42 CFR Part 489, Provider Agreements under Medicare, and revisions to 42 CFR Part 1001, Program Integrity—Medicare, and Part 1003, Civil Money Penalties and Assessments. Basically, the proposed provisions paralleled the statutory requirements that were then in effect. We note that, as discussed above in section II.D. of this preamble, OBRA 89 and OBRA 90 included amendments to section 1867 of the Act.

1. Requirements for Hospitals With Emergency Care Departments

• We proposed to revise § 489.20, which discusses basic commitments, by adding a new paragraph to require hospitals with emergency departments, as part of their participation agreement, to agree to comply with the new § 489.24, which incorporates the statutory requirements.

• We proposed to add a new section § 489.24, Special responsibilities of Medicare hospitals in emergency cases, to set forth requirements for emergency cases for all hospitals that have provider agreements with Medicare. We planned to require a hospital to take the following measures:

+ Medical screening requirement—

For any individual, regardless of his or her eligibility for Medicare, for whom emergency treatment or examination is requested, we proposed to require a hospital with an emergency department to provide for an appropriate medical screening examination within the emergency department's capability to determine whether an emergency medical condition exists or whether the individual is in active labor, as defined below. The examinations would be conducted by individuals determined qualified by hospital by-laws and who meet the requirements of § 482.55, which are that emergency services be supervised by a qualified member of the medical staff and that there be adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility. We proposed to allow hospitals maximum flexibility in their utilization of emergency care personnel by not including specific requirements concerning education or credentials for individuals conducting emergency medical examinations.

+ Necessary stabilizing treatment for emergency medical conditions and active labor—

If the individual has an emergency medical condition or is in active labor, we proposed that the hospital be required to provide either further medical examination and treatment to stabilize the medical condition or treatment of the labor or transfer the individual appropriately to another medical facility. We would not hold the hospital responsible if the individual, or a legally responsible person acting on the individual's behalf, refuses to consent in writing to the further examination and treatment or the appropriate transfer to another hospital.

Under these provisions, the hospital would be responsible for treating and stabilizing any individual, regardless of eligibility for Medicare, who presents himself or herself with an emergency condition at the hospital, and for providing such care until the condition ceases to be an emergency or until the individual is properly transferred to another facility. We interpreted this to mean, for example, that if a hospital were to admit and then transfer an individual before his or her condition is stabilized, except as provided below, it would be a violation of section 1867 of the Act.

+ Transfers and restrictions—

If an individual at a hospital has an emergency medical condition that has not been stabilized or the individual is in active labor, the hospital could not appropriately transfer the individual unless one of the following conditions exist:

—The individual (or a legally responsible person acting on the individual's behalf) requests the transfer.

—A physician (or other qualified medical personnel if a physician is not readily available in the emergency department) has certified in writing that, based upon the reasonable risks and benefits to the individual and the information available at the time, the medical benefits reasonably expected from the provision of appropriate medical treatment at the other facility outweigh the increased risks to the individual's medical condition from the transfer.

We considered a transfer to be appropriate only if the receiving medical facility has available space and qualified personnel for the treatment of the individual and has agreed to accept the transfer of the individual and to provide appropriate medical treatment. The transferring hospital would have to furnish the receiving medical facility with timely appropriate medical records (for example, copies of the available history, examination, and treatment records as well as any available reports of diagnostic studies performed). The patient would have to be accompanied by qualified personnel during the transfer; transportation arrangements would have to include the use of necessary and medically appropriate life support measures.

Although the statute authorized the Secretary to find that the transfer must meet "other requirements" in the interest of the health and safety of individuals transferred, we did not propose to adopt any. We did, however, specifically invite public comment concerning any "other requirements" the Secretary should consider adopting regarding the health and safety of

emergency department patients being transferred between medical facilities.

• Definitions.

We proposed to include in § 489.24 the following definitions as included in the statute, without interpretation—

+ "Active labor" means labor at a time when delivery is imminent, there is inadequate time to effect safe transfer to another hospital before delivery, or a transfer may pose a threat to the health and safety of the patient or the unborn child.

+ An "emergency medical condition" means a medical condition manifested by acute symptoms of sufficient severity (including severe pain) that the absence of immediate medical attention could reasonably be expected to result in: (a) Placing the patient's health in serious jeopardy; (b) serious impairment to bodily functions; or (c) serious dysfunction of any bodily organ or part.

+ "To stabilize" means, with respect to an emergency medical condition, to provide the medical treatment of the condition necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from the transfer of the individual from a facility.

+ "Stabilized" means, with respect to an emergency medical condition, that no material deterioration of the condition is likely, within reasonable medical probability, to result from the transfer of an individual from a facility.

+ "Transfer" means the movement (including the discharge) of a patient to outside a hospital's facilities at the direction of any person employed by (or affiliated or associated with, directly or indirectly) the hospital, but it does not include moving a patient who has been declared dead or who leaves the facility without the permission of any person responsible for directing transfers.

For the purpose of these definitions, the term "hospital" means a Medicare facility certified as a hospital with its own provider number.

We did not plan to define "participating provider" in part 489; 42 CFR 400.202 defines terms applicable to all of 42 CFR Chapter IV and already defines "provider". A provider by definition agrees to participate in Medicare. We proposed to add a definition of "participating hospital" and the remaining statutory definition, that of "responsible physician", to 42 CFR Chapter V (Parts 1001 and 1003), since these terms are used in conjunction with monetary penalties, which is under the jurisdiction of the Office of Inspector General. We discuss the proposed definition of "responsible physician" below under "Civil Monetary Penalties."

• We proposed to amend 42 CFR Parts 489, 1001 and 1003 to provide for types of sanctions that would be applied by the Department, as appropriate—

+ Resolution of allegations and determination of liability.

If the evidence available establishes that a hospital knowingly and willfully, or negligently, failed to provide the appropriate screening and treatment or transfer as explained above, it would be subject to either termination of its provider agreement by HCFA in accordance with section 1866(b) of the Act, or suspension of its provider agreement by the OIG. In addition, the OIG could also impose civil monetary penalties for knowing violations.

When the Department receives a complaint, or any information or allegation, to the effect that a Medicare hospital did not appropriately comply with the emergency medical screening, stabilizing, treatment or transfer requirements, HCFA would, upon receipt of all available information and evidence, conduct sufficient review to determine whether the complaint falls within the jurisdiction of section 1867. If so, HCFA would consider the complaint a substantial allegation and would investigate the allegation thoroughly.

If complaints allege acts of discrimination in violation of the civil rights laws, HCFA will refer them to the Office for Civil Rights. In the case of other complaints, HCFA would send each complainant a letter acknowledging receipt of the complaint, advising him or her of his or her rights to consider independently the civil enforcement provisions of section 1867 and stating that it will refer the complaint to other agencies if, during the complaint investigation, it determines that the matter falls under the jurisdiction of other agencies. Thus, HCFA would refer a complaint to the Office for Civil Rights if it determines that a hospital may be in violation of the Hill-Burton Subpart G Community Service regulations at 42 CFR 124.603(b)(1), which require Medicare participating hospitals that receive Hill-Burton construction grants and loans to provide emergency medical services to any person who resides (or, in the case of some hospitals, works) in the hospital's designated health service area. HCFA would, of course, inform complainants of the outcome of its investigations.

HCFA would notify State Medicaid authorities, State licensing bodies, the Office of Inspector General, appropriate PROs and the Office for Civil Rights concerning all complaint investigations and all termination actions.

HCFA would determine whether the hospital knowingly and willfully, or negligently, failed to comply with the requirement of § 489.24 based on evidence of: (a) Inadequate treatment or treatment not being provided; (b) patients in unstable condition or in active labor not being properly transferred as defined in § 489.24(d)(2); (c) the hospital's actions, or lack of actions, causing a patient's or infant's death or serious or permanent impairment to a patient's bodily functions; or (d) a hospital's actions placing a patient's health in serious jeopardy. HCFA would determine the hospital to have been negligent if the hospital and its personnel failed to exercise care that should normally be supplied to a patient experiencing an emergency medical condition or active labor as defined in § 489.24(b).

+ Termination of a provider agreement by HCFA.

HCFA's termination authority under this provision was designed so that quick action may be taken to protect Medicare beneficiaries and other individuals from any potential harm. The termination of a provider agreement was to be the initial action contemplated against a hospital that knowingly and willfully, or negligently, failed to meet the requirements set forth in § 489.24. This section would allow for the termination of the hospital's provider agreement under Medicare in accordance with section 1866(b) of the Act. The termination requirement was to be contained in § 489.24(e). (The authority to terminate has been delegated from HHS through the HCFA Administrator to HCFA Regional Offices.)

HCFA was to revise § 489.53, Termination by HCFA, to include in paragraph (b) failure to comply with the requirements of § 489.24 as a mandatory cause for termination of a provider agreement. HCFA would also revise paragraph (c) to state that, if it determines that a hospital is in violation of § 489.24(a) through (d), HCFA would usually consider the violation to pose an immediate and serious threat to the health and safety of persons presenting themselves to the hospital for emergency services and would terminate the hospital's approval for Medicare participation within 2 days of the determination unless the violation is corrected.

In those instances in which HCFA determined that a hospital was in violation of the requirements of the Act, it would initiate termination action. When that action was resolved, HCFA would refer the case to the OIG for possible imposition of civil monetary

penalties. If the OIG, upon further investigation, discovered past violations that did not form the basis of the termination action, it could decide that a sanction is warranted and exercise its authority to impose a suspension against the reinstated provider. (See the next section.)

In instances where HCFA found no violation, and therefore did not take an action, the closed case would still be transmitted to the OIG. If the OIG, upon reviewing the case file, believed that further case development was warranted, it would be free to do so. If OIG's investigation indicated that there were additional violations that were not reflected in HCFA's case file, it would refer the new case information back to HCFA with a recommendation on whether HCFA should terminate the hospital's provider agreement based on the new findings.

Whether or not HCFA took a termination action on a given case, all investigated cases were to be referred to the OIG for possible imposition of civil monetary penalties.

+ Suspension of a provider agreement by the OIG and imposition of civil monetary penalties.

We proposed for the OIG to suspend providers, impose monetary penalties on violators and exclude responsible physicians. The proposed rule stated that the OIG would not be precluded from suspending a hospital if, upon further investigation, it determined there were additional violations of section 1867 beyond those warranting the HCFA termination that indicated a pattern of dumping more widespread than initially believed by HCFA, or that additional instances of dumping were so egregious that a penalty of suspension was appropriate. In addition, the proposed rule stated that the OIG could also impose a civil monetary penalty (of not more than $50,000 per violation) for a hospital knowingly violating the screening, treatment and transfer requirements of the statute and a civil monetary penalty (also of not more than $50,000) against each responsible physician. The proposed regulations also stated that, in addition to imposing civil monetary penalties, the OIG may exclude the responsible physician from Medicare participation for up to five years.

Congress repealed the suspension authority in section 4008(b) of OBRA 90.

• Civil enforcement.

An individual who suffers personal harm, or a medical facility that suffers a financial loss, as a direct result of the hospital's violation of a requirement in § 489.24, may bring a civil action, in an appropriate Federal district court, against the hospital for damages and other equitable relief as appropriate. No civil action may be brought more than 2 years after the date of the violation. The Federal district court will apply the law of the State in which the hospital is located.

We continue to believe that it was neither necessary nor appropriate to revise the regulations to reflect this provision.

• Preemption of State law.

The legislation provides that it does not preempt State or local law except where there is a conflict with the statutory provision. Since Federal law ordinarily supersedes State law where there is a conflict, it was not necessary to propose this provision for the regulations.

2. Responsibilities of Hospitals Receiving Improperly Transferred Individuals

Preliminary findings of a study being conducted by the OIG ("Patient Dumping After COBRA: Assessing the Incidences and the Perspectives of Health Care Professionals" (August 1988)) confirmed that a number of individuals in unstable condition have been transferred improperly and that the cases were not reported to HCFA. Because we needed to know about all improper transfers, we proposed to add new paragraphs § 489.20(g) and § 489.24(f) to require a hospital that suspects it may have received an improperly transferred individual to promptly report the matter to HCFA and to the State survey agency. To be in compliance with this requirement, the receiving hospital would have to report any suspected incident within 72 hours of its occurrence; this requirement would appear in manual instructions.

We also proposed to add material to § 489.53(a) to show that failure to report improper transfers may subject the receiving hospital to termination of its provider agreement.

In those instances in which HCFA determines that a hospital is in violation of § 489.20(g) and § 489.24(f), we proposed to initiate termination action.

3. State Survey Agency Responsibilities

The preliminary findings of the OIG study previously cited also identified incidents of improper transfer being reported to the State survey agency that were not then reported to HCFA.

To assure that we are aware of all instances of improper transfer, we also proposed to require the State survey agencies to report promptly any credible complaints (that is, complaints that are specific and detailed enough to be investigated) related to violations of section 1867 of the Act. Therefore, we intended to revise § 405.1903 (recodified as § 488.18), Documentation of findings, by adding a new paragraph (d) that would require State survey agencies to inform HCFA of credible reports of violations of § 489.24.

IV. Comments and Responses

A. Participation in the CHAMPUS, CHAMPVA and VA Health Care Programs

We received comments from nine commenters concerning the CHAMPUS/CHAMPVA and VA issues. They were from hospitals, professional organizations and one individual.

Comment: Two commenters raised numerous issues relating to the operations of the CHAMPUS/CHAMPVA programs and the operation of the prospective payment system under those programs (CHAMPVA payments are made under CHAMPUS' DRG-based payment system). The issues concerned such items as the status of hospitals operating under demonstration programs conducted by those programs, and the obligation of CHAMPUS/CHAMPVA patients for making cost-share amounts required under those programs.

Response: The purpose of these regulations is to require hospitals that participate in Medicare to participate as well in the CHAMPUS/CHAMPVA and VA programs. These regulations do not relate to rules under which those programs function and do not make any changes in their operations. We have referred questions concerning operational issues to appropriate administrative officials at OCHAMPUS who assure us that providers who are participating in the CHAMPUS Reform Initiative area will not be forced to accept payment less than the DRG amounts. They also tell us that the adjusted standardized amount used in the CHAMPUS DRG-based payment system contains a factor to reimburse hospitals for CHAMPUS' share of the hospitals' bad debts. These regulations do not change the beneficiary's obligation to pay required cost-share amounts.

Comment: Four commenters stated that the provider's freedom of choice in making management decisions of participating or not in these additional programs would be taken away by implementing these regulations.

Response: The legislation clearly ties participation in Medicare to acceptance, as well, of the CHAMPUS and CHAMPVA participation responsibility. We recognize that this change in the law

alters the range of discretion that a hospital may have in selecting participation options but the law offers no alternative to accepting all the programs or declining to participate in Medicare.

Comment: One commenter believed that, as a provider of services to CHAMPUS/CHAMPVA and VA beneficiaries for many years, his institution has the right to receive a notice of government action and have a chance to respond to the government decision-making. He received no notice of government action until reading this notice of proposed rulemaking.

Response: Under the Administrative Procedure Act (5 U.S.C. 553 et seq.), it is the notice of proposed rulemaking that is the vehicle for providing notice of this type of government action. Should a provider be subject to termination for not being in compliance with requirements added by this rule, we believe the procedures for termination by HCFA located at § 489.53 are fundamentally fair. These procedures include our proposed rules under § 489.53(a)(11) that allow HCFA to terminate an agreement with any provider, if HCFA finds that the provider no longer meets the appropriate conditions of participation such as those found in new § 489.25 or § 489.26, which address providing medical services to CHAMPUS/CHAMPVA or VA beneficiaries. Before we find a hospital in violation, we expect, as discussed in the preamble of the proposed rule, that efforts to resolve any problem will have taken place. If problems are not resolved then the actual notice of termination procedures listed in § 489.53(c) will be initiated.

Comment: Four commenters stated that third party payors, such as Medicaid and CHAMPUS, pay smaller and smaller proportions of the costs these hospitals incur in serving those covered by these programs. In their view, if hospitals are to continue to provide full access, then Congress, HCFA, the Department of Defense, and State governments must recognize their responsibility to adequately finance the care that they require to be provided.

Response: We believe that the prospective payment system results in fair payments. As implemented under Medicare, the prospective payment system differentiates payments by location and type of provider as well as by the relative resource intensity of individual cases. The CHAMPUS and VA DRG-payment systems are similar to that used by Medicare; however, they have been tailored to their own health care utilization patterns. Under a prospective payment system, many of the operational costs have been factored into the DRG.

We have been informed that under the CHAMPUS DRG-payment system the cost sharing provisions have been changed to ensure that the amount of the shared cost incurred by the beneficiary will be more equitable. In fact, we have learned that most beneficiaries will pay less under this new system than the old, and no beneficiary is expected to pay more in cost share amounts. As under the Medicare prospective payment system, annual evaluations to recalculate DRG weights are taking place under the CHAMPUS DRG-based system using the most recent period of CHAMPUS data. During annual evaluations, consideration can be given to any problems which have surfaced.

For services provided to CHAMPVA patients, inpatient hospital services are being reimbursed through the CHAMPUS DRG-based payment system with, we expect, similar results. With regard to VA beneficiaries, for admissions on or after November 23, 1990, hospital reimbursements are being made in accordance with the regulations published on October 24, 1990 (55 FR 42848) concerning the payment methodology and amounts that the VA provides for those hospitals that furnish inpatient hospital care to veterans whose care has been authorized or will be sponsored by the VA. As noted in section I.B. of this preamble, this rule was developed jointly by VA and HHS, and the VA payment system conforms to Medicare's inpatient hospital prospective payment system in most cases.

Comment: One commenter believes that, at a minimum, disproportionate share providers should receive special protection. He stated that since Congress recognized that additional Medicare payments under the prospective payment system should be made to hospitals that admit a disproportionate share of low-income patients, a similar disproportionate share status may be necessary to protect Medicare providers located in areas surrounding military bases or other military installations.

Response: The preamble to the final rule implementing the CHAMPUS DRG-Based Payment System (52 FR 32992) provides information to suggest that there should not be a disproportionate number of CHAMPUS beneficiaries seeking care in Medicare participating hospitals (civilian hospitals). Specifically, when discussing "emergency treatment" (page 32996, first column), it states that "* * *all CHAMPUS beneficiaries who live within catchment areas of military treatment facilities (MTFs) are required to first seek inpatient care at the MTF before going to a civilian hospital* * *" The catchment area is defined as within 40 miles of an MTF. On the other hand, however, we have been informed that CHAMPVA beneficiaries are not eligible for care in MTFs; therefore, they must use either VA or civilian hospitals.

We believe the payment rates under CHAMPUS are adequate to pay for treatment of its enrolled population. If the commenter believes otherwise he should furnish the VA with data on this matter and present detailed findings to support the need for a suggested adjustment to payment rates.

Comment: Two commenters stated that these regulations should not be imposed until the joint regulations are issued and thereafter should be prospective in nature only.

Response: The joint regulations to which the statute refers are regulations establishing payment procedures and amounts, not regulations requiring participation. Such regulations have already been published (55 FR 42848 for VA and 52 FR 32992 for CHAMPUS/CHAMPVA). In addition, we consulted on these regulations with pertinent members of OCHAMPUS and VA before publication; thus, these regulations are also a joint action. They are also prospective, not retroactive.

B. Discharge Rights Notice

Twenty-five commenters addressed the hospital discharge rights notice. These comments were from a physician, citizen organizations, professional organizations, hospital associations, a consultant group, and hospitals.

Comment: Three commenters suggested alternatives to the notice, including the posting of signs in the hospital, sending a copy of the notice with each beneficiary's social security check, and having the hospital mail the notice to the beneficiary before his or her admission to the hospital.

Response: We do not believe that most of these methods would serve the purpose Congress intended. Posting a sign could still result in many, if not most, beneficiaries not noticing it at all; a mass mailing would be untimely for most patients and thus subject to being ignored. Moreover, the law requires that the notice be furnished by the hospital. Finally, many admissions are not planned or occur with little advance notice; so, having the hospital mail the statement before admission would be a viable method of informing some but not all beneficiaries of their discharge rights on a timely basis. We note, however, that hospitals may choose this

approach with patients whose admissions are planned in advance.

Comment: One commenter stated that the public had not had adequate opportunity to participate in developing the discharge rights statement.

Response: Section 1866(a)(1)(M) of the Act requires a Medicare participating hospital to furnish a statement concerning discharge rights to each Medicare beneficiary.

The law is self-implementing; that is, it did not require public comment or regulations in order to be implemented. However, we did consult extensively with major beneficiary and provider organizations (such as the Gray Panthers, American Hospital Association, and the American Association of Retired Persons) and have subsequently revised the final version of "An Important Message from Medicare" (the "Message") after these consultations.

Comment: One commenter stated that the "Message" is inadequate, especially as it pertains to discharge planning, and suggested either a separate notice or an expanded notice to focus on the discharge planning requirements of section 1861(e)(6) of the Act. Another commenter asserted that the original "Message" was poorly written, as it tries to cover legal requirements. The commenter also asserted that there is a need for the "Message" to be more supportive and informative.

Response: The revised "Message" contains several references to the availability of hospital discharge planning and the need to consult a physician or appropriate hospital staff for assistance. Beneficiaries have a current need for the "Message," and we do not believe it would have been appropriate to delay its distribution until after the condition of participation for discharge planning, proposed to be included in our regulations at § 482.43 (see 53 FR 22506, June 16, 1988), is published as a final rule. Requiring a notice of hospital discharge rights and requiring hospitals to provide a discharge planning process are two separate statutory provisions of OBRA 86 that were not meant to be combined. Further, Congress did not specify explicitly in section 1866(a)(1)(M) that discharge planning should be included in the notice. We have revised the original "Message" to improve its readability as well as its content. We note that it has always been our intention to revise the "Message" in the future as patient needs change.

Comment: One commenter thought we should include an explanation of the content of the "Message" in the final rule and that an outline of it in the regulations would aid in its later interpretation.

Response: We are including as Appendix I to this interim final rule the current "Message"; it is self-explanatory. We do not believe it is necessary to outline its content in the regulations text, as the "Message" is readily available at hospitals.

Comment: One commenter thought we should advise the public how they can obtain a copy of the "Message" or that we should send each commenter a copy.

Response: The "Message" was distributed to all hospitals via Medicare Hospital Manual Transmittal No. 545, dated July 1988. The "Message" is readily available to the public since it has been reproduced in the 1989 through 1994 editions of "The Medicare Handbook." As stated above, we are also publishing it as Appendix I to this final rule.

Comment: We received four comments, all from beneficiary organizations, in favor of our requirement that the hospital obtain a signed acknowledgement of the discharge rights notice. We also received 17 comments against it, primarily from hospitals and hospital organizations. Four of these commenters stated that there is no need for this requirement. They cited HCFA's statement in the preamble to the proposed rule that, "we believe we already have full cooperation from hospitals."

Response: We strongly believe that the requirement that a hospital furnish a statement concerning discharge rights to each Medicare beneficiary must be fully met. However, we are persuaded by the commenters that full compliance has already been achieved in most hospitals. Therefore, we have eliminated the requirement for a signed acknowledgement. In its place, we now specify under § 489.27 that a hospital must be able to demonstrate that it complies with the requirement that each beneficiary be furnished with a discharge rights notice at or about the time of admission. We note, however, that signed acknowledgements could be required as part of a plan of correction for a hospital that was found to be out of compliance with this requirement.

Comment: Fourteen commenters objected to the requirement that hospitals retain the signed acknowledgement by the beneficiary, as they anticipate it will be a tremendous burden in terms of cost of the forms, storage of the acknowledgements, and added processing time by the admissions staff.

Response: In conjunction with the elimination of the signed acknowledgement requirement, we have deleted the accompanying retention requirement from this interim final rule. When we published the proposed rule, our PRO program was oriented towards review of hospital medical records, and so we chose initially to implement the discharge rights requirement specifically in terms of an acknowledgement in the medical record. More recently, however, we have reoriented our PRO program towards efforts more likely to bring about general improvements in quality and have minimized our funding of more limited "process" requirements such as review of individual medical records. Accordingly, we recognize that the proposed acknowledgement and retention requirements have become obsolete and are eliminating them. Again, the final rule does require hospitals to demonstrate compliance with the discharge rights notification requirement, but does not specify the manner of compliance. We expect some hospitals may continue to seek and retain signed acknowledgements but believe they should have other, less burdensome, options as well.

Comment: Eight commenters believed that this requirement would be a burden on the beneficiary and his or her family as there are already too many forms to complete at admission; one commenter felt that securing a signed acknowledgement would do little to improve beneficiary attention to the "Message" because it is the presence of a problem, rather than the presence of the notice, that generates beneficiary attention to discharge rights issues.

Response: We realize that being admitted to a hospital is a stressful event for patients and their families. As noted above, we have removed the requirement for a signed and dated acknowledgement, in part because of its impact on beneficiaries. We expect in the future to look more carefully at innovative ways to ensure that patients get the information they need when they need it.

Comment: In addition to the concerns discussed above, commenters also addressed specific aspects of the requirement that hospitals obtain and retain signed acknowledgement statements. For example, one commenter suggested that we require that the date and time of the patient's signature on the acknowledgement statement be recorded; another recommended that the acknowledgement statement be accompanied by an additional statement that signing the acknowledgement in no

way compromises a patient's discharge rights; another suggested that the acknowledgement specify that the beneficiary has been given the name of an individual at the hospital who is available to explain the "Message." Similarly, commenters asked that we specify where, in what form, and for how long acknowledgements be retained. Finally, several commenters recommended that we allow hospitals as much flexibility as possible in implementing the acknowledgement and retention requirements.

Response: Given that we have decided to eliminate the requirement for a signed acknowledgement and its retention, most of these comments are now moot. Thus, we agree with the commenters who believe that hospitals should be given maximum flexibility in determining how they can best comply with the requirement that all beneficiaries be furnished with a notice of discharge rights. We do not intend to specify the actual mechanics of having this notice presented to patients. Instead, we expect individual hospitals to exercise their own discretion in dealing with the associated administrative issues. We emphasize that, for survey purposes, hospitals that do not choose to obtain and retain signed acknowledgement statements must be able to document compliance by some other means with the requirement for timely distribution of the discharge rights notice.

Comment: One commenter contended that we should have done more consulting with organizations knowledgeable about hospital management practices before developing a proposal that related to the creation and retention of a record.

Response: We believe that the publication of the proposed rule represents a valuable form of consultation. The issue we dealt with in the proposed rule was primarily an issue relating to beneficiary awareness and the creation of a record that it has been successfully accomplished. As discussed above, we received comments on the recordkeeping and management aspects of the issue, and we have fully considered them in developing the final regulation.

Comment: Some commenters believed that the regulations should address those situations in which the patient is physically and/or mentally unable to understand the message or to sign the acknowledgement and has no one to perform these functions.

Response: We do not agree that the regulations themselves should address these situation. Such situations will be relatively rare. Hospitals will need to be in compliance with applicable State statutes in dealing with informing patients who cannot receive information on their own behalf. Program instructions are a more appropriate vehicle for discussing specific difficulties if they occur and additional guidance is needed.

Comment: One commenter recommended that we specify whether we are requiring hospitals to educate Medicare beneficiaries about the patient's rights listed in the "Message" and to assure that the patient fully understands his or her rights.

Response: We are not requiring the hospital to educate beneficiaries as to their rights, beyond having beneficiaries read the "Message" and signing an acknowledgement that they have read it, nor are we requiring the hospitals to assure that the beneficiaries understand their rights. Beneficiaries are instructed in the "Message" to consult the PRO, their physician or the hospital's patient representative if they do have questions.

Comment: Four commenters believe HCFA, rather than the hospitals, should educate beneficiaries about their rights. One commenter noted that PROs, as part of their Federal contracts, are responsible for community education programs.

Response: HCFA carries out a variety of activities to educate beneficiaries and will continue to do so. However, section 1866(a)(1)(M) of the Act requires that this explanation of patient rights be provided by the hospital. This is an appropriate hospital responsibility since inpatient hospital care is under the control of the hospital and the patient looks to the hospital for information about rights and options concerning care. Also, these rights are related to discharge planning, which is most appropriately a hospital function.

Comment: One commenter wanted us to specify what, if any, changes a hospital can make to the "Message." The commenter also requested that some monitoring requisites from the new PRO scope of work requirements be included in the regulation.

Response: We believe these items are better addressed in program operating instructions. Medicare Hospital Manual Transmittal No. 545, dated July 1988, and subsequent transmittals, inform hospitals that they may use their own letterhead but may not alter or change the language of the "Message." Peer Review Organization Manual Transmittals instructions will be updated, as needed, to reflect this final regulation.

Comment: Three commenters believed that termination for failure to comply with provisions of this regulation is too extreme a penalty.

Response: Although a hospital may be terminated for failing to meet our requirements we will not institute termination before providing an opportunity for correction. As stated in the preamble to the proposed rule, the speed with which we move to termination would depend on HCFA's judgment as to the scope of the failure and the hospital's correction or plan for correction of the failure. This approach will be reflected in implementing program instructions.

Comment: One commenter thought that the acknowledgement requirement should not be subject to the 2-day termination procedure.

Response: The 2-day termination procedure was not proposed to apply to the discharge rights provision, but only to the "anti-dumping" provision.

C. Hospital Responsibility for Emergency Care

We received comments from 68 commenters on the anti-dumping provisions as they existed before the passage of OBRA 89. Commenters included hospitals, professional health organizations, State hospital associations and medical societies, State agencies, physicians, attorneys and other individuals. We have taken into account the OBRA 89 and OBRA 90 statutory changes when responding to the comments we received, and we are adding the OBRA 89 and OBRA 90 requirements to this interim final rule. We are doing this without publishing a second notice of proposed rulemaking pertaining to the OBRA 89 and OBRA 90 requirements because we believe the extensive detail of the statute makes many provisions self-executing and because commenters suggested changes similar to many of those embodied in the legislation.

(Please note that, with respect to the anti-dumping provisions, the statute now uses the term "individual" and not "patient." While our response to comments refers to "individuals," we have not made the parallel change when the term "patient" appears in a commenter's statement.)

General

Comment: A number of commenters suggested that HCFA require hospitals to post signs in their emergency departments advising patients of the hospital's obligation to provide emergency care. Two other commenters recommended that we require emergency room personnel to give emergency room patients both written and oral notice of the hospital's

obligations and the patient's rights under these regulations.

Response: The provisions of section 1867 of the Act address what is appropriate performance on the part of hospitals in meeting medical needs of individuals who need emergency services. Additionally, as amended by section 6018(a)(2) of OBRA 89, section 1866(a)(1)(N)(iii) of the Act explicitly directs the Secretary to require Medicare participating hospitals to post conspicuously in all emergency departments a sign (in a form specified by the Secretary) specifying rights of individuals under section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor. Further, since some hospitals do not have traditional emergency departments, we are amending § 489.20 to include a new paragraph (q)(1) to reflect this statutory requirement and to specify other hospital areas in which such signs should be posted. It should be noted that Medicare participating hospitals that do not offer emergency services do not have to comply with this requirement. However, all hospitals do have to comply with the provision of section 1866(a)(1)(N)(iv) of the Act, as also amended by section 6018(a)(2) of OBRA 89, that directs hospitals to post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital participates in the Medicaid program under a State plan approved under title XIX. (See § 489.20(q)(2).)

We have also published an interim manual instruction (IMI)(IM–90–1, June 1990) in HCFA Pub. 10, the Medicare Hospital Manual, listing minimum criteria for the signs and an example of language for this sign that would meet such criteria. We are including the IMI language as shown in the IMI exhibit for informational purposes in Appendix II to this final rule and request comments on the exhibit.

We believe that the statutory requirement for the posting of signs, which does not also require individual written or oral notice, is adequate for the general purpose of informing patients of their rights to a medical screening and stabilizing treatment under the anti-dumping statute. This is consistent with the overall drafting of section 1867 of the Act, which specifically requires individual notice in other situations such as consent to transfer. Accordingly, when an individual's specific treatment is involved, we agree with the commenters that it is essential for patients to be fully informed about all the critical medical issues with which they are faced. That is why we require a more detailed process for ensuring that hospitals obtain the informed consent of an individual who is faced with the prospect of a transfer. (See § 489.24(c).) In such cases, we agree that both oral and written interaction are necessary.

Comment: A number of commenters objected to our proposal concerning furnishing emergency services on the grounds that our rule applies to all patients (rather than Medicare patients only). They believe that any problems were of limited scope and noted that implementation of the requirement will establish an adversarial relationship among HCFA, providers, and patients.

Response: The protections of the statute are expressly extended to all individuals who come to a facility regardless of whether the individual is eligible for benefits under Medicare. The Federal Government has always viewed that a provider's obligation is to all persons, regardless of entitlement. This obligation has been well understood and universally applied to all providers. Congress, in apparent awareness of this universal obligation, has in some instances limited the scope of a provider's obligation. An example of this is discharge planning, as provided under section 1861(ee) of the Act, which limits the scope of this requirement specifically to individuals covered under the Act. Since Congress has not chosen to narrow the scope of section 1867 by limiting it only to persons entitled to benefits under the Act, we are confident that the provisions of section 1867 of the Act extend to all persons.

We believe that section 1867 of the Act also applies to all individuals who attempt to gain access to the hospital for emergency care. An individual may not be denied services simply because the person failed to actually enter the facility's designated emergency department. To read the statute in such a narrow fashion would in our view frustrate the objectives of the statute in many cases and lead to arbitrary results. For the same reason, a facility may not prevent an individual from gaining access to the facility in order to circumvent these requirements. If an individual is on a facility's property, which includes ambulances owned and operated by the facility, even if the ambulance is not on hospital property, and a request is made on the individual's behalf for examination or treatment for a medical condition, we believe the statute reasonably requires the facility to provide a screening examination and treatment or transfer in accordance with section 1867 of the statute. An individual in a nonhospital-owned ambulance on hospital property is considered to have come to the hospital's emergency department. However, an individual in a nonhospital-owned ambulance located off hospital property is not considered to have come to the hospital's emergency department if someone staffing the ambulance contacts the hospital by telephone or telemetry communications and informs the hospital that they want to transport the individual to the hospital for examination and treatment. This is in accordance with the recent court decision that, for purposes of section 1867 of the Act, a hospital-operated telemetry system is distinct from the same hospital's emergency department. (See *Johnson* v. *University of Chicago Hospitals*, 1992 U.S. App. Lexis 25096 (7th Cir. 1992).) Thus, the hospital may deny such access when it is in "diversionary" status because it does not have the staff or facilities to accept any additional emergency patients at that time. However, if the ambulance disregards the hospital's instructions and does bring the individual on to hospital grounds the hospital cannot deny the individual access to hospital services whether or not the hospital is in "diversionary" status.

Comment: A number of commenters noted that these requirements could have a greater impact on some hospitals than on others. For example, rural hospitals would have a greater recordkeeping burden in documenting transfers because they have smaller emergency room (ER) staffs; hospitals with high ER rates for non-Medicare or Medicaid patients would have to provide care for which these programs will not directly compensate, and some hospitals will have to accept larger numbers of indigent patients presenting themselves for treatment.

Response: The law specifically applies to all hospitals that participate in Medicare and that offer emergency services. We have, therefore, inserted the following definition in § 489.24(b): "Hospital with an emergency department means a hospital that offers services for emergency medical conditions (as defined in this paragraph) within its capability to do so." It is also clear that the statute only requires hospitals that offer emergency services to provide screening and stabilizing treatment within the scope of their capabilities (sections 1867(a) and (b) of the Act). We acknowledge, however, that any participating hospital providing emergency services, regardless of size or patient mix, must provide screening and stabilizing treatment, as needed, to individuals who present themselves for

examination or treatment. We recognize that this could create uneven uncompensated care burdens on some hospitals because of larger than usual concentrations of indigent patients; however, we do not believe that this will often be the case. Since the requirements apply to all 6,700 Medicare participating hospitals, among 7,000 U.S. hospitals offering emergency services, we also believe that the statute will lighten the burden on some hospitals now subject to increased patient loads due to inappropriate transfers because patients are more likely to be treated and stabilized at the hospitals where they first present themselves for treatment.

Medical Screening Examination

Comment: Two commenters stated that a hospital should not be required to designate in its by-laws which personnel are qualified to perform the initial medical screening examination because it is unreasonable to require a hospital to amend its by-laws. A recommendation was made that those personnel qualified to perform screening examinations be approved by the medical director of the emergency department. Another recommendation was made that those personnel qualified to perform screening examinations be set forth in the rules and regulations governing the medical staff and not the by-laws.

Response: It is important to require the hospital to determine formally what type of personnel is qualified to perform the initial medical screening examinations because such a formal determination will insure that the hospital's governing body recognizes the "capability of the hospital" and is properly accountable for this function. For this reason, we believe that the delegation should be set forth in a document that is approved by the governing body of the hospital, rather than merely allowing the medical director of the emergency department to make what may be informal delegations that could frequently change. If the rules and regulations are approved by the board of trustees or other governing body, we agree that those personnel qualified to perform these examinations may be set forth in the rules and regulations, instead of placing this information in the hospital by-laws. We are amending § 489.24(a) to reflect this change. Although we are requiring the hospital to specify in its by-laws or its rules and regulations who is a "qualified medical person" for purposes of providing an appropriate medical screening examination, this does not mean that HHS must accept the hospital's specification when determining whether an appropriate medical screening examination was done. So, for example, if a hospital specifies that a nurse is always the "qualified medical person" who should do the medical screening examination, HHS may, in some instances, determine that there was not an appropriate medical screening examination because the condition of the individual required the expertise of a physician to determine whether that individual had an emergency medical condition.

Comment: Several commenters suggested that the regulations require hospitals to perform the medical screening examination without first inquiring about an individual's ability to pay because such inquiries may encourage patients to refuse treatment or request transfer, even when it is not in the best interests of the patient's health.

Response: We agree with the commenter, as did Congress as evidenced by the provisions added to section 1867(h) of the Act by section 6211(f) of OBRA 89:

> A participating hospital may not delay provision of an appropriate medical screening examination required under subsection (a) or further medical examination and treatment required under subsection (b) in order to inquire about the individual's method of payment or insurance status.

We have included this language in the regulations at § 489.24(c)(3). However, we note that we believe that it means hospitals may continue to follow reasonable registration processes for emergency room individuals, including requesting information about insurance, as long as these procedures do not impede provision of necessary treatment and as long as all individuals to whom the procedures apply are treated similarly. That is, all individuals who have an emergency medical condition are served regardless of the answers they may give to insurance questions asked during routine admissions screening. A hospital should not delay treatment to any individual while it verifies information provided.

Comment: Three commenters recommended that the regulations affirmatively state that every patient, regardless of ability to pay, should receive a medical screening examination performed by a physician.

Response: Section 1867(a) of the Act provides that a hospital must give an appropriate medical screening examination to all individuals who come to the emergency department and request examination or treatment. While it may be prudent for a hospital to require a physician to conduct this screening examination in every instance, there may be hospitals, especially rural primary care hospitals, in which a physician is not available to provide a medical screening examination. Even when physicians are present in the hospital, there may be circumstances that are so clearly not emergency medical conditions that other qualified medical personnel may conduct the initial screening examination. However, although it is up to the hospital to determine under what circumstances a physician is required to perform an appropriate medical screening examination, that does not mean that HHS must accept the hospital's determination of what circumstances require that the screening exam be performed by a physician.

Comment: Several commenters asked us to define "appropriate medical screening examination," so that hospitals and physicians are subject to unambiguous requirements for carrying out the statutory mandate.

Response: It is impossible to define in advance all of the circumstances in which an individual may come to a hospital emergency department. What constitutes an appropriate medical screening examination will vary according to the condition and past history of the individual and the capabilities of the hospital's emergency department—both its facilities and available personnel. Within those capabilities, the examination must be sufficient to permit the hospital to decide whether or not the individual has an emergency medical condition. Because the law does not require hospitals, among which there are variations in staffing and procedures, to adopt standard procedures or use standard staffing to meet these requirements, determinations about whether a hospital is in compliance with these regulations must be based on the facts in each individual case.

Comment: One commenter stated that the regulations should permit other qualified medical personnel to perform an initial medical screening examination if a physician is not available in the emergency department. Another asked if hospitals could use labor and delivery nurses, in consultation by phone with an obstetrician, to examine emergency obstetric patients to determine whether they are in labor.

Response: The regulations presently allow a hospital to delegate its responsibility to perform initial medical screening examinations to qualified medical personnel if it does so in its by-laws or in its rules and regulations.

Such a delegation must also be consistent with the provisions of § 482.55 with respect to emergency services personnel. Obviously, the Department cannot anticipate every situation in which an individual with an emergency medical condition may come to an emergency department. Hence, we cannot state unequivocally that an examination by a nurse or other non-physician medical personnel will be appropriate under all circumstances.

Capability

Comment: One commenter suggested that we revise the regulation to permit a hospital to transfer an unstabilized patient when it does not have the personnel or equipment to stabilize the patient's condition within the meaning of the statute.

Response: No revision is necessary. A hospital is only required to treat individuals with the staff and facilities available at the hospital. Under § 482.55(b)(2), a hospital must have available "adequate medical and nursing personnel qualified in emergency care to meet the written emergency procedures and needs anticipated by the facility." Subject to the discussion below concerning on-call physicians, if the hospital does not have at its disposal the personnel or equipment necessary to stabilize a particular person's emergency medical condition, section 1867(c)(1) of the Act permits an unstabilized individual to be transferred if (a) the individual or the individual's representative has been informed of the risks and benefits of the transfer and requests the transfer in writing; or (b) the individual has not refused an appropriate transfer and the physician signs a written certification that the benefits of appropriate treatment at another facility outweigh the risks associated with the transfer.

Comment: One commenter recommended that the services of on-call physicians should be considered in determining the capabilities of the staff and facilities "available" to conduct a medical screening examination and further treatment that may be necessary to stabilize the emergency medical condition or treat the labor. Another asked that the regulations specify that a hospital is deemed to be capable of providing emergency services in all fields in which the hospital is normally engaged, regardless of the staff's reluctance to be available for emergency services.

Response: We agree that on-call physicians and ancillary services should be considered available to the hospital. This was further clarified in section 6018(a)(1) of OBRA 89, which amended section 1866(a)(1) of the Act to require hospitals to maintain a list of physicians who are on call and available to provide treatment needed to stabilize individuals with emergency medical conditions. Accordingly, we have amended § 489.20 to include a new paragraph (r)(2) requiring hospitals to comply with this OBRA 89 provision. The statute (as revised by COBRA, OBRA 89, and OBRA 90) and the current regulations state that the hospital must provide a medical screening examination, within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine if the patient has an emergency medical condition. If a hospital chooses to meet its responsibility under § 482.55 to provide adequate medical personnel to meet its anticipated emergency needs by using on-call physicians either to staff or to augment its emergency department, then the capability of its emergency department includes the services of its on-call physicians.

The statute (as revised by COBRA, OBRA 89, and OBRA 90) and current regulations also require the hospital to provide whatever further examination and treatment are necessary to stabilize the medical condition or to provide for treatment of the labor within the staff and facilities available at the hospital. If a staff physician is on call to provide emergency services or to consult with an emergency room physician in the areas of his or her expertise, that physician would be considered to be available at the hospital.

We also believe that when COBRA was enacted, Congress intended that the resources of the hospital and the staff generally available to patients at the hospital would be considered available for the examination and treatment of individuals coming to the hospital's emergency department, regardless of whether staff physicians had heretofore been obligated by the hospital to provide services to those coming to the hospital's emergency department. This was also clarified by section 6211(a) of OBRA 89, which specifies that the capability of hospital emergency departments must include "ancillary services routinely available to the emergency department." Therefore, if a hospital has a department of obstetrics and gynecology, the hospital is responsible for adopting procedures under which the staff and resources of that department are available to treat a woman in labor who comes to its emergency department.

Comment: One commenter expressed concern about the liability of small rural hospitals because many times they are not equipped to treat certain emergencies, in which case the patient must be transferred. Another commenter asked if each hospital's emergency room is required to treat emergency psychiatric disorders regardless of the hospital's capabilities.

Response: Neither the statute nor the regulations mandate that hospitals expand their resources or offer more services. Rather, they focus on a hospital's existing capabilities. The thrust of the statute is that a hospital that offers emergency services to some members of a community who need their emergency services (for example, those that can pay) cannot deny such services to other members of the community with a similar need.

As previously indicated, the statute and the regulations specifically state that the hospital must provide treatment that is within the capabilities of the staff and facilities it has available. If a hospital does not have the capability to treat psychiatric disorders or a small rural hospital lacks the staff or resources to treat certain emergencies, it must determine whether the benefits to an individual's medical condition outweigh the risks associated with transferring the individual. If a physician certifies that the benefits of transfer to a more suitable facility outweigh the risks, the hospital may transfer the individual to a facility that has the capability to treat that individual and agrees to accept transfer. The certification may be signed by a qualified medical person if a physician is not physically present in the emergency department and that qualified medical person first consults with a physician who later countersigns the certification. Also, a person seeking medical treatment may make an informed decision to request transfer to such a facility.

Comment: Several commenters asked whether the determination of liability and penalties will be the same for a hospital that has limited capabilities as that for a hospital that has a trauma center.

Response: Any participating hospital that offers emergency services is liable for violations of the statute regardless of whether it is a small rural hospital or a major metropolitan tertiary care facility with a trauma center. The statute requires any subject hospital to provide for treatment within the capabilities of the staff and facility it has available. However, hospitals with fewer than 100 State-licensed, Medicare-certified beds are subject to a maximum civil monetary penalty of $25,000, as compared to a maximum civil monetary

penalty of $50,000 for hospitals with 100 or more State-licensed, Medicare-certified beds.

Comment: One commenter questioned the responsibility of a hospital that is a Medicare certified hospital but does not have an emergency department. Another wanted to exempt from the reach of the statute facilities, such as college infirmaries, that provide emergency services exclusively to students.

Response: The statute and these regulations apply only to hospitals that participate in the Medicare program and that offer emergency services. HHS considers any participating hospital that provides emergency services to have an emergency department and thus to be subject to the provisions of the statute and these regulations. However, even a Medicare participating hospital that does not provide emergency services must continue to meet the standard of § 482.12(f), which requires hospitals to have written policies and procedures for appraisal of emergencies, initial treatment, and referral where appropriate. Also, to our knowledge, college infirmaries are not hospitals having Medicare provider agreements and are thus not subject to section 1867 of the Act.

Hospital

Comment: One commenter noted that in the proposed regulations and COBRA, the term "hospital" is defined as "a Medicare facility certified as a hospital with its own provider number." The commenter recommended that the definition be expanded to require that the transfer be made to the "nearest appropriate facility" that happens to be a Medicare provider, so that Medicare providers will be required to receive transfers from other hospitals.

Response: The intent of the statute is to provide equal treatment for all individuals who come to a hospital and request a medical screening examination or treatment for an emergency medical condition, as well as to provide for protected transfers of individuals who have unstabilized emergency medical conditions. Such individuals are at the greatest risk of severe physical impairment, dysfunction, or delivery of a baby in the absence of immediate medical attention. We believe that after assessing an individual's medical condition and weighing the risks versus benefits of effectuating an appropriate transfer to another facility, the amount of travel time required to transport the individual should be considered. Situations will occur where an individual's condition requires a hospital to effectuate a transfer to the nearest appropriate facility that has the capability and capacity to treat in order to minimize the risks to the individual by reducing the transportation time as much as possible. Transfer of an unstabilized patient to a hospital with which there is a prior transfer agreement can be justified when the condition of the unstabilized individual is such that the additional travel time would not increase the danger to the patient.

Emergency Department

Comment: Two commenters believe that we should define emergency department to include the provision of emergency services, as not all hospitals have a formal "emergency department."

Response: We believe that section 1867 of the Act applies to all Medicare participating facilities that offer emergency services. It was not Congress' intent to limit the scope of the provision to only those facilities that have organized areas specifically labelled as emergency departments or emergency rooms. If so, a facility could easily circumvent its responsibilities under the Act simply by renaming the department to something other than "emergency department" or by using an approach other than departmentalization in providing hospital services. This would clearly contravene the underlying principle of the statute that obligates hospitals to render emergency care within their capacity when they normally undertake to render such care in individual cases.

For example, many psychiatric hospitals do not have organized emergency departments. However, many of these facilities offer 24-hour psychiatric services on a walk-in basis for persons who are not patients of the hospital. Although these hospitals do not have organized emergency departments, they are presenting themselves to the public as providing care for psychiatric emergencies. We believe this type of facility must comply with the requirements of section 1867 of the Act and render emergency care within their capability to do so (or provide for a transfer in accordance with section 1867(c) of the Act).

In order to clarify this issue, we believe it is helpful if the regulations define the term "hospital with an emergency department" to clarify which hospitals are subject to the requirements of section 1867. Therefore, as we previously indicated, we have inserted in § 489.24(b) the definition of a hospital with an emergency department.

Patient Consent

Comment: One commenter noted that the first sentence of proposed § 489.24(a) contains a conflict in language as it appears to refer to individuals coming in alone and then refers to a request made on the individual's behalf.

Response: The statute and the regulations focus on the individual coming to an emergency department who may need treatment, whether or not that individual is alone or with his or her entire family. However, we are clarifying the language to state that the request for treatment may be made by the individual or on the individual's behalf.

Comment: Eleven commenters questioned the hospital's responsibility to a patient who refuses treatment or refuses a medically appropriate transfer.

Response: The statute deems a hospital as having met its statutory obligations under this provision if an individual refuses treatment or a medically appropriate transfer. We are adding requirements, discussed below, to ensure that the individual's refusal is informed and not obtained under duress.

Comment: One commenter stated that proposed § 489.24(c) (2) and (3) are inconsistent in that an individual's refusal to consent to treatment must be in writing, but a refusal to consent to transfer does not. Other commenters urged HCFA to require that refusals to consent to treatment be in writing and that they reflect that the individual, or a legally responsible person acting on his or her behalf, understands the hospital's obligations under the statute and is aware of the risks of refusing treatment.

Response: We agree that the decision to refuse or consent to treatment must be an informed one, and we believe that the hospital is obliged to inform the individual (or the person requesting examination or treatment on his or her behalf) of the reasonably foreseeable risks and benefits of refusing or consenting to treatment. Sections 6211(b) (1) and (2) of OBRA 89 amended section 1867(b) of the Act to require hospitals to inform individuals (or persons acting on their behalf) of the risks and benefits to the individual of examination and treatment and/or transfer, and to "take all reasonable steps to secure the individual's (or person's) written informed consent to refuse such examination and treatment," transfer, or both. We are therefore amending § 489.24(c) (2) and (4) to comply with these OBRA 89 requirements. Thus, the medical record should contain a description of the examination and treatment offered to the individual. We also believe that hospitals should not attempt to coerce

individuals into making judgments against their best interest by informing them that they will have to pay for their care if they remain, but that their care will be free or at low cost if they transfer to a charity hospital.

It should also be noted that hospitals generally require an individual's consent to treatment to be in writing. (See § 482.24(c)(2)(v) requiring properly executed informed consent forms for procedures and treatments specified by hospital medical staff or Federal or State law requirements.)

Comment: One commenter stated that HCFA should require a request for transfer to be in writing to ensure that it is not coerced. It should acknowledge the individual's awareness of his or her right to emergency treatment under the statute and outline the benefits and risks of transfer.

Response: We agree and, based upon this comment and section 6211(c)(1) of OBRA 89, are revising § 489.24(d)(1)(ii)(A) to provide that requests for transfer must be in writing and signed by the individual requesting the transfer or by a legally responsible person acting on the individual's behalf. The requests should contain a brief statement of the hospital's obligations under the statute and the benefits and risks that were outlined to the person signing the request. The request should be made a part of the patient's medical record, and a copy of it should be sent to the receiving facility along with the individual transferred. It is reasonable to conclude that, by permitting requests for transfer to be made only by the individual or a legally responsible person acting on the individual's behalf, Congress intended requests to be documented in the manner suggested by the commenter. Moreover, this requirement will reduce litigation about whether an individual requested the transfer.

Comment: Three commenters recommended that a person acting on the patient's behalf does not have to be "legally" responsible for the patient.

Response: We agree and are revising §§ 489.24(c)(2) and (c)(4) to reflect this change because section 9307 of OBRA 86 deleted the phrase "legally responsible" from sections 1867(b)(2) and (b)(3) of the Act. However, as section 1867(c) of the Act continues to contain the phrase "legally responsible", it is being retained in § 489.24(d).

Medical Records and Certification

Comment: Three commenters suggested we specify in the regulations what constitutes a certification that a transfer is in the patient's best interests. They asked if an entry in the patient's medical record would be sufficient certification.

Response: Before an unstabilized individual may be transferred in the absence of a request for transfer, the statute requires a physician to sign a certification that based upon the information available at the time, the medical benefits reasonably expected from appropriate medical treatment at another medical facility outweigh the increased risks to the individual and, in the case of labor, to the unborn child, from effecting the transfer. If a physician is not physically present in the emergency department at the time of transfer, a qualified medical person may sign the certification after consulting with a physician who later countersigns that certification. Section 1867(c)(1)(A)(ii) and (iii) of the Act, both as added by COBRA (section 9121(b)) and revised by OBRA 89 (section 6211(c)(4)), requires an express written certification by a physician or other qualified medical personnel attesting to the elements just delineated; the certification, while it may be written explicitly into the medical record, cannot simply be inferred from the findings in the medical record and the fact that the individual was transferred.

We agree with the Fifth Circuit, in *Burditt* v. *U.S. Dept. of Health and Human Services*, 934 F.2d 1362 (5th Cir. 1991) wherein the court, in addressing whether there had been a knowing violation of section 1867 of the Act, held that:

> A hospital may violate [the certification] provision in four ways. First, before transfer, the hospital might fail to secure the required signature from the appropriate medical personnel on a certification form. But the statute requires more than a signature; it requires a signed certification. Thus, the hospital also violates the statute if the signer has not actually deliberated and weighed the medical risks and the medical benefits of transfer before executing the certification. Likewise, the hospital fails to make the certification required by 42 U.S.C. 1395dd(c)(1)(A)(ii) if the signer makes an improper consideration a significant factor in the certification decision. Finally a hospital violates the statute if the signer actually concludes in the weighing process that the medical risks outweigh the medical benefits of transfer, yet signs a certification that the opposite is true.

Section 1867(d)(1)(B)(i) of the Act, as amended by section 6211(e) of OBRA 89, now allows imposition of civil monetary penalties if the physician "knew or should have known that the benefits did not outweigh the risks." We are therefore revising § 489.24(d)(1)(ii)(B) to require that a certification state the reasons for the transfer and include a summary of the risks and benefits upon which it is based. As the statute requires that a physician or other qualified medical personnel in consultation with a physician weigh the benefits and risks associated with the transfer before an unstabilized individual may be transferred, it should not be unduly burdensome for the physician or other medical personnel to state the risks and benefits that have been weighed. It should be noted, however, that, under the statute, the physician, not the qualified medical personnel, makes the transfer determination in all cases. The narrative rationale need not be a lengthy discussion of the individual's medical condition reiterating facts already contained in the medical record, but it should give a complete picture of the benefits to be expected from appropriate care at the receiving facility and the risks associated with the transfer, including the time away from an acute care setting necessary to effect the transfer.

Revised § 489.24(d)(2)(iii) (formerly a part of paragraph (d)(2)(ii)) requires that the certification be included in the individual's medical record and that it be sent to the receiving hospital along with the transferred individual. We believe that this will assist the receiving hospitals in determining whether the individual was transferred appropriately under the statute.

Comment: Three commenters believe it is unreasonable and burdensome to require physicians to sign for every patient transferred and that it is unduly harsh to assess a criminal penalty for a decision that could be a mistake.

Response: Section 1867(c)(1)(A)(ii) of the Act requires a physician to certify patient transfers because it was the intent of Congress to protect emergency patients and women in labor against erroneous transfers. However, the statute and the regulations do allow other qualified medical personnel, in consultation with a physician, to certify patient transfers when a physician is not physically present in the emergency department so long as the physician later countersigns. Penalties, however, are civil in nature, not criminal.

Comment: One commenter wants the regulations revised to require that medical records accompany not only unstabilized but stabilized patients being transferred.

Response: We see no need to revise these medical record requirements of the regulation. Records must accompany an individual whether or not his or her condition is stabilized. Under § 489.24(d)(2)(iii) (formerly paragraph (d)(2)(ii)), hospitals transferring

unstabilized individuals must provide the receiving facility with all medical records related to the emergency condition for which the individual has presented in addition to other information required by the statute and regulations. Under the current conditions of participation for hospitals (§ 482.21(b)(2)), all patients, including stabilized patients being discharged from hospitals to other facilities and agencies, must be accompanied by necessary medical information. This is a routine requirement that was in place before the dumping statute was enacted.

Comment: One commenter stated that in order for a receiving hospital to make an informed assessment about whether a transferring hospital has inappropriately transferred an individual, the transferring hospital should be required to send a memorandum of transfer, any consent or refusal forms signed by the patient, and reports by the doctors.

Response: We agree that it would be helpful for many reasons for the receiving hospital to have the individual's medical record at the time the individual is actually transferred. The medical record usually includes doctors' reports, consent or refusal forms and transfer certifications. We are therefore amending proposed § 489.24(d)(2)(ii) (now paragraph (d)(2)(iii)) to require a transferring hospital to send with the transferred individual whatever records are available at the time and place of the transfer.

Comment: Four commenters wanted the regulations to specify what information is to be in the "appropriate medical records" and listed what they thought should be in them, including, in one case, records of previous admissions.

Response: We agree with this comment, and section 6211(d)(2) of OBRA 89 amended section 1867(c)(2)(C) of the Act to address this issue. The statute now directs transferring hospitals to send receiving hospitals all medical records related to the individual's emergency condition "available at the time of transfer" (note next Comment and Response) and specifically lists some of the information that should be included in these records. We have, therefore, amended proposed § 489.24(d)(2)(ii) (now paragraph (d)(2)(iii)) to reflect the new legislative requirements. The conditions of participation in § 482.24(c) contain other Federal requirements relating to medical records. To the extent that services are performed before transfer we expect them to be reflected in the records transferred, consistent with the conditions of participation. Although it may be desirable, depending on the patient's condition, to send along records of previous admissions, the patient's transfer should not be delayed.

Comment: Several commenters recommended that "timely" medical records be defined as those available at the time the patient is transferred. Those commenters also recommended that records, such as test results, that were not available at the time of transfer should be sent to the receiving hospital as soon as possible.

Response: We agree with both points, and we have amended proposed § 489.24(d)(2)(ii) (now paragraph (d)(2)(iii)) accordingly to require that a transferring hospital send with the transferred individual whatever records (including copies of results of diagnostic studies or telephone reports of the studies) are available at the time and place of the transfer. If a transfer is in an individual's best interests, it should not be delayed until records are retrieved or test results come back from the laboratory. Whatever documents are available at the time the individual is transferred should be sent to the receiving hospital with the individual. Test results that become available after the individual is transferred should be telephoned to the receiving hospital. Records that become available after the patient is transferred, such as hard copies of test results or relevant records of earlier admissions, for example, should be sent to the receiving hospital as expeditiously as possible.

Comment: Two commenters wanted us to define what medical personnel may be qualified, in addition to the physician, to certify that a transfer is appropriate.

Response: The regulations require hospitals to determine which of their personnel are qualified to certify, in consultation with a physician who later countersigns, that a transfer is appropriate. This decision will vary among hospitals and States as availability, qualifications, and practice limitations of a particular category of staff differ. HCFA holds the governing body of a hospital responsible for assuring that its staff functions within the bounds of State law and this and other federal health and safety regulations. Based upon these comments and section 6211(c)(2)(D) of OBRA 89, we are amending § 489.24(d)(1)(ii)(C) to specify that, if a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person may sign a certification stating that the transfer is in the individual's best interest. However, the qualified medical person may sign a transfer certification only after a physician, in consultation with the qualified medical person, has made the determination to transfer. The physician must subsequently countersign the certification. The regulation also provides that the hospital must determine who are "other qualified medical personnel."

Transportation

Comment: One commenter wanted us to recognize that requiring trained emergency medical technicians to accompany a patient being transferred will meet the requirements that a transfer be effected through "qualified personnel" as required under proposed § 489.24(d)(2)(iii) (now paragraph (d)(2)(iv)) because, in many communities, transfers are made by volunteer rescue squads with trained emergency medical technicians.

Response: We cannot state unequivocally that emergency medical technicians are "qualified personnel" for purposes of transferring an individual under these regulations. Depending on the individual's condition, there may be situations in which a physician's presence, or some other specialist's presence, might be mandatory.

Comment: One commenter proposed that we amend the regulations to clarify that the hospital is responsible for providing transportation services, either directly or indirectly, stating that the proposed regulations did not address the need for the hospital to provide transportation services to carry out the physician's orders.

Response: We disagree. The statute (section 1867(c)(2)(C) of the Act) imposes a duty on the hospital to ensure that the transfer is effected through qualified personnel and transportation equipment. Frequently the determination of what equipment and personnel will be required will be a medical decision. The hospital by-laws, rules and regulations, or State law may dictate that the decision be made by the transferring physician. If the hospital delegates its duty under the statute to the transferring physician, both the hospital and physician would be obligated to ensure that the transfer is effected through qualified personnel and necessary equipment. To say that the hospital is ultimately responsible for ensuring that the transfer is appropriately effected is not, however, to dictate the means by which it meets that responsibility. Neither the statute nor the regulations requires a hospital to operate an emergency medical transport

service. To this extent, the hospital may meet its obligations as it sees fit; however, that does not mean HHS must accept the hospital's determination.

We also note that with regard to the general area of transportation, although no specific comments were received concerning "transportation equipment", the term has now been interpreted to include all physical objects reasonably medically necessary for safe patient transfer. *Burditt* v. *U.S. Dept. of Health and Human Services*, 934 F.2d 1362, 1373 (5th Cir. 1991). We agree with this interpretation. To limit the appropriate transfer requirement to just that equipment that is necessary and medically appropriate for life support measures is too narrow an interpretation.

Other Requirements

Comment: Five commenters wrote in response to our request for comments concerning the "other requirements" the Secretary may find necessary in the best interests of transferred patients' health and safety. They recommended that we require the use of a standardized memorandum of transfer to be sent with every transferred patient to be signed by both transferring and receiving physicians and to include information regarding the patient's medical condition, treatment received and reasons for transfer. One of the commenters also recommended that calls between hospitals requesting transfers be tape recorded.

Another commenter suggested that the certification requirement in proposed § 489.24(d)(1)(i)(B) (now § 489.24(d)(1)(ii)(B)) be made a part of a standard transfer form. The commenters believed these suggestions would educate hospital personnel, provide a record for enforcement of the statute, help assure that the receiving physicians receive appropriate medical information for each patient, and deter patient dumping.

Response: We believe that the requirements for requests for transfer, certification, and the sending of medical records are sufficient to provide the information necessary for the receiving hospital to treat the individual and to detect inappropriate transfers in order to fulfill its reporting requirement. While a memorandum of transfer might provide a useful summary, we do not believe it is necessary in light of our other requirements. Also note the earlier Comment and Response concerning another recommendation for the use of memoranda of transfer. Hospitals that frequently receive inappropriate transfers may choose to document their transfers by tape recording telephone requests in accordance with applicable State laws; however, we believe it both costly and impractical to require all hospitals to invest in technology to document transfer circumstances verbatim in this way. In addition, since these additional requirements would need to be adopted through the rulemaking process and the Secretary has not elected to establish further requirements in this regulation, we are not including in this final rule the language in proposed § 489.24(d)(2)(iv) concerning other requirements to avoid the implication that there may be additional requirements not included in this regulation.

"Appropriate" Transfer

Comment: One commenter raised the issue of whether all transfers must be appropriately made (that is, effectuated) or whether the rules governing appropriateness applied only to a physician-directed transfer.

Response: All transfers must be effectuated appropriately and the statute and regulations already make this point. It is true that an individual may demand a transfer that the physician does not believe is appropriate, but once the decision to transfer has been made—by the physician or the individual—the regulations and the law require that it be done appropriately.

Also with regard to appropriate transfers, we note that the Secretary has taken the position that in proving that a hospital or physician violated section 1867 of the Act, there is no requirement to prove that the transfer was effected due to some "impermissible motive." This position has been upheld in *Burditt* v. *U.S. Dept. of Health and Human Services*, 934 F.2d 1362, 1373 (5th Cir. 1991), wherein the court rejected Dr. Burditt's argument that the statute requires proof that the transfer was motivated by an improper or nonmedical reason.

Comment: One commenter thought that the phrase "without prior arrangement" in § 489.20(g) may imply that a hospital may transfer a patient in violation of § 489.24 if it is done with prior arrangement.

Response: We agree and are removing the phrase "without prior arrangement."

Comment: Two commenters believed that we should make the requirements for appropriate transfer more specific. Another raised a series of hypothetical questions and asked how the regulations would apply.

Response: We decline the invitation to attempt to define in advance all circumstances making the transfer of an unstabilized individual "appropriate." There will be many medical emergencies arising in a variety of settings. The proper handling of those emergencies will depend upon the resources available and the exercise of medical judgment focused on the best interest of the individual's health and safety. We find the broad guidelines offered by Congress in section 1867(c)(2)(C) of the Act sufficiently specific to guide the exercise of that discretion and our evaluation of cases in which dumping is alleged. For the present we do not believe that any additional elaboration is required or desirable.

Comment: One commenter suggested that the regulations prevent any transfers, including those of stable patients, unless that patient requires services or facilities not available at the hospital when the patient first arrived. Another commenter wanted "stable" patients to be subject to the same "appropriate transfer" criteria as patients in unstable condition because the regulatory definition of "stabilized" does not require the emergency medical condition to be alleviated; it only requires that no material deterioration be likely.

Response: To accept these comments would go beyond the scope of the statute, which does not regulate the transfer of stabilized individuals. The statute allows hospitals to transfer an individual, without meeting the requirements of an appropriate transfer, after his or her emergency medical condition is stabilized. The statute does require, however, that the transferring hospital provide whatever medical treatment it can, within its capacity, to minimize the risks to the individual with an unstabilized medical condition, and, in the case of a woman in labor, to the unborn child.

Comment: One commenter wanted the regulations to define the situations in which obstetrical transfers are appropriate because in the commenter's State, hospitals that do not offer obstetrical services must always transfer pregnant patients in active labor, especially high risk patients.

Response: It is not necessary to revise the regulations to be this specific. Regardless of practices within the State, COBRA and OBRA 89 permit a woman in labor or with an unstabilized emergency medical condition to be transferred only if she (or someone acting on her behalf) requests the transfer or if a physician signs a certification that the benefits outweigh the risks. If the hospital does not provide obstetrical services, the benefits may outweigh the risks of transfer or the woman or her representative may request a transfer. However, we cannot

say categorically and in all cases that this will be true. (Note also Response to next Comment.) Regardless of State law or practice, a hospital must fulfill the requirements of the statute and cannot simply cite State law or practice as the basis for a transfer under the statute. We note that OBRA 89 removed the term "active labor" from section 1867 of the Act and included the full range of symptoms that term was intended to include within the scope of the term "emergency medical condition," which it redefined.

Comment: A number of commenters suggested that we require a hospital to accept a transfer when it has the capacity to treat the patient and the requesting hospital does not. One suggested that we require, as JCAHO does, that hospitals help to develop and promote community-based plans for providing emergency services.

Response: If an individual is to be transferred, section 1867(c)(2)(B)(ii) of the Act requires that the hospital obtain agreement from the receiving hospital before a transfer is made. The changes made to title XVIII of the Act by COBRA did not require hospitals to accept all transfers, even when the transfer would be in the individual's best interest. However, under the nondiscrimination provision of section 1867(g) of the Act, as added by section 6211(f) of OBRA 89, hospitals with specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers as defined in § 412.96), cannot refuse to accept an appropriate transfer of an individual who requires such specialized capabilities or facilities if the hospital has the capacity to treat the individual. Accordingly, we have added the nondiscrimination provision to § 489.24 as new paragraph (e).

In determining whether new § 489.24(e) applies, we will assess whether the individual required the recipient hospital's specialized capabilities or facilities and if the hospital had the capacity to treat the individual. The recipient hospital with specialized capabilities or facilities has an obligation under section 1867(g) of the Act to accept a transfer if the individual has an unstabilized emergency medical condition and if the hospital has the capacity to treat the individual. If a hospital desires to transfer an individual to another hospital and the individual does not require any treatment beyond the capabilities or facilities available at the transferring hospital, the intended receiving hospital may refuse to accept the transfer of the individual in accordance with section 1867(c)(2)(B)(ii) of the Act.

The purpose of this requirement is to prevent hospitals with emergency departments from automatically transferring patients before screening simply because the hospital does not offer a particular service. For example, a hospital with an obstetrical department is not required to accept a transfer of a woman in labor just because the transferring hospital does not have an obstetrical department. If the woman in labor is having a normal, uncomplicated delivery, and the first hospital has the capacity to handle a normal, uncomplicated delivery, despite the fact that it does not have an obstetrical department, the first hospital is required under section 1867(b) of the Act to provide the necessary stabilizing treatment, that is to deliver the baby and the placenta, or to effect an appropriate transfer to another hospital willing to accept the patient. Similarly, for an individual with a simple, closed fractured arm, a hospital with an orthopedic department and orthopedic physicians on call would not be required to accept a transfer of the individual just because the transferring hospital does not have an orthopedic service. The first hospital is required under section 1867(b) of the Act to provide the necessary stabilizing treatment or to effect an appropriate transfer to another hospital willing to accept the patient.

If a transferring hospital does not have the specialized capabilities necessary to stabilize the patient's condition, the intended receiving hospital with the specialized capabilities and facilities must accept the patient under 1867(g) of the Act if it has the capacity to treat the individual. The number of patients that may be occupying a specialized unit, the number of staff on duty, or the amount of equipment on the hospital's premises do not in and of themselves reflect the capacity of the hospital to care for additional patients. If a hospital generally has accommodated additional patients by whatever means (for example, moving patients to other units, calling in additional staff, borrowing equipment from other facilities) it has demonstrated the ability to provide services to patients in excess of its occupancy limit. For example, a hospital may be able to care for one or more severe burn patients (a common example of specialized service) without opening up a "burn unit." In this example, if the hospital has the capacity, the hospital would have a duty to accept an appropriate transfer of an individual requiring the hospital's capabilities, provided the transferring hospital lacked the specialized services required to stabilize the individual.

Situations may arise where a hospital in another country desires to transfer an individual to a United States hospital because of the United States hospital's specialized capabilities or facilities. However, we note that the provisions of section 1867 of the Act are applicable only when the transferring hospital is located within the boundaries of the United States. Accordingly, Medicare participating hospitals are not obligated to accept transfers from hospitals located outside of the boundaries of the United States. This does not change the requirement that a Medicare participating hospital that offers emergency services, must provide, upon request and within its capabilities, an appropriate medical screening examination, stabilizing treatment, and/or an appropriate transfer to another medical facility to any individual with an emergency medical condition, even if the individual is not a United States citizen.

Concerning community plans, the use of cooperative agreements to facilitate appropriate transfers would be a positive step, and we recognize that a suggestion for using the JCAHO approach is constructive; however, we do not believe that this regulation is an appropriate vehicle to mandate community-based plans for the delivery of emergency services.

Comment: One commenter suggested that after a patient is stabilized we require hospitals to undertake either medically indicated treatment or transfer the patient, rather than discharge him or her. The commenter stated that a person in stable condition could be seriously ill and, if discharged, the condition could worsen.

Response: Section 1867 of the Act does not impose any requirements on hospitals with respect to the treatment or transfer of individuals whose emergency condition has been stabilized.

Comment: One commenter suggested that we revise the definition of "appropriate transfer" to state that the receiving hospital "has indicated that it has available space and qualified personnel for the treatment of the patient." This would clarify the responsibility for determining the capability of the receiving hospital.

Response: We do not believe it is necessary to add any further specificity to this requirement because, as indicated above, it is understood that the records will have to verify that the receiving hospital has indicated to the transferring hospital that it has agreed to

treat the individual, which implies that it had the available space and qualified personnel to treat that individual.

Comment: Two commenters recommended that the regulations specify which person(s) at the receiving hospital may consent to receive the patient.

Response: We believe it is properly the receiving hospital's decision as to who may consent to receive patients and how to implement this policy among its staff.

Comment: One commenter suggested that the regulations specifically state that the transferring physician is legally responsible for the patient's care until the patient is admitted to the receiving hospital.

Response: We do not believe it is appropriate to make this an explicit requirement of the regulations. The statute makes clear that the transferring hospital is responsible for ensuring that when the individual is transferred, the transfer is "appropriate." The hospital, in ensuring that the individual is appropriately transferred, may, for example, delegate to the transferring physician the duty to ensure that the transfer is made through the use of appropriate personnel or equipment. Further, section 1867 of the Act and the regulations require that the hospital must provide medical care within its capabilities to minimize the risks associated with transfer; this too may be delegated to a physician. In this way, the physician may be responsible for the patient's care during the transfer.

Reporting Violations

Comment: One commenter suggested that we allow transferring and receiving hospitals an opportunity to work out an agreement for handling transfers before we mandate formal reporting procedures, which might have the unintended result of pitting one hospital against another.

Response: We encourage local hospitals, municipalities, and States to develop cooperative transfer agreements; however, the formal reporting procedures are an integral part of the Department's enforcement scheme to ensure that hospitals are complying with the statute. To the extent that hospitals do have agreements for handling transfers in accordance with the statute, and act in accordance with that agreement, then the statute will not be violated and the necessity for reporting violations will be diminished.

Comment: Four commenters believe that the requirement that hospitals report suspected violations of section 1867 of the Act within 72 hours of their occurrence is too rigid and should be changed to "with reasonable promptness" to deter excessive reporting and to allow for investigation by the hospital to assure that reporting is warranted.

Response: If transfers occur that needlessly jeopardize people's lives, HCFA must have that information immediately to meet its responsibility to assure that these inappropriate transfers cease quickly. Therefore, we have made no changes.

Comment: One commenter recommended that the 72-hour reporting requirement for receiving hospitals suspecting improper transfers should begin from the time a problem is first identified rather than from the date of the transfer.

Response: The time of the receipt of an improperly transferred patient is the time of the occurrence. We do not see any substantive time difference between the time of receipt and the time of identification that a patient had been improperly transferred. However, to make reporting less onerous, we are revising § 489.20(m) and § 489.53(a)(10) to require a hospital to report to either HCFA or the State agency, rather than both as proposed.

Comment: One commenter suggested that the regulation be amended to permit HCFA to terminate a receiving hospital only for a "knowing" failure to report suspected violations.

Response: We see no reason to require that HCFA prove that a hospital "knowingly" violated its obligation to report instances of suspected dumping before it may take action against a non-complying hospital. As with other conditions of participation imposed on providers for the protection of the health and safety of those benefitted by title XVIII, including those protected by section 1867 of the Act, whether a hospital fails to meet its obligations knowingly is of little concern to those the requirement is designed to benefit. We believe this is especially true since section 4008(b)(3) of OBRA 90 deleted the provision under which HCFA had to show first that the hospital's actions were either knowing and willful or negligent before terminating the hospital's provider agreement. We do not believe the enhanced enforcement and, hence, deterrence, behind requiring receiving hospitals to report instances of suspected dumping, would be advanced by adding any requirement that the violation be knowing before a hospital's failure to report could result in its termination. We expect hospitals to have and enforce policies and procedures to require its employees and staff physicians to report to the administration instances where an individual has been inappropriately transferred under this statute.

Comment: Two commenters believe that HCFA and State survey agencies should protect the receiving hospitals and their personnel from legal actions for reporting alleged cases of improper transfer.

Response: We do not have the authority to confer immunity on a provider that identifies an alleged improper transfer under these regulations. However, HCFA has a history of protecting the identity and confidentiality of entities who report program violations and this protection will be extended to hospitals and individuals reporting improper transfers. Additionally, we also note that section 4027(k)(3) of OBRA 90 amended section 1867(i) of the Act (Whistleblower Protections), which was enacted under OBRA 89, to prevent a hospital from penalizing or taking adverse action against any hospital employee because the employee reported a violation of this requirement. We have revised § 489.24(d)(3) of the regulations to reflect this statutory amendment.

Comment: Eight commenters claimed that the statute does not support the obligation to report suspected dumping or provide for the termination of a provider that does not report suspected violations. Five commenters suggested that we extend the responsibility to report suspected dumping violations to all Medicare providers and suppliers; ambulance service suppliers, in particular, are in a position to suspect violations if the hospital to which the ambulance is transporting the patient refuses to accept that patient. Several commenters recommended that the reporting requirements be extended to physicians and that a failure to comply with these requirements would subject the physician to a civil monetary penalty.

Response: We believe our requirements relating to reporting instances of dumping are supported by current law. Section 1861(e)(9) of the Act permits the Secretary to impose on hospitals such other requirements as he finds necessary in the interest of the health and safety of individuals who are furnished services in the institution. It is under this authority that the Secretary has obligated hospitals that participate in Medicare to report when they receive patients that have been inappropriately transferred. Under section 1866(b)(2) (A) and (B) of the Act, the Secretary may terminate the provider agreement of a hospital that is not complying substantially with the statute and

regulations under title XVIII or that no longer substantially meets the provisions of section 1861 of the Act.

Application of the anti-dumping provisions to all Medicare providers and suppliers should occur through a statutory amendment. Section 1867 of the Act imposes duties directly only on hospitals that provide emergency services to which individuals come for screening or treatment. No similar statutory authority generally exists to regulate the conduct of non-providers, suppliers and practitioners.

Comment: Many commenters believe that we should not require receiving hospitals to report suspected cases of dumping, since it may lead to overreporting or malicious reporting in addition to unnecessary work and extra costs for HCFA and hospitals.

Response: We disagree. We are looking to those institutions in the best position to discern when an inappropriate transfer has taken place in violation of the statute, because Congress regards them also as victims of "dumping". (See section 1867(d)(2)(B) of the Act.) This reporting requirement is not, however, an impediment to negotiation among hospitals for the care of emergency patients. Indeed, it should encourage hospitals to cooperate in planning for appropriate emergency care by eliminating inappropriate transfers.

Comment: Several commenters wanted us to define "suspected," so hospitals will have further guidance concerning when they must report violations. These commenters also recommended that we define which individuals in the hospital must hold the suspicion.

Response: We agree that "suspected" is a vague term. As a result we are revising proposed § 489.53(a)(10) to require a hospital to report violations when a hospital has reason to believe that a violation has occurred. However, we see no need to define which individuals in a hospital must hold the suspicion since we do not want to narrow the source of reports.

Definitions

Active Labor

Comment: Several commenters recommended that we adopt the definition of active labor used by the Office for Civil Rights (OCR) in enforcing a hospital's Hill-Burton obligations contained in 42 CFR 124.603(b). One commenter stated that there are also written decisions and directives interpreting this issue and that using the OCR definition would relieve Hill-Burton facilities of the risk of being required to comply with inconsistent treatment standards for women in active labor.

Response: We have not adopted the commenters' suggestion, because section 6211(h)(1)(B) of OBRA 89 deletes the definition of "active labor" in section 1867(e)(2) of the Act. However, the concepts contained in that definition have now been clarified and included in the definition of "emergency medical condition" defined in section 1867(e)(1) of the Act.

Comment: One commenter asked us to make it clear that even though it may be difficult to state whether delivery is imminent, a woman would be in "active labor" as that term is defined in section 1867(e)(2) of the Act (as added by COBRA), if there was either inadequate time to effect safe transfer to another hospital before delivery or if a transfer might pose a threat to the health and safety of the woman or the unborn child.

Response: We agree. The proposed regulation restated the statutory definition, and, hence, reiterated that the transfer of a woman in labor is subject to the provisions of section 1867 of the Act if any of the following three conditions pertain: (a) delivery is imminent; (b) there is inadequate time to effect safe transfer to another hospital prior to delivery; or (c) a transfer may pose a threat to the health and safety of the woman or the unborn child. Section 6211(h)(2) of OBRA 89 amended section 1867(e) of the Act by deleting both the term "active labor" and the part of the definition that covers women in labor where delivery is imminent. The definition of "emergency medical condition", however, was expanded to include a woman who is having contractions when there is inadequate time to effect safe transfer to another hospital before delivery or a woman who is having contractions where the transfer may impose a threat to the health or safety of the woman or the unborn child. The OBRA 89 amendments clarified the scope of the statutory protections. We have amended § 489.24(b) accordingly. In addition, the statute also refers to women in labor. We have defined the term "labor" in § 489.24(b).

Comment: Two commenters wanted the regulations to emphasize that the "active labor" definition applies only in prenatal situations in which no other prenatal emergency is present and that a pregnant woman with an emergency medical condition should be admitted even if not yet in active labor.

Response: The regulations that apply to emergency medical conditions apply equally to a pregnant woman whose emergency condition does not involve active labor. As noted above, OBRA 89 changes eliminated the term "active labor" and included pregnant women within the meaning of the term "emergency medical condition."

Emergency Medical Condition

Comment: Many commenters recommended that we adopt the definition of "emergency" used by the American College of Emergency Physicians (ACEP), standards that are already widely applied in the profession.

Response: We believe that the ACEP definition is not suitable for purposes of requirements under section 1867 of the Act because it is designed to assure that cases in which the patient believes that an emergency medical condition exists are, in fact, emergencies. We believe that section 1867 of the Act only applies to actual emergencies as determined by appropriate medical screening. Therefore, we have not adopted this recommendation.

Comment: One commenter asked us to cite the court cases from which the phrases "serious impairment to bodily function" and "serious dysfunction of any bodily organ or part" emanated.

Response: These phrases are taken directly from the definitions in section 1867(e)(1) of the statute. There is no legislative history that indicates that Congress took them from reported court decisions.

Comment: One commenter wanted the phrase "placing the patient's health in serious jeopardy" removed from the definition of emergency medical condition because it is not a result or an outcome from not providing emergency medical treatment but rather is only speculation.

Response: We do not agree to delete the phrase "placing the patient's health in serious jeopardy." The definition parallels the statute and as such reflects Congressional intent. All of the phrases contained in the definition of emergency medical condition describe outcomes that are likely to result from the denial of immediate attention upon the exercise of medical judgment to predict what would happen to the individual if appropriate medical attention was not provided immediately.

Comment: Nine commenters wanted the definition to include psychiatric emergency; one commenter wanted the definition to include acute alcohol or drug intoxication.

Response: We believe that the statutory definition already encompasses these types of cases. However, for clarification purposes, we have revised § 489.24(b) to add acute

alcohol or drug intoxication (substance abuse) and psychiatric manifestations as sufficiently severe medical symptoms to warrant the label "emergency medical condition."

Stabilized

Comment: Nine commenters stated that the definitions of "stabilized" or "stabilization" are too vague or ambiguous to be useful in determining whether a patient was appropriately transferred. Some commenters suggested alternative definitions while others suggested we prohibit transfers not based solely on explicit medical reasons.

Response: The statutory and regulatory definitions of "to stabilize" and "stabilized" are necessarily broad to apply to all types of emergency medical conditions. The basic precept of these definitions is to ensure that no material deterioration occurs to a patient's condition either as a result of the transfer or because the patient is outside a hospital, and thus without the facilities and services available in a hospital. We do believe, however, that at least one clarifying revision should be incorporated into the regulations to ensure that a patient with an emergency medical condition will not be transferred unless, within reasonable medical probability, no material deterioration of the condition is likely to result from, or occur during, the transfer. This revision is also consistent with section 6211(h)(1)(C)(ii) of OBRA 89. The regulations are being revised accordingly. The regulations do prohibit hospital-initiated transfers that are not based solely on explicit medical reasons. This does not imply, however, in proving that a hospital or physician violated section 1867 of the Act, that the Secretary must prove the transfer was effected due to an impermissible or nonmedical motive. (See *Burditt* v. *U.S. Department of Health and Human Services*, 934 F.2d 1362, 1373 (5th Cir. 1991).) It should be noted that the regulations also allow an individual to request and receive a transfer for any reason as long as the individual is aware of the risks and benefits of the transfer.

Comment: One commenter stated that a woman in active labor should never be considered stabilized until after the baby is born.

Response: COBRA and the proposed regulations require emergency medical conditions to be stabilized. We agree with the commenter and pursuant to sections 6211(c)(3)(A), 6211(c)(5)(B) and 6211(h)(1) of OBRA 89 we are revising § 489.24(b), (d)(1)(ii)(B) and (d)(2)(i) to indicate that a woman falling within the scope of section 1867(e)(1)(B) of the Act is not stabilized at least until the child and the woman's placenta are delivered.

Comment: One commenter suggested that the regulations mandate that if an individual is going through alcohol detoxification, 5 to 7 days is necessary to stabilize the condition.

Response: We cannot specify the length of time that it will take to stabilize a specific condition, as a specific time period would rarely be applicable in all cases. The statutory definition, as applied, prevents a hospital from transferring an individual who is going through alcohol detoxification if that condition constitutes an emergency medical condition, until that individual can make the transfer without a material deterioration of the condition occurring during, or resulting from, the transfer. Therefore, we are not adopting this suggestion.

Screening Examination

Comment: Several commenters asked us to define the term "appropriate medical screening examination" so that hospitals and physicians are not subject to ambiguous requirements.

Response: It is impossible to define in advance all of the circumstances in which an individual may come to a hospital emergency department. What will constitute an appropriate medical screening examination will vary according to the condition of the individual and the capabilities of the hospital's emergency department—both its facilities and available personnel, including on-call physicians. Within those capabilities, the examination must be sufficient to detect whether or not the individual has an emergency medical condition or is in labor because the law only requires hospitals to provide screening and stabilizing treatment within their existing capabilities. Our current condition of participation for emergency departments contains basic requirements, the specificity of which were subject to public comment in connection with the revision of the hospital conditions of participation.

Investigations

Comment: Six commenters recommended that HCFA should notify the involved hospital or physician of a decision to investigate.

Response: HCFA ordinarily conducts only unannounced surveys in response to complaints, as to do otherwise could compromise the investigation.

Comment: One commenter stated that we have not been informing complainants of the outcome of investigations; another recommended that we consult with complainants during the course of investigations, especially when there is conflicting evidence or the hospital raises mitigating circumstances.

Response: On June 4, 1987, HCFA issued interim implementing procedures requiring HCFA regional offices to notify complainants of the outcome of investigations. This is HCFA practice; complainants may address their specific inquiries to their respective HCFA regional offices. Complainants are consulted when there are conflicts.

Comment: Two commenters recommended that the OIG seek the maximum civil monetary penalty for every violation of the statute. One commenter believes that there should be a presumption in favor of imposing the statutory maximum and that a lack of prior offenses should not be considered a mitigating circumstance unless the hospital can produce a log of prior transfers showing its history of compliance.

Response: Congress did not specify a fixed monetary penalty for every violation. Instead, it provided for hospitals and responsible physicians to be subject to a civil monetary penalty "of not more than" $25,000 for violations occurring before December 22, 1987 and "of not more than" $50,000 for violations occurring on or after that date. The civil monetary penalty section was amended in OBRA 90 to provide a maximum penalty of $25,000 for hospitals with fewer than 100 state-licensed, Medicare-certified beds. By setting a maximum amount, Congress implied that the Secretary was to exercise her discretion in selecting an appropriate amount up to that maximum.

The OIG will not consider the lack of a prior history of offenses to be a mitigating circumstance, but it may consider a history of inappropriate transfers to be a factor that would warrant imposition of a penalty at or near the statutory maximum. Only if a hospital or physician could offer positive evidence of a history of statutory compliance (for example, by producing logs of its disposition of individuals who had come to the emergency department) would the OIG be inclined to regard the violation as an isolated aberration.

Comment: One commenter suggested that if the hospital has identified, evaluated, and taken action or determined that action need not be taken to correct a transfer or emergency care problem, a penalty should not be imposed against the hospital or responsible physician.

Response: We disagree. To deter future violations of the statute, Congress intended that violations be sanctioned regardless of whether a violating hospital took remedial action. Such remedial action may prevent the hospital from suffering the consequences of a termination of its provider agreement and the resulting loss of Medicare payment, but it does not shield it from liability for civil monetary penalties if the violations were negligent. Congress enacted section 1867 of the Act because it perceived that hospitals were not policing themselves sufficiently to prevent inappropriate transfers.

Comment: One commenter questioned how the regulations can impose a civil monetary penalty of up to $50,000 when the statute only allows a penalty of up to $25,000.

Response: Section 4009(a)(1) of OBRA 87 amended section 1867(d) of the Act to increase the maximum civil monetary penalty from $25,000 to $50,000, effective December 22, 1987. Any violation occurring after December 22, 1987 is therefore subject to a maximum fine of up to $50,000 while violations occurring prior to December 22, 1987 are only subject to a maximum fine of up to $25,000. We are amending 42 CFR 1003.103 accordingly. However, section 4008(b)(2) of OBRA 90 again amended the statute by reducing the maximum penalty against hospitals with fewer than 100 state-licensed, Medicare-certified beds of $25,000.

Comment: One commenter stated that civil monetary penalties of up to $50,000 constituted a criminal sanction that will place physicians in the position of balancing responsible medical judgment against the fear of fines for an unanticipated event that may occur during transfer; this will have negative effect on emergency care.

Response: The maximum amount of the penalty is determined by the statute and cannot be changed in these regulations. The statute expressly provides for a civil monetary penalty of not more than $50,000 if a hospital or physician who is responsible for the examination, treatment or transfer of an individual in a participating hospital violates a provision of section 1867 of the Act. This penalty is civil in nature and does not constitute a criminal sanction.

Civil Enforcement

Comment: One commenter stated that there is no statutory authority or Congressional intent allowing citizens to bring suit in the Federal courts for personal harm.

Response: Section 1867(d)(2)(A) of the Act specifies that an individual who suffers personal harm as a direct result of a hospital's violation may bring a civil action against the participating hospital, thus creating a Federal private right of action by such an individual. See *Bryant* v. *Riddle Memorial Hospital*, 689 F. Supp. 490 (E.D. Pa. 1988).

Preemption of State and Local Laws

Comment: Three commenters expressed concerns about the statutory provision that states that section 1867 of the Act does not preempt State or local law except where they conflict. One of these commenters thought that Federal law should not supersede State and local law except where the State is not fulfilling its obligation under the law; another commenter believed we should grant immunity to hospitals following Federal statute in conflict with State law. The third commenter said this provision would result in more State regulation where States have similar laws.

Response: Section 1867(f) of the Act explicitly states that the provisions of section 1867 do not preempt any State or local law requirement except in cases of a direct conflict. This statutory statement cannot be removed based on negative public comment. We believe, however, that the second commenter misunderstood the provision: when Federal law conflicts with State law, Federal law prevails.

Disclosure

Comment: One commenter believes that the investigative file on an alleged violation should not be subject to public disclosure.

Response: The Freedom of Information Act (5 U.S.C. 552) permits public access to agency records except to the extent that such records or parts thereof fall within specified exemptions under 5 U.S.C. 552(b). A statutory amendment would be required to adopt the commenter's suggestion, since there is no blanket exemption under the Freedom of Information Act for documents compiled in investigating complaints of violations of section 1867 of the Act.

Comment: Twelve commenters believe that it is not appropriate for HCFA to notify other components of the Department about alleged violations as each will then conduct its own investigations. The commenters recommended that HCFA notify the OIG and the Office for Civil Rights only when it determines that there was a violation.

Response: The authority for enforcing the requirements of this provision was delegated by law to the Secretary of Health and Human Services. All of the components of the Department mentioned by the commenters have responsibilities in connection with the enforcement of this provision and/or other provisions, such as the civil rights and rehabilitation acts. We believe it is entirely appropriate that these components be notified early in the process and begin to carry out their functions.

Comment: One commenter expressed concern that a provider may be subject to double jeopardy if HCFA is allowed to terminate the provider agreement for violating section 1867 of the Act and then, for the same violation, the OIG is authorized to suspend the provider. Several commenters expressed concern that a provider is subject to double jeopardy since, for an alleged single inappropriate transfer, OIG may suspend a provider and subject the provider to civil monetary penalties even if HCFA determines there is no violation.

Response: A provider agreement can no longer be suspended for a violation of section 1867 of the Act since, as we previously indicated, section 4008(b)(3) of OBRA 90 deleted the suspension provisions contained in the original legislation. If, however, HCFA begins a termination action based on a violation of the statute, but the hospital avoids termination by demonstrating to HCFA's satisfaction that it has in place effective policies and procedures to prevent a recurrence, the OIG remains free to seek civil monetary penalties against the hospital and physician for the violation of the statute on which the termination action was originally based.

Comment: Seven commenters believe that when HCFA notifies a complainant and other entities about the receipt of alleged violations, this implies guilt and may result in frivolous lawsuits.

Response: HCFA notifies organizations of complaints before investigating expressly to make the point that no decision has been made about the complaint but that an investigation is being conducted. We do not believe that the subject of a complaint should be unaware of the complaint, and we certainly do not believe that receipt of a complaint establishes or even implies that there is a violation.

Comment: One commenter stated that, in order to avoid duplication of effort, the regulations should limit OIG investigation to those cases where it finds a pattern of noncompliance, with willful violation of the provisions, or where there is some indication of fraud or abuse against the Medicare program.

Response: The law does not require a pattern of violations or willful noncompliance for the Department to invoke sanctions. The OIG may impose a civil monetary penalty for a single violation of the statute. The statute was amended in OBRA 90, however, to allow the OIG to exclude physicians from participation in the Medicare and State health care programs only if the violation is "gross and flagrant or repeated."

The term "gross and flagrant" is also used in section 1156 of the Act, 42 U.S.C. 1320c–5, and has been defined in regulations at 42 CFR 1004.1(b). This definition has been challenged for being unconstitutionally vague and the courts have disagreed, upholding the Department's interpretation of the term. See, for example, *Lavapies* v. *Bowen*, 883 F.2d 465 (6th Cir. 1989); *Doyle* v. *Secretary of Health and Human Services*, 848 F.2d 296 (1st Cir. 1988); *Varandani* v. *Bowen*, 824 F.2d 307 (4th Cir. 1987). It is against this background that Congress amended section 1867 of the Act to allow a physician to be excluded only if the violation is "gross and flagrant or repeated." ("The legislature is presumed to know the prior construction of the original act or code and if previously construed terms in the unamended sections are used in the amendment, it is indicated that the legislature intended to adopt the prior construction of those terms." Sutherland Stat. Const. § 22.35 (4th Ed.).) As a result, we have defined this term in § 1003.105 to be consistent with the definition contained in § 1004.1(b). The regulation now states:

> For purposes of this section, a gross and flagrant violation is one that presents an imminent danger to the health, safety, or well-being of the individual who seeks emergency examination and treatment or places that individual unnecessarily in a high-risk situation.

Comment: One commenter believes that HCFA and the OIG should coordinate enforcement activities to avoid duplication of effort and unnecessary administrative costs. In addition, the commenter suggested there be a central review to prevent components from taking multiple enforcement measures against a hospital or physician for the same violation.

Response: We agree that every effort should be made to coordinate enforcement actions. However, some of the issues relating to multiple enforcement measures have been mitigated by the amendments in OBRA 90 that deleted the suspension authority. HCFA's authority is to determine compliance with the requirements of section 1867 of the Act. The OIG has the authority for civil monetary penalties and physician exclusion from the Medicare program.

Comment: One commenter objected to the OIG, rather than the Secretary, having the discretion to waive an exclusion under § 1003.105.

Response: The Secretary has delegated the discretion to waive an exclusion under § 1003.105 to the OIG, and the regulations were amended in 1986 (51 FR 34777) to reflect this.

Comment: One commenter objected to suspending a provider from the Medicare program for a single instance of an inappropriate transfer.

Response: Section 4008(b)(3) of OBRA 90 deleted the suspension authority from section 1867(d) of the Act.

Comment: One commenter believes that the statute and the regulation will unduly penalize hospitals that are making good faith efforts to comply with the provisions.

Response: We disagree. As long as a hospital complies with the provisions it will not be subject to penalty.

Comment: Two commenters believe that active enforcement of these provisions will force many hospitals to close their emergency departments to avoid potential liabilities.

Response: We disagree. The impact of discontinuing an emergency services department, which is among the top income producers in a hospital, will outweigh the risk of potential losses due to violations of this regulation, especially since improved management of emergency departments can avoid the risk of violation.

Comment: One commenter stated that these regulations would give the government carte blanche authority to investigate any and all records for suspected violations. He felt that this ability would enable one hospital to slow down another with unnecessary, costly, and time-consuming investigations if it makes frivolous complaints about it.

Response: Congress has mandated that the Secretary enforce section 1867 of the Act. All credible alleged violations require a thorough investigation. Rather than overzealousness, the OIG has to date found and reported a marked reluctance on the part of hospitals to report suspected inappropriate transfers. (Office of Inspector General, "Patient Dumping After COBRA: Assessing the Incidences and the Perspectives of Health Care Professionals" (Aug. 1988).)

Comment: One commenter believes that the HCFA Administrator should retain the termination authority, rather than delegate it to the regional offices, as these termination decisions are best administered on a national level.

Response: All terminations are authorized by the respective HCFA regional office as part of its general responsibility for operating the survey and certification function for HCFA. This authority is delegated to the regional office because of its knowledge of State and local matters and its proximity to the providers it is overseeing and to the beneficiaries within its region.

Comment: Nineteen commenters objected that 2 days was too short a period to correct a problem or deficiency before a termination. One commenter agreed that the termination should occur within 2 days.

Response: Violations of section 1867 of the Act have the potential to be immediate and serious threats to patient health and safety. Therefore, we believe that it is essential that a violation that poses an immediate and serious threat be corrected as rapidly as possible.

In cases where it has been determined that the violation poses an immediate and serious threat to patient health and safety, a hospital will be placed on a 23-day termination track. On day 1, the hospital will receive a preliminary notice of termination from the regional office stating that a violation has been identified and that the projected date of termination will be on day 23. The preliminary notice of termination will also inform the hospital that the HCFA regional office will issue a final notice of termination and inform the public of the date of termination at least 2 days, but not more than 4 days, before the projected date of termination. Thus, the final notice to the hospital and the public concerning the termination of the hospital's provider agreement for a violation that poses an immediate and serious threat to patient health and safety will be issued between day 19 and day 21 of the 23-day termination track.

The preliminary notice of termination will also inform the hospital that it may avoid the termination action by either providing credible evidence of correction of the deficiencies or by successfully showing that the deficiencies did not exist. The hospital will have an opportunity to make such a showing to the regional office between day 1 and day 19 of the termination process. If the hospital is successful, the regional office will stop the termination process, and there will not be a public notice of termination. If verification of correction does not occur before the 19th day of the termination track, the hospital receives a final notice of termination, and the public is

concurrently notified by publication of the effective date of the termination in the newspaper.

In cases that do not involve an immediate and serious threat to patient health and safety, a hospital will be placed on a 90-day termination track. The hospital will receive a preliminary notice of termination on day 1, and will be notified that the projected termination date will be on day 90. We will continue our current practice, set forth in § 489.53(c)(1), of issuing a final notice of termination to the hospital and the public 15 days prior to the effective date of termination. Thus, in situations where the violation does not constitute an immediate and serious threat to patient health and safety, public notice of the effective date of the termination will be given on approximately day 75 of the 90-day termination process unless the hospital successfully shows that correction has occurred.

Comment: One commenter requested that a hospital be given an opportunity to meet informally with the State agency, HCFA and possibly a third party (such as a PRO) before HCFA makes a determination that there is a violation. Problems could be resolved without resorting to a termination.

Response: With regard to possible civil monetary penalties or physician exclusion, OBRA 90 responds to the commenter's suggestion. Under section 1154(a)(16) of the Act, as added by section 4027(a)(1)(B) of OBRA 90, PRO must provide reasonable notice of the review to the physician and hospital involved and a reasonable opportunity for discussion and submission of additional information prior to providing their report to HCFA. Thus, we believe that the commenter's concerns are mitigated by this new statutory language.

With regard to termination, HCFA regional office staff may meet with the hospital's representatives before determining compliance or noncompliance if they decide they need additional information to make a compliance determination. If, after reviewing the State agency finding and medical review findings (if requested), the regional office staff has sufficient information to make a determination, they may decide not to meet informally with the hospital's representatives. Options for resolving the deficiencies do not affect the compliance determination.

Comment: One commenter stated that mandatory termination is not consistent with the statute. Seven commenters recommended that the regulations not state that any violation will result in termination; termination should be imposed only for particularly egregious violations or a pattern of repeated violations. Several commenters questioned the basis for considering a violation to pose an immediate and serious threat, especially when there is only one violation. Five of these commenters thought single violations should be sanctioned with civil monetary penalties.

Response: Section 1866(b)(2) of the Act permits HCFA to terminate but does not require HCFA to do so. There are cases in which a violation has occurred but in which HCFA has not chosen to terminate. For example, if a routine recertification survey shows that a hospital's internal quality assurance identified a violation that occurred 6 months ago, and since then the hospital has been functioning effectively under a corrective action plan, and the hospital is in compliance with all other conditions of participation, HCFA may determine that although the hospital did violate the statute 6 months earlier, a termination is not warranted at the time of the survey.

The statute does not limit termination action to hospitals that have a pattern of violations. A single violation may result in the initiation of termination procedures. However, HCFA is more interested in hospitals correcting their deficiencies and remaining available to serve patients than in terminating them from Medicare participation. As a result, HCFA regional office staff have generally exercised their authority to permit correction before the effective date of termination as justification for rescinding the termination. On the other hand, hospitals that do not correct the deficiencies that permitted a violation to occur may represent an immediate and serious threat to people seeking emergency care. In such a case, HCFA will move quickly to either assure that the deficiencies that led to the violation are corrected or to terminate the hospital's provider agreement. It should be noted that section 4008(b)(3) of OBRA 90 deleted the termination and suspension language from section 1867(d) of the Act. Terminations due to violations of section 1867 of the Act are now subject to the regular provider agreement rules in section 1866 of the Act.

We believe that the immediate and serious threat concept applies to a provider's potential for causing harm as a result of lax policies and procedures as well as the danger posed by patently unsafe physical conditions or staffing shortages. Thus, we believe that operating in a manner that potentially subjects individuals to the threat of summary transfer without treatment may pose an immediate and serious threat to individuals who present themselves to the hospital for treatment. As noted above, if the provider is able to demonstrate that this is not the case, the termination is withdrawn and the provider's participation in the program is uninterrupted.

Hence, while a single violation may very well be sanctioned with civil monetary penalties, nothing in the statutory scheme suggests that the authority to terminate a hospital's provider agreement should be limited by the number of violations.

Comment: One commenter objected to the application of "fraud and abuse" concepts to quality of care issues; for example, degree of culpability of the hospital or responsible physician.

Response: The factors to be considered in determining the amount of civil monetary penalty that are set forth in § 1003.106(a)(4) are adapted from those mandated by section 1128A(d) of the Act. Section 1867(d)(1) of the Act requires that the provisions of section 1128A of the Act other than subsection (a) and subsection (b) apply to the imposition of a civil monetary penalty against a participating hospital and physician.

As thus incorporated by reference, section 1128A(d) of the Act requires that the OIG consider the nature of claims and circumstances under which they were presented, the degree of culpability, history of prior offenses, and financial condition of the person presenting the claims, and such other matters as justice may require.

We are revising proposed § 1003.106(a)(4) to reflect the essence of these statutory considerations as modified to fit violations of section 1867 of the Act. Section 1003.106(a)(4) also now includes among the factors "financial condition" and "nature and circumstances of the violation." These were omitted from the notice of proposed rulemaking but are required under section 1128A(d) of the Act.

Comment: One commenter stated that, before termination, HCFA should consider all circumstances of the case including such mitigating factors as: the previous sanction record of the hospital; the hospital's willingness and ability to comply with its obligations to emergency room patients; prior history of transfer; and the impact the termination may have on the community.

Response: Congress has provided that any hospital that has failed to comply with the requirements of section 1867 of the Act is subject to termination of its provider agreement. It did not provide, or suggest in legislative history, that the Secretary should create a system of

lesser measures to account for the factors mentioned by the commenter. Rather, it intended the gravity of the sanction to cause hospitals to comply with their obligations. When a hospital does violate its duties under section 1867 of the Act, we must take immediate action to prevent that hospital from jeopardizing the health and safety of the next person who may seek help in an emergency situation. Vigorous enforcement of these provisions is essential to remedy the problem that prompted Congress to legislate against the denial of screening and/or treatment and the inappropriate transfer of individuals with emergency medical conditions. A hospital will not suffer the loss of Medicare funding if it can demonstrate to HCFA's satisfaction that it has taken the steps necessary to ensure that the mandates of the statute are observed by its employees, contractors, and staff. If a hospital demonstrates its unwillingness or inability to meet that commitment within the time provided, it will be terminated. When a hospital has had a history of violations, the situation may make the regional office skeptical about the hospital's willingness and ability to enforce its own policies to guarantee that emergency services are available to all.

We recognize that the termination of a hospital's provider agreement would have a serious impact on the community. This is the remedy the law provides. We believe that this remedy provides the hospital (and its community) with the incentive to assure compliance.

Comment: One commenter wanted us to notify a hospital that it is under investigation and will be observed for a specific period of time to see if there is a pattern of inappropriate care and, if one is found, will be given a period of time to correct the problem before termination.

Response: In view of the nature of the problems that this provision addresses, it is not appropriate to take a general approach that permits a provided to avoid immediate inspection in all cases. The HCFA regional office will determine whether there is an advantage to conducting an unscheduled survey. We note, however, that when continued monitoring is appropriate to assure that corrective action has been taken, we will inform the provider of the period for which monitoring will continue.

Comment: One commenter believes that all violations, whether or not "knowing and willful, or negligent", should be subject to penalty. Another thought termination should only apply to knowing violations, as with civil monetary penalties.

Response: As we previously indicated, section 4008(b)(3) of OBRA 90 deleted section 1867(d)(1) of the Act, which provided for termination or suspension of a hospital's Medicare provider agreement for "knowingly and willfully, or negligently" failing to meet these statutory requirements. However, section 1866(a)(1)(I)(i) of the Act was also amended to require hospitals to meet the provisions of section 1867 in order to participate in the Medicare program. We have, therefore, revised § 489.24(f) of this regulation to delete the requirement that a hospital must knowingly and willfully, or negligently, fail to meet the regulation's requirements to be subject to termination. It should also be noted that because of the deletion of section 1867(d)(1) of the Act, hospitals are no longer subject to suspension of their provider agreement based upon violation of these provisions. By requiring that all hospitals comply with the provisions of section 1867 of the Act, Congress indicated that section 1867 violations by hospitals could result in termination of a hospital's Medicare provider agreement and civil monetary penalties. In addition, as discussed below, civil monetary penalties may now be imposed for a negligent, rather than a knowing, violation.

Comment: Two commenters suggested that the term "knowingly" be defined to include "should have known" to prevent physicians from escaping liability because the physician did not know of the law or the physician failed to inquire thoroughly about the patient's condition.

Response: The language of the statute does not permit us to adopt the commenter's suggestion. "Knowingly" is a legal term with a well-developed history. The accepted meaning of the term does not include "should have known." Indeed, the latter term denotes a lack of knowledge and is used in those contexts where a person is held liable for not knowing what he or she would have known had he or she exercised due care. A person need not know the terms of the statute in order to commit a knowing violation of the statute. A knowing violation of the statute requires only that the person do a proscribed act, knowing the character of the proscribed act. In this context, for example, a physician would knowingly violate the statute if he or she certified that the transfer of an individual with an emergency medical condition that had not been stabilized was in the best interests of the patient if the physician knew that the patient had an emergency condition that had not been stabilized and that the risks of transfer outweighed the benefits the physician could reasonably expect by the delivery of appropriate care in the receiving hospital. The physician would not need to know that section 1867 of the Act prohibited such transfer.

Although the term "knowingly" does not encompass "should have known," it does embrace the concepts of "reckless disregard" and "deliberate ignorance." That is, it includes a form of constructive knowledge in which an individual is deemed to have actual knowledge of the facts and circumstances about which he or she would have had knowledge if the individual had not deliberately or recklessly disregarded facts that were readily available. We are amending § 1003.102(c) to make it clear that the term "knowingly" encompasses these two concepts.

The statute was amended in OBRA 90, however, changing the standard for imposing civil monetary penalties from "knowingly" to "negligently" for violations on or after May 1, 1991. The term "negligently" encompasses the concept of "should have known."

Comment: One commenter suggested that § 1003.114 be amended to read: "The Inspector General must prove by a preponderance of evidence that the hospital and responsible physician or physicians knowingly failed to provide emergency care as described in § 1003.102(c)."

Response: Section 1003.114 was substantially rewritten in the OIG final regulations issued on January 29, 1992 (57 FR 3298) to essentially reflect the substance of this comment.

Comment: One commenter contended that we should not find any hospital or physician in violation of section 1867 of the Act until we have issued final regulations.

Response: We do not agree with this comment. The detailed language of the statute contains sufficient guidance to provide a legal basis for implementing its provisions before regulations are issued.

Comment: One commenter contended that the penalties in the proposed rule are too harsh because there are too many emergency department personnel to control all the time.

Response: The penalties in the proposed rule are statutory requirements and must be enforced by the Secretary.

Additionally, a hospital has always been responsible for the actions of all personnel it allows to provide services on site.

Comment: Two commenters believe we should include in the regulations the standards for determining what is a violation that will lead to termination and the procedures to be followed; otherwise, reviewing courts may find termination arbitrary.

Response: Hospitals in violation of the statute are subject to termination and civil monetary penalties. Thus, any substantiated violation may result in termination. Once these regulations are published, specific guidelines for assessing whether a case represents a violation will be included in the State Operations and Regional Office Medicare Certification Manuals. While the manuals in no way purport to be exhaustive in their description of potential section 1867 violations, they do provide a sense as to how HCFA intends to interpret this provision. The manuals are sent to HCFA's regional offices and each State agency. They are also available on a subscription basis from the Department of Commerce's National Technical Information Service, 5825 Port Royal Road, Springfield, Virginia, 22161. These manuals are continually updated to reflect new regulations.

Comment: Twenty commenters stated that we should not be able to terminate a provider without providing due process such as a hearing before an administrative law judge or some type of summary hearing; nine of the commenters asserted that the final decision should be appealable before a Federal court.

Response: This is an issue that has been litigated extensively in the past. The courts have widely held that due process for providers of health services under the Medicare program does not require a formal hearing before adverse action is taken. Our regulations at § 498.5(b) have long provided for a post-termination hearing before an administrative law judge for providers that have been terminated. Also, in accordance with § 498.5(c), any provider dissatisfied with a hearing decision may request Appeals Council review and has a right to seek judicial review of the Council's decision.

In addition, of course, providers that have been terminated always have the right to reapply for Medicare certification after correcting the deficiencies that led to the termination.

Comment: Two commenters believe that we should impose a timeframe on hospitals to obtain reinstatement.

Response: The statute at section 1866(c)(1) of the Act provides that a hospital that has been terminated from the Medicare program may not file another agreement unless the Secretary finds that the reason for the termination has been removed and that there is reasonable assurance that it will not recur. Thus, terminated hospitals may reapply for Medicare certification whenever they have corrected the deficiencies that caused the termination. We reserve the right to determine an appropriate reasonable assurance period before reinstatement on a case-by-case basis.

Comment: Four commenters stated that we should clarify how HCFA will monitor and enforce compliance with the regulations. They recommended that the regulations more specifically explain what constitutes a violation of these provisions and how HCFA will investigate violations and make negligence determinations.

Response: We will publish in our State Operations and Regional Office Manuals our investigation and enforcement procedures.

Comment: One commenter suggested that HCFA disclose the names of violators to the public and include them in the Medicare Data Base for adverse decisions. Another recommended that we also notify intermediaries and carriers.

Response: We agree. This information is published and is included in the Medicare Data Base and is passed on to intermediaries and carriers.

Comment: Two commenters suggested that we negotiate with PROs to provide case-by-case monitoring of patient dumping cases, since State survey agencies are not staffed or organized to do this. Another commenter recommended that we require PROs to report suspected violations and that we consider PRO information before concluding an investigation.

Response: Section 1867(d)(3) of the Act, as added by section 4027(a)(1) of OBRA 90, sets forth the role of PROs in patient dumping cases. Specifically, for sanctions imposed on or after February 1, 1991, section 1867(d)(3) of the Act requires the appropriate PRO to review the case prior to the imposition of a civil monetary penalty or physician exclusion sanction, except when a delay would jeopardize the health and safety of individuals or when an individual is denied a screening examination. Given this statutory direction, we do not believe it would be appropriate to place additional requirements on PROs in this regard.

Comment: One commenter recommended that HCFA require hospitals to maintain a record of the disposition of all individiuals seeking emergency care. If the individual were transferred, such a log would bear the initials of the physician authorizing the transfer and identify the reasons for the transfer, the receiving hospital, and the person accepting transfer for that hospital. Such records would educate hospital personnel about the statutory requirements, deter violations, and provide an audit trail to assist HHS in performing its monitoring and enforcement duties.

Another commenter suggested that we require each hospital to maintain a record of all patients it transfers and of those it receives, as recommended by Report No. 100–531 of the House Committee on Government Operations on March 25, 1988. Another commenter believes HCFA should periodically review a random sample of transfer files from every transferring and receiving hospital.

Response: We agree that the hospital must maintain a central log or record of how it handles every individual that comes to its emergency department for HHS and its agents to monitor compliance with the statute. The OIG has reported that a lack of a central record on the disposition of persons seeking emergency services hampers HHS' ability to monitor compliance (Office of Inspector General, "Patient Dumping After COBRA: Assessing the Incidences and the Perspectives of Health Care Professionals" (August 1988)). Hence, we are amending the regulations at § 489.20(r)(3) to require a hospital to maintain a central log of all individuals who come to its emergency room seeking assistance and the disposition of such individuals, whether they were or are refused treatment, transferred, admitted and treated, stabilized and transferred, or discharged. Such a record will permit HHS and the State survey and certification agencies to select and gain access to individual medical records for further inquiry. However, we are not prescribing a standard form at this time. Our condition of participation for medical record services, at § 482.24(b), requires hospitals to maintain a medical record for each inpatient and outpatient. Additionally, our enforcement procedures include a review of a simple of patient records. The sampling technique takes into account emergency room triage and unreimbursed care.

Approximately 80 percent of the 6600 hospitals participating in the Medicare program are accredited by the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). JCAHO-accredited hospitals are required to maintain a control register and initiate a medical record every time an individual visits the emergency service (Standard ES.6). The JCAHO-mandated control register must contain

at least the names of all persons (including the names of individuals dead on arrival) seeking care, as well as their age and sex; date, time, and means of arrival; nature of the complaint; disposition; and time of departure. The regulation at § 489.20(r)(3) merely requires the name of the individual and the disposition of his or her case. We believe maintaining a register of individuals seeking care is an industry standard and will not impose an additional burden on the 20 percent of hospitals that are not accredited. We have found a control register or control log to be invaluable in identifying records to be reviewed during our complaint investigations. We have not found any hospital that is not maintaining a log of some sort.

Comment: One commenter suggested that we clarify that hospitals and physicians investigated under these provisions be held to the standard of care based on accepted medical practice. Alternatively, they should be held to the standard of care utilized by the PROs under section 1154(a)(6)(A) of the Act.

Response: All physicians and hospitals are required to provide adequate medical care. PRO physician reviewers base their assessments on their education, training and experience, and assess the issues noted previously.

Comment: Two commenters recommended that we include provisions similar to the PRO quality assurance corrective action methods in section 1154 of the Act to allow for education and other actions to bring about positive improvement, instead of resorting to sanctions.

Response: This regulation emphasizes correction over sanctions. Hospitals that have violated these requirements are permitted the opportunity to correct the deficiencies and avoid termination. To date, 96 percent of violating hospitals have been able to avoid termination by correcting the deficiencies that led to the violations. However, the Department's primary responsibility is toward people who need health care, and in cases in which a hospital either cannot or does not correct its deficiencies, we believe it is appropriate to terminate the hospital from the Medicare program quickly. In addition, the law includes authority to exclude physicians and impose civil monetary penalties against hospitals and physicians. This serves as both a remedial function and a deterrent function. This may also motivate corrections and improvements to prevent future violations of the statute.

Comment: Three commenters indicated that hospitals should be involved in the investigation's fact finding process and should be advised of all evidence before HCFA receives the deficiency report. In addition, they recommended the hospital be permitted to submit documentation regarding the evidence and a response to the information submitted to HCFA, so that HCFA will have all the information before taking action.

Response: When the onsite investigation of a violation of section 1867 of the Act is completed, the hospital's representatives have an opportunity to be informed of the scope of the survey agency's investigation and findings at an exit conference. The survey agency, however, will inform the hospital that, unlike other surveys, an investigation of a violation of section 1867 of the Act usually does not end with its onsite investigation; it may require medical review. The HCFA regional office will make the final determination based on all of the relevant information, including the results of medical review, if needed.

When the regional office makes a determination of noncompliance, it will notify the hospital via a preliminary determination letter. The date the hospital receives the preliminary determination letter becomes the date for commencement of the termination process, which lasts approximately 23 days in situations where it has been determined that the violation resulted in an immediate and serious threat to patient health and safety, or approximately 90 days where the violation was not considered to pose an immediate and serious threat. If the regional office receives additional information that proves the hospital did not violate section 1867 of the Act, or regional office verification reveals that the hospital has taken remedial action to prevent further violations before the actual date of termination, the termination action will be rescinded. As noted in a previous response to a comment, if there was a violation of section 1867 of the Act and the hospital does not take corrective action, a final termination letter will be sent to the hospital and the public will be notified concurrently through a notice in the newspaper (at least 2 days, but no more than 4 days, before the actual termination date in immediate and serious threat situations, or at least 15 days before the actual termination date in situations that do not pose an immediate and serious threat). Therefore, the change in the notice requirement in immediate and serious threat situations offers the provider approximately 19 days to correct the deficiencies before termination becomes effective in immediate and serious threat cases and continues to offer the provider approximately 75 days to correct deficiencies before termination becomes effective for situations that do not pose an immediate and serious threat.

From the onset, the hospital is aware of the problem, HCFA's intended course of action, and that it must take corrective action or prove that the violation did not exist in order to halt the termination process. During and after this period, the hospital may submit documentation regarding the violation if it chooses; however, the termination process continues until proof is submitted to establish that a violation had not occurred, corrective action is verified, or the termination date is reached. HCFA's primary responsibility is to the people who come to the hospital in emergency situations. Their urgent need for proper medical care is a higher priority than providing for time-consuming historical re-review before action is taken against a hospital with improper practices.

Comment: One commenter believes the OIG should revise its policy of prohibiting the PRO from consulting with the physician under investigation during the investigatory stage in cases in which the OIG requests an evaluation from the local PRO.

Response: Section 4027(a) of OBRA 90 added section 1867(d)(3) to the Act to require the OIG, in considering whether to impose a civil monetary penalty or physician exclusion, to obtain and consider PRO review except when a delay would jeopardize the health or safety of individuals.

The PRO, in turn, is required to assess whether the individual involved had an emergency medical condition that had not been stabilized and to provide the physician and hospital involved with a reasonable opportunity for discussion and to submit additional information.

Comment: One commenter disagreed with HCFA's intention to rely on State survey agencies to investigate initial complaints of violation because in many States these agencies have an inherent conflict of interest. The commenter recommended that, to guarantee that there are no conflicts of interest, HCFA should at least apply certain minimum performance standards and investigatory guidelines in determining in which States the State survey agency can be entrusted with the role of investigating complaints.

Response: As provided for by section 1864(c) of the Act, HCFA contracts with the State survey agency to conduct

surveys to evaluate compliance with Federal health and safety requirements. We provide training, survey report forms and interpretive guidelines and perform Federal surveys and oversight to monitor the States' performances. Consequently, we are confident of the States' abilities to conduct compliant investigations.

Comment: One commenter believes that complainants should be asked but not required to give their names or other identifying information, as many anonymous complaints have proven reliable in other health care enforcement contexts.

These complaints are often made by hospital employees, who are in a position to know what constitutes an actual violation and who are fearful of losing their jobs if identified.

Response: We agree that requesting, rather than requiring, a complainant's name would protect an employee with anonymity. This will be reflected in HCFA's revised Medicare Survey and Certification, State Operations and Regional Office Manuals instructions. We also note, as previously indicated, under section 4027(k)(3) of OBRA 90 hospitals are not allowed to penalize or take action against any hospital employee because the employee reported a violation of these provisions.

State Agency Involvement

Comment: Two commenters believe that our regulations dealing with documentation of findings at § 405.1903(d) (recodified as § 488.18(d)) should be revised to require State survey agencies to forward all complaints to HCFA, not just those they deem "credible", in order to maintain the integrity of the enforcement process.

Response: We agree that HCFA should decide whether a complaint alleges a violation of these requirements and warrants an investigation. We are revising recodified § 488.18(d), accordingly.

Physician Role

Comment: Three commenters contended that the regulations should differentiate more between the roles and responsibilities of physicians and hospitals in determining whether a hospital has violated section 1867 of the Act, as hospitals do not have the legal authority to admit, transfer or discharge patients.

Response: The statute imposes duties on a hospital, many of which can only be effectively carried out by physicians in some way affiliated with the hospital. Neither the statute nor the regulations attempt to define the means by which the hospital meets its statutory obligations to provide emergency screening examination, treatment or transfer.

Comment: Three commenters raised a question concerning the hospital's responsibility in a case in which a physician who is not responsible for providing emergency care, but whose specialty is required to perform stabilizing care, refuses to treat or examine a patient.

Response: Although the term "responsible physician" is no longer used in the statute, the Department has maintained the term in these regulations, defining it to be consistent with the present statute. Hence, the definition of a "responsible physician" as drafted in these regulations includes any physician to whom the hospital has delegated responsibility to examine, treat, or transfer an individual that comes to the hospital emergency department seeking help. A hospital may use physicians on its medical staff to carry out its responsibilities under the statute. As indicated in the OBRA 89 amendments to section 1867, these physicians, including those who provide emergency services on-call as a condition of enjoying staff privileges, may be held liable for violating the statute and regulations.

Comment: One commenter recommended that "responsible physician" be defined to prevent a physician from being held liable for not providing treatment that is beyond his clinical area of competence or hospital privileges or for treatment decisions that are made in the physician's absence when the physician is available only by telephone.

Response: We do not believe that the comment requires a change in the definition. The commenter is concerned that a physician not be held responsible for aspects of an individual's care that are beyond his competence or hospital privileges. Consistent with the statute, the regulations use the term "responsible physician" to denote a physician with the responsibility to examine, treat, or transfer a patient. A hospital cannot require a physician to perform duties that are either beyond the physician's competence or the scope of the physician's hospital privileges.

On the other hand, where a responsible physician makes treatment or transfer decisions by telephone, the physician remains liable for such decisions.

Comment: Several commenters believe that the definition of "responsible physician" should include any physician on the hospital medical staff, including on-call physicians.

Response: We have amended the definition of "responsible physician" to comport with the OBRA 89 amendments to section 1867 of the Act. The definition encompasses any physician, including those physicians on-call, to whom the hospital has delegated responsibility to examine, treat, or transfer an individual that comes to the hospital emergency department seeking help. A hospital may use physicians on its medical staff to carry out its responsibilities under the statute. OBRA 89 amended section 1866(a)(1)(I) of the Act to require the hospital, as a condition of participation, to "maintain a list of physicians who are on-call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition."

Comment: One commenter asked about the hospital's liability when the attending physician determines that the patient requires the skills of a specialist who has staff privileges, but the specialist has never agreed to provide emergency services.

Response: As previously indicated, pursuant to OBRA 89, the hospital has a duty to ensure that, within the capabilities of the hospital's staff and facility, the medical needs of an individual who comes to an emergency room can be met. The hospital's capabilities include the skills of a specialist who has staff privileges to the extent that the hospital can require the specialist to furnish these services. However, it is up to the hospital to determine how it will comply with its statutory obligations.

Comment: One commenter recommended that the regulations exempt from liability a physician who attempts to admit a patient if the hospital refuses admission.

Response: To be a responsible physician under the terms of the statute and regulations, a physician must be responsible for examining, treating, or transferring an individual whom the statute protects. If an emergency room physician, for example, is under contract with the hospital to provide emergency care and treatment, but does not have admitting privileges, that physician is still under an obligation to provide an appropriate medical screening examination and either stabilizing treatment within the capabilities of the staff and facilities of the hospital or an appropriate transfer under the statute. Section 1867(d)(1)(C) of the Act specifically states that if a physician determines that an "individual requires the services of a physician listed by the hospital on its list of on-call physicians . . . and

notifies the on-call physician and the on-call physician fails or refuses to appear within a reasonable period of time, and the physician orders the transfer of the individual because," without the on-call physician's services, the benefits of transfer outweigh the risks of transfer, the transferring physician will not be subject to penalties under section 1867 of the Act. However, this does not absolve the hospital and the on-call physician from liability under the statute.

Comment: One commenter believes that these regulations may cause emergency room physicians to hesitate to transfer patients when appropriate because their decisions might be reviewed through hindsight and without consideration of the pressure of the specific circumstances.

Response: We do not agree with the commenter's contention. In reviewing allegations of patient dumping, we will look at all the information available to the treating or transferring physician at the time the decision is made. We believe that the physician's concern should be for the patient rather than for possible consequences of this requirement. To further strengthen the protection of emergency room physicians with regard to their transfer decisions, section 6211(f) of OBRA 89 added paragraph (i) to section 1867 of the Act to prevent hospitals from penalizing physicians who refuse to authorize the transfer of an individual with an unstabilized emergency medical condition. In addition, section 4027(k)(3) of OBRA 90 amended section 1867(i) of the Act to provide similar protection to qualified medical emergency room staff with regard to their transfer decisions when a physician is not available in the emergency room. We are amending § 489.24(d)(3) to include these new provisions so that it conforms to the statute as amended.

Miscellaneous

Comment: One commenter suggested that the regulations include the requirement that the patient or a third party payer must pay for the patient's medical screening or examination.

Response: A patient's obligations to pay for services provided by a hospital is beyond the scope of these regulations. However, if an individual is unable to pay for services, the hospital, nonetheless, remains subject to the requirements of the statute and regulations with respect to that individual. Section 1867(h) of the Act, as added by section 6211(f) of OBRA 89, states expressly that the "hospital may not delay provision of an appropriate medical screening examination . . . or further medical examination and treatment . . . to inquire about the individual's method of payment or insurance status."

Comment: One commenter stated that many managed health care plans require hospital emergency departments to call the plan for permission to examine and treat the plan's patients; the commenter believed that this violates the law. He also stated that a plan can retroactively determine that an emergency condition did not exist.

Response: Managed health care plans cannot deny a hospital permission to examine or treat their enrollees. They may only state what they will and will not pay for. However, regardless of whether a hospital is to be reimbursed for the treatment, it is obligated to provide the services specified in the statute.

Comment: One commenter contended that hospitals should not be allowed to pass along the costs of any civil monetary penalties to the Medicare or Medicaid programs.

Response: We agree; these penalties are not reimbursed by the Medicare or Medicaid programs.

V. OBRA 90: Peer Review Organization Review

As stated above in section II.D. of this preamble, Responsibilities of Medicare Participating Hospitals in Emergency Cases, and in several responses to comments, before imposing civil monetary penalties and exclusions, section 1867(d)(3) of the Act requires that we request the appropriate PRO to assess whether the individual involved had an emergency medical condition that had not been stabilized and report on its findings before the OIG may impose a civil monetary penalty or exclusion. [Note: PRO review is not required in cases where a delay in effecting a sanction would jeopardize the health or safety of individuals or in situations where medical review is inappropriate, for example, in cases where an individual was denied a medical screening examination.] The Secretary must provide the PRO with at least 60 days for the review. The PRO is required to provide reasonable notice of the review to the hospital and physician involved. The PRO is also required to provide them with a reasonable opportunity for discussion and an opportunity to submit additional information. This provision is effective for sanctions imposed on or after February 1, 1991.

During the possible termination phase of a case's development, the HCFA regional office has the responsibility and authority to make a determination of compliance or noncompliance. Termination procedures provide for an opportunity for the provider to comment. During this phase, the HCFA regional office is not required to instruct the PRO to offer the affected hospital an opportunity for discussion and submission of additional information. Subsequent to this phase, the OIG has the responsibility and authority to direct that the PRO conduct an assessment. In conducting such as assessment, the PRO is required to offer the affected physician and/or hospital an opportunity for discussion and submission of additional information before the PRO issues its report.

We are adding a new paragraph (g) to proposed § 489.24 to implement the statutory provision that PROs have at least 60 days to make their assessments and to specify that PROs must provide affected physicians and hospitals reasonable notice of review and opportunity for discussion and submission of additional information.

In addition, we are adding a new § 489.24(h) to clarify that, upon request, HCFA may release a PRO assessment to the physician or hospital (or both where applicable), or the affected individual, or his or her representative. However, we specify that the PRO physician's identity is confidential unless he or she consents to release his or her identity, in accordance with the PRO disclosure regulations set forth at §§ 476.132 and 476.133. If the case goes to litigation, the PRO is required to provide expert testimony and it is preferable, but not required, that the testifying physician be the same physician who reviewed and reported on the case.

As stated earlier, the statutory change requiring PRO review applies only in situations involving civil monetary penalties and exclusions. Termination proceedings pursuant to section 1866 of the Act as a result of violations of the anti-dumping provisions of section 1866 and section 1867 do not require PRO review. We note that a facility could be the subject of a termination proceeding and also be assessed civil monetary penalties.

VI. Summary of Revisions

In this interim final rule with comment period, we are adopting as final the provisions of the June 16, 1988 proposed rule, as amended by the revisions discussed below and clarifications discussed elsewhere in this preamble. (To accommodate changes to the Code of Federal Regulations since the publication of the June 16, 1988 proposed rule, proposed paragraphs (k) through (q) of § 489.20

have been redesignated as paragraphs (l) through (r).) Unless otherwise noted, revisions are based on our evaluation of public comments.

1. CHAMPUS, CHAMPVA and VA: We made no revisions.

2. Hospital discharge rights notice.

We have revised this section to eliminate the requirement that the beneficiary or his or her representative acknowledge receipt of the "Message" by signing the acknowledgement statement on the "Message." We have also eliminated the requirement that an acknowledgement of the "Message" be retained by the hospital. Instead, we will rely on hospitals to determine how they can best comply with the requirement that each beneficiary be provided with a discharge rights notice.

3. Hospital responsibility for emergency care.

We are revising the proposed regulations as discussed below.

• Section 489.20(m): We have clarified § 489.20(m) to eliminate any implication that a hospital may improperly transfer a patient as long as it is done with prior arrangement. In addition, we are requiring that when a hospital has reason to believe that an individual was transferred in violation of the requirements of § 489.24, it will report the violation to either HCFA or the State survey agency, rather than to both, as required by the proposed regulation.

• Section 489.20(q): We are adding provisions based on section 6018(a)(2) of OBRA 89, requiring hospitals to post conspicuously in their emergency departments signs specifying rights of individuals under section 1867 of the Act with respect to examination and treatment and to post conspicuously information indicating whether or not the hospital participates in the Medicaid program under a State plan approved under title XIX. Some public commenters also wrote in support of the posting of signs.

• Section 489.20(r)(1): Pursuant to section 6018(a)(1) of OBRA 89 and in response to public comment, we are adding the requirement that both transferring and receiving hospitals maintain medical and other records related to individuals transferred for a period of 5 years.

• Section 489.20(r)(2): Also pursuant to section 6018(a)(1) of OBRA 89 and public comment, we are adding the requirement that a hospital maintain a list of physicians who are on call for duty after the initial examination to provide treatment.

• Section 489.20(r)(3): We are requiring each hospital (both transferring and receiving) to keep a log of each individual who came to the emergency department seeking assistance and whether he or she refused treatment or was refused treatment, transferred, admitted and treated, stabilized and transferred, or discharged.

• Section 489.24(b): We are expanding the definition of "emergency medical condition" to include psychiatric disturbances, symptoms of substance abuse, and situations with respect to pregnant women having contractions. We add definitions of "capacity", "comes to the emergency department", "hospital", "hospital with an emergency department", "labor", and "participating hospital." We clarify other definitions to make them consistent with other versions of the text. We have deleted the term "active labor" in accordance with section 6211(h)(1)(B) of OBRA 89.

• Section 489.24(c) (2) and (4) and (d) (1) and (2): We are adding provisions to require a written informed refusal from the patient or individual acting on his or her behalf when the patient refuses treatment or transfer. We specify that the medical record must contain a description of the examination and treatment, or transfer, or refusal. The refusal must indicate that the patient (or person acting on his or her behalf) is aware of the risks and benefits of the transfer, or the examination or treatment.

• Section 489.24(c)(3): We are adding the requirement that a hospital may not delay providing an appropriate medical screening examination in order to inquire about payment method or insurance status. This is the result of public comment and section 6211(h) of OBRA 89.

• Section 489.24(d)(1)(ii)(A): Based on section 6211(c)(1) of OBRA 89 and public comment, we are adding a requirement that an individual (or legally responsible person acting on the individual's behalf) who wants to be transferred must indicate in writing the reason for the request for transfer and that he or she is aware of its risks and benefits.

• Section 489.24(d)(3): Based on section 6211(i) of OBRA 89 and section 4027(k)(3) of OBRA 90, we are prohibiting a hospital from penalizing or taking adverse action against a physician or a qualified medical person who refuses to authorize the transfer of an individual with an emergency condition that has not been stabilized or against any hospital employee because the employee reports a violation of this regulation.

• Section 489.24(e): Based on section 6211(f) of OBRA 89 and public comment, we are requiring that a hospital with specialized capabilities or facilities accept transfer of any individual requiring those specialized capabilities or facilities if it has the capacity to treat the individual.

• Section 489.24(f): Because of section 4008(b)(3)(A) of OBRA 90, the standard for terminating a hospital has changed. HCFA is no longer required to prove that the hospital knowingly and willfully, or negligently, failed to meet the requirements of this regulation. We may now terminate such hospitals for failing to meet these requirements under section 1866 of the Act based upon section 4008(b)(3)(B) of OBRA 90, which requires hospitals to meet the requirements of section 1867 of the Act in order to participate in the Medicare program.

• Section 489.24(g): Based on section 4027(a)(1) of OBRA 90, we are requiring PRO review to assess whether the individual involved had an emergency medical condition that had not been stabilized, in addition to other medical issues, before imposing a civil monetary penalty or exclusion, unless obtaining such review would cause delay that would jeopardize the health or safety of individuals or if there is no medical issue to review (that is, no screening examination was conducted). In cases that do not present jeopardy, the PRO review and report to HCFA must be completed in 60 calendar days.

• Section 489.24(h): We are clarifying in new § 489.24(h) that, upon request, HCFA may release a PRO assessment to the physician or hospital, or the affected individual or his or her representative.

• Section 489.53(a): We are revising the proposed rule to require a receiving hospital to report incidents it has reason to believe may be violations.

• Section 489.53(b): We are adding to the reasons for termination—(a) a refusal of a hospital with specialized capabilities or facilities that has the capacity to accept an appropriate transfer; (b) failure to maintain an on-call duty roster, medical records for 5 years, and a log of individuals seeking emergency assistance; and (c) failure to post notices as required concerning participation in Medicaid and the rights of individuals under 42 CFR part 489, subpart B.

• Section 489.53(c)(2)(ii): We are specifying that a hospital found in violation of §§ 489.24(a) through (h) will receive a final notice of termination and the public will be concurrently notified at least 2 but no more than 4 days before the effective date of the termination. This allows a hospital approximately 19 to 21 days to correct or refute alleged deficiencies. We also clarify that we will

not terminate if the hospital has corrected or refuted the deficiencies that gave rise to the termination.

- We are adding "or rural primary care hospital" wherever "hospital" appears in § 489.24, as required by section 6003(g) of OBRA 89.
- We are also removing all references to suspension of the provider from the regulations at §§ 489.24 and 489.53, based on the deletion of the suspension authority by section 4008(b)(3) of OBRA 90.
- We are making none of the proposed revisions to part 1001, which all concerned suspension of providers.
- Section 1003.100: We are revising the proposed section to conform with several rulemaking documents that have been published since our proposed rule. The requirements contained in proposed § 1003.100(b)(1)(ii) are now set forth in § 1003.100(b)(1)(vi).
- Section 1003.101: We are adding or revising in this section the definitions for the terms "participating hospital" (to comport with the statute), "respondent", and "responsible physician".
- Section 1003.102: This section also has been revised by several rulemaking documents since the publication of our June 16, 1988, proposed rule. In this interim final rule, we are clarifying in paragraph (c)(2) that the term "knowingly" encompasses reckless disregard and deliberate ignorance of a material fact. We are also revising this section to comport with the OBRA 89 amendments that allow the Inspector General to impose civil monetary penalties when a physician signs a certification when he or she knew or should have known that the benefits did not outweigh the risks of transfer, or when the physician misrepresents an individual's condition or other information. We are also revising proposed § 1003.102(d) to eliminate the reference to a "knowing" standard (that is, a physician knowingly failed to provide care). This results in a clearer approach that sets forth our basis for imposing civil monetary penalties for violations of section 1867 of the Act and is consistent with the statutory amendments and with other revisions to the regulations.
- Section 1003.103: We are revising this section in accordance with section 1867(d) of the Act, as amended by section 4008 of OBRA 90, to clarify that the OIG may impose a penalty of not more than $50,000 against a participating hospital and a penalty of not more than $50,000 against each responsible physician (and not more than $25,000 against a participating hospital and each responsible physician for violations on or after August 1, 1986, but before December 22, 1987) for violations determined under § 1003.102(d). For penalties imposed on or after May 1, 1991, if the hospital has fewer than 100 State-licensed, Medicare-certified beds, the maximum penalty will be $25,000.
- Section 1003.105: We are revising this section to comport with the OBRA 90 amendments to section 1867 of the Act by specifying in § 1003.105(a)(1) that a physician who grossly and flagrantly or repeatedly violates the statute or § 489.24 may be excluded from Medicare and any State health care program. We are also revising § 1003.105(b) to clarify that, for determinations under §§ 1003.102 (b)(2) and (b)(3), and for violations under § 1003.102(c)(1)(ii) occurring on or after December 22, 1987 and before July 1, 1990, a physician may not be excluded if the OIG determines he or she is a sole community physician or the sole source of specialized services in that community. We are moving references to limitations in time periods of exclusion to § 1003.107.
- Section 1003.105: Effective December 22, 1987, the statute was amended to allow the Secretary, pursuant to section 1842(j)(2) of the Act, to exclude a physician who knowingly violated section 1867 of the Act. In OBRA 89 Congress amended section 1867, allowing the Secretary, pursuant to section 1128A (instead of section 1842(j)(2)), to exclude a physician who knowingly and willfully or negligently violated the statute. The statute was then amended in OBRA 90, changing the standard for exclusion from "knowing and willful or negligent" to "gross and flagrant or repeated", effective May 1, 1991. We are implementing this provision in § 1003.105(a)(1)(ii)(C). In addition, in accordance with section 1842(j)(3) of the Act, the physician may not be excluded if the physician is the sole community physician or sole source of essential specialized services in a community. We are revising § 1003.105(b) to include these exceptions.
- Section 1003.106: As indicated in a response to one of the comments, in accordance with the requirements of section 1128A(d) of the Act, the final regulation includes two additional factors for consideration in determining the amount of the penalty and the length of the exclusion under part 1003: (1) "The financial condition of the hospital and each responsible physician who have violated any requirement of section 1867 of the Act," and (2) "The nature and circumstances of the violation." We are adding § 1003.106(a)(4) to reflect these provisions.
- Section 1003.107: The regulations now reflect the requirement of section 1842(j)(3) of the Act that if an exclusion is based upon section 1842(j)(2) of the Act, then the access of beneficiaries to physician's services must be considered.
- Section 1003.108: We are revising this section to include the terms "assessment" and "exclusion."

4. Technical revisions.

We have revised the regulation to reflect the statutory amendments relating to the term "active labor." Section 6211(h)(1)(B) of OBRA 89 removed the term from the statutory definitions section (section 1867(e) of the Act) and the concept it applied to was incorporated into the definition of emergency medical condition. Hence, in many areas of the regulations, only the term "emergency medical condition" is included. However, the statute still uses the term "labor" in certain circumstances, and the regulations reflect this where appropriate.

Under sections 6211(g) (1) and (2) of OBRA 89, the words "patient," "patients" and "patient's" are replaced by the words "individual," "individuals" and "individual's", respectively, each place they appear in §§ 489.24 and 489.53 in reference to hospitals.

In addition, we have redesignated proposed § 405.1903 in this interim final rule as § 488.18(d).

VII. Impact Statement

Unless the Secretary certifies that an interim final 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, we consider all hospitals 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 the Secretary to prepare a regulatory impact analysis for any final 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. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that has fewer than 100 beds and is located outside a Metropolitan Statistical Area.

The provisions of this rule merely conform the regulations to the legislative provisions of sections 912. and 9122 of COBRA (as amended by

section 4009 of OBRA 87), section 233 of the Veteran's Benefit Improvement and Health Care Authorization Act of 1986, sections 9305 (b)(1) and 9307 of OBRA 86, section 4009 of OBRA 87, sections 6003(g)(3)(d)(XIV), 6018 and 6211 of OBRA 89 and sections 4008(b), 4027(a) and 4027(k)(3) of OBRA 90.

The provisions of this rule will require Medicare participating hospitals to provide inpatient services to individuals with insurance coverage under CHAMPUS, CHAMPVA, and VA programs, provide each Medicare beneficiary a statement of his or her rights concerning discharge from the hospital and provide an appropriate medical screening examination to anyone who requests examination or treatment, and stabilizing treatment in the emergency room to any individual with an emergency medical condition.

As required by the statute these provisions are in effect and are being enforced. Although hospitals may incur incremental costs to ensure compliance with these provisions, we believe the costs are minimal and the benefits to individuals far outweigh those costs. These provisions will allow military personnel and their families to receive inpatient services in hospitals that may be closer to their homes as opposed to receiving services in military hospitals that may be some distance away. Another benefit will be that all individuals will receive medical screening and, if an emergency medical condition exists, will also receive stabilizing treatment and protections against inappropriate transfers regardless of the individual's eligibility for Medicare. We believe that these provisions will improve access to care and reduce patient complaints. The potential use of sanctions provides the incentive for hospitals to ensure continued compliance with these provisions.

We included a voluntary impact analysis in section VII of the preamble in the June 16, 1988 proposed rule (53 FR 22513). We received no comments on that analysis, and we believe that none of the changes incorporated into this interim final rule have any significant impact. Therefore, we are not preparing a similar analysis.

For the reasons discussed above, we have determined, and the Secretary certifies, that these final regulations will not have significant economic impact on a substantial number of small entities and will not have a significant impact on the operations of a substantial number of small rural hospitals. Therefore, we have not prepared a regulatory flexibility analysis or an analysis of effects on small rural hospitals.

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

VIII. Paperwork Reduction Act

Sections 488.18(d), 489.20 (m) and (r), and 489.24 (c), (d) and (g) of this interim final rule contain information collection requirements that are subject to the Office of Management and Budget review under the Paperwork Reduction Act of 1980. The information collections in §§ 488.18, 489.20(m), and 489.24 require the State agencies to notify HCFA when hospitals are not in compliance with provisions contained in the Medicare provider agreement. Section 489.20(m) also requires that a hospital report to HCFA or a Medicare state survey agency when the hospital believes it has received an individual who has been transferred in an unstable emergency medical condition from another hospital in violation of the requirements of § 489.24(d). Section 489.20(r) now requires both transferring and receiving hospitals to develop and maintain lists of on-call physicians and central logs containing information about what services the individual did or did not receive and applicable patient records on admissions, discharges, and transfers.

In addition, under § 489.24 (c) and (d), transferring hospitals must send receiving hospitals an individual's medical records (or copies) available at the time of the transfer, and the individual's other medical records must be sent as soon as practicable after the transfer. The provisions also require hospitals to record certain information on individuals' medical records, require individuals to sign consent forms pertaining to examinations, treatments and transfers, and require physicians and other qualified medical personnel, when a physician is not present in the emergency department but in consultation with the physician, to sign transfer certifications containing specific information. Section 489.24(g) also requires PROs to prepare reports regarding individuals' medical conditions when requested by HCFA.

Section 489.27 of the proposed rule required that hospitals that participate in the Medicare program obtain from the beneficiary or his or her representative a signed acknowledgement of receipt of a notice of discharge rights. We also required these hospitals to retain both a copy of the inpatient notice of discharge rights ("Message") and of the signed acknowledgement for 1 year. As discussed in section IV.B. of this preamble, this interim final rule eliminates the requirement for an acknowledgement statement. Thus, the accompanying recordkeeping burden also is eliminated.

The annual reporting and recordkeeping burden imposed by these information collection requirements is estimated, based on past experience, to be as follows:

§ 488.18(d)—101.5 hours for Medicare State survey agencies
§ 489.20(m)—25.25 hours for all hospitals and 50.5 hours for Medicare State survey agencies
§ 489.20(r)(2)—7,000 hours for all hospitals
§ 489.20(r)(3)—7,665,400 hours for all hospitals
§ 489.24(c)(2) and § 489.24(c)(4)—373,900 hours for all hospitals and 46,700 hours for the public for each subsection
§ 489.24(d)(1)(ii)(A)—46,700 hours for the public
§ 489.24(d)(1)(ii)(B) and § 489.24(d)(1)(ii)(C)—373,900 hours for all hospitals for each subsection
§ 489.24(g)—336 hours for all PROs

The new information collection and recordkeeping requirements associated with §§ 488.18, 489.20, and 489.24 have been sent to OMB for approval in accordance with the Paperwork Reduction Act and will not be effective until OMB approval is received. A notice will be published in the **Federal Register** when approval is obtained. Organizations and individuals desiring to submit comments on the burden estimates, the usefulness of central logs for enforcement purposes, the possibility of any unintended effects in connection with the use of such logs, or other aspects of the information collection and recordkeeping requirements in §§ 488.18, 489.20, and 489.24 should direct them to the OMB official whose name appears in the **ADDRESSES** section of this preamble.

IX. Waiver of Proposed Rulemaking

The Administrative Procedure Act (5 U.S.C. 553) requires us to publish general notice of proposed rulemaking in the **Federal Register** and afford prior public comment on proposed rules. Such notice includes a statement of the time, place and nature of the rulemaking proceeding, reference to the legal authority under which the rule is proposed, and the terms or substance of the proposed rule or a description of the subjects and issues involved. However, this requirement does not apply when an agency finds good cause that prior notice and comment are impracticable, unnecessary, or contrary to the public

interest, and incorporates a statement of the finding and its reasons in the rules instead.

This interim final rule with comment period includes a number of revisions to our regulations that implement revisions to the Act under OBRA 89 and OBRA 90 and for which we did not propose rulemaking. These particular regulation revisions implement the statute without interpretation; the statutory changes are self-implementing. Most of the revisions are technical; some substantive ones (such as the notice hospitals are required to post concerning Medicaid) have already been implemented; others are changes that would respond to public comments we have already received. Affording a proposed rulemaking process under these circumstances is not in the public interest as it would delay the promulgation of regulations that correspond to the current statute; because the statutory revisions are self-implementing, we do not anticipate that public comment would substantively modify regulations. Therefore, we find good cause to waive proposed rulemaking for those regulatory provisions necessary to implement OBRA 89 and OBRA 90. However, we are providing a 60-day period for public comment, as indicated at the beginning of this rule, on changes to the regulations resulting from the provisions of OBRA 89 and OBRA 90. After considering comments that are received timely, we will respond to the comments, include any changes in the rule that might be necessitated in light of those comments, and publish a final rule in the **Federal Register.**

X. Response to Comments

Because of the large number of items of correspondence we receive on a rulemaking document, we are not able to acknowledge or respond to them individually. However, we will consider all comments that we receive by the date and time specified in the "Dates" section of this preamble, and, we will respond to the comments in the preamble of the final rule.

List of Subjects

42 CFR Part 488

Health facilities, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 489

Health facilities, Medicare.

42 CFR Part 1003

Administrative practice and procedure, Fraud, Grant programs—health, Health facilities, Health professions, Maternal and child health, Medicaid, Medicare, Penalties.

Title 42 of the Code of Federal Regulations is amended as follows:

A. Part 488, subpart A, is amended as follows:

PART 488—SURVEY AND CERTIFICATION PROCEDURES

1. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102, 1814, 1861, 1865, 1866, 1871, 1880, 1881, 1883, and 1913 of the Social Security Act (42 U.S.C. 1302, 1395f, 1395x, 1395bb, 1395cc, 1395hh, 1395qq, 1395rr, 1395tt, and 1396l).

Subpart A—General Provisions

2. Section 488.18 is amended by adding a new paragraph (d) to read as follows:

§ 488.18 Documentation of findings.

* * * * *

(d) If the State agency receives information to the effect that a hospital or a rural primary care hospital (as defined in section 1861(mm)(1) of the Act) has violated § 489.24 of this chapter, the State agency is to report the information to HCFA promptly.

B. Part 489 is amended as follows:

PART 489—PROVIDER AGREEMENTS UNDER MEDICARE

1. The authority citation for part 489 is revised to read as follows:

Authority: Secs. 1102, 1861, 1864, 1866, 1867, and 1871 of the Social Security Act (42 U.S.C. 1302, 1395x, 1395aa, 1395cc, 1395dd, and 1395hh), and sec. 602(k) of Pub. L. 98–21 (42 U.S.C. 1395ww note).

Subpart A—General Provisions

2. In § 489.20, the introductory text is republished, and paragraphs (l) through (r) are added to read as follows:

§ 489.20 Basic commitments.

The provider agrees to the following:

* * * * *

(l) In the case of a hospital as defined in § 489.24(b) to comply with § 489.24.

(m) In the case of a hospital as defined in § 489.24(b), to report to HCFA or the State survey agency any time it has reason to believe it may have received an individual who has been transferred in an unstable emergency medical condition from another hospital in violation of the requirements of § 489.24(d).

(n) In the case of inpatient hospital services, to participate in any health plan contracted for under 10 U.S.C. 1079 or 1086 or 38 U.S.C. 613, in accordance with § 489.25.

(o) In the case of inpatient hospital services, to admit veterans whose admission has been authorized under 38 U.S.C. 603, in accordance with § 489.26.

(p) In the case of a hospital that participates in the Medicare program, to comply with § 489.27 by giving each beneficiary a notice about his or her discharge rights at or about the time of the individual's admission.

(q) In the case of a hospital as defined in § 489.24(b)—

(1) To post conspicuously in any emergency department or in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments (that is, entrance, admitting area, waiting room, treatment area), a sign (in a form specified by the Secretary) specifying rights of individuals under Section 1867 of the Act with respect to examination and treatment for emergency medical conditions and women in labor; and

(2) To post conspicuously (in a form specified by the Secretary) information indicating whether or not the hospital or rural primary care hospital participates in the Medicaid program under a State plan approved under title XIX.

(r) In the case of a hospital as defined in § 489.24(b) (including both the transferring and receiving hospitals), to maintain—

(1) Medical and other records related to individuals transferred to or from the hospital for a period of 5 years from the date of the transfer;

(2) A list of physicians who are on call for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition; and

(3) A central log on each individual who comes to the emergency department, as defined in § 489.24(b), seeking assistance and whether he or she refused treatment, was refused treatment, or whether he or she was transferred, admitted and treated, stabilized and transferred, or discharged.

3. New §§ 489.24 through 489.27 are added to read as follows:

§ 489.24 Special responsibilities of Medicare hospitals in emergency cases.

(a) *General.* In the case of a hospital that has an emergency department, if any individual (whether or not eligible for Medicare benefits and regardless of ability to pay) comes by him or herself or with another person to the emergency department and a request is made on the individual's behalf for examination or treatment of a medical condition by

qualified medical personnel (as determined by the hospital in its rules and regulations), the hospital must provide for an appropriate medical screening examination within the capability of the hospital's emergency department, including ancillary services routinely available to the emergency department, to determine whether or not an emergency medical condition exists. The examinations must be conducted by individuals determined qualified by hospital by-laws or rules and regulations and who meet the requirements of § 482.55 concerning emergency services personnel and direction.

(b) *Definitions.* As used in this subpart—

Capacity means the ability of the hospital to accommodate the individual requesting examination or treatment of the transferred individual. Capacity encompasses such things as numbers and availability of qualified staff, beds and equipment and the hospital's past practices of accommodating additional patients in excess of its occupancy limits.

Comes to the emergency department means, with respect to an individual requesting examination or treatment, that the individual is on the hospital property (property includes ambulances owned and operated by the hospital, even if the ambulance is not on hospital grounds). An individual in a nonhospital-owned ambulance on hospital property is considered to have come to the hospital's emergency department. An individual in a nonhospital-owned ambulance off hospital property is not considered to have come to the hospital's emergency department, even if a member of the ambulance staff contacts the hospital by telephone or telemetry communications and informs the hospital that they want to transport the individual to the hospital for examination and treatment. In such situations, the hospital may deny access if it is in "diversionary status," that is, it does not have the staff or facilities to accept any additional emergency patients. If, however, the ambulance staff disregards the hospital's instructions and transports the individual on to hospital property, the individual is considered to have come to the emergency department.

Emergency medical condition means—

(i) A medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain, psychiatric disturbances and/or symptoms of substance abuse) such that the absence of immediate medical attention could reasonably be expected to result in—

(A) Placing the health of the individual (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy;

(B) Serious impairment to bodily functions; or

(C) Serious dysfunction of any bodily organ or part; or

(ii) With respect to a pregnant woman who is having contractions—

(A) That there is inadequate time to effect a safe transfer to another hospital before delivery; or

(B) That transfer may pose a threat to the health or safety of the woman or the unborn child.

Hospital includes a rural primary care hospital as defined in section 1861(mm)(1) of the Act.

Hospital with an emergency department means a hospital that offers services for emergency medical conditions (as defined in this paragraph) within its capability to do so.

Labor means the process of childbirth beginning with the latent or early phase of labor and continuing through the delivery of the placenta. A woman experiencing contractions is in true labor unless a physician certifies that, after a reasonable time of observation, the woman is in false labor.

Participating hospital means (i) a hospital or (ii) a rural primary care hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act.

Stabilized means, with respect to an "emergency medical condition" as defined in this section under paragraph (i) of that definition, that no material deterioration of the condition is likely, within reasonable medical probability, to result from or occur during the transfer of the individual from a facility or, with respect to an "emergency medical condition" as defined in this section under paragraph (ii) of that definition, that the woman has delivered the child and the placenta.

To stabilize means, with respect to an "emergency medical condition" as defined in this section under paragraph (i) of that definition, to provide such medical treatment of the condition necessary to assure, within reasonable medical probability, that no material deterioration of the condition is likely to result from or occur during the transfer of the individual from a facility or that, with respect to an "emergency medical condition" as defined in this section under paragraph (ii) of that definition, the woman has delivered the child and the placenta.

Transfer means the movement (including the discharge) of an individual outside a hospital's facilities at the direction of any person employed by (or affiliated or associated, directly or indirectly, with) the hospital, but does not include such a movement of an individual who (i) has been declared dead, or (ii) leaves the facility without the permission of any such person.

(c) *Necessary stabilizing treatment for emergency medical conditions*—(1) *General.* If any individual (whether or not eligible for Medicare benefits) comes to a hospital and the hospital determines that the individual has an emergency medical condition, the hospital must provide either—

(i) Within the capabilities of the staff and facilities available at the hospital, for further medical examination and treatment as required to stabilize the medical condition; or

(ii) For transfer of the individual to another medical facility in accordance with paragraph (d) of this section.

(2) *Refusal to consent to treatment.* A hospital meets the requirements of paragraph (c)(1)(i) of this section with respect to an individual if the hospital offers the 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) refuses to consent to the examination and treatment. 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. 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). The written document should indicate that the person has been informed of the risks and benefits of the examination or treatment, or both.

(3) *Delay in examination or treatment.* A participating hospital may not delay providing an appropriate medical screening examination required under paragraph (a) of this section or further medical examination and treatment required under paragraph (c) in order to inquire about the individual's method of payment or insurance status.

(4) *Refusal to consent to transfer.* A hospital meets the requirements of paragraph (c)(1)(ii) of this section with respect to an individual if the hospital offers to transfer the individual to another medical facility in accordance with paragraph (d) 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) refuses to consent to the transfer. 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). 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. The medical record must contain a description of the proposed transfer that was refused by or on behalf of the individual.

(d) *Restricting transfer until the individual is stabilized*—(1) *General.* If an individual at a hospital has an emergency medical condition that has not been stabilized (as defined in paragraph (b) of this section), the hospital may not transfer the individual unless—

(i) The transfer is an appropriate transfer (within the meaning of paragraph (d)(2) of this section); and

(ii)(A) The individual (or a legally responsible person acting on the individual's behalf) requests the transfer, after being informed of the hospital's obligations under this section and of the risk of transfer. The request must be in writing and indicate the reasons for the request as well as indicate that he or she is aware of the risks and benefits of the transfer;

(B) A physician (within the meaning of section 1861(r)(1) of the Act) has signed a certification that, based upon the information available at the time of transfer, the medical benefits reasonably expected from the provision of appropriate medical treatment at another medical facility outweigh the increased risks to the individual or, in the case of a woman in labor, to the woman or the unborn child, from being transferred. The certification must contain a summary of the risks and benefits upon which it is based; or

(C) If a physician is not physically present in the emergency department at the time an individual is transferred, a qualified medical person (as determined by the hospital in its by-laws or rules and regulations) has signed a certification described in paragraph (d)(1)(ii)(B) of this section after a physician (as defined in section 1861(r)(1) of the Act) in consultation with the qualified medical person, agrees with the certification and subsequently countersigns the certification. The certification must contain a summary of the risks and benefits upon which it is based.

(2) A transfer to another medical facility will be appropriate only in those cases in which—

(i) The transferring hospital provides medical treatment within its capacity that minimizes the risks to the individual's health and, in the case of a woman in labor, the health of the unborn child;

(ii) The receiving facility—

(A) Has available space and qualified personnel for the treatment of the individual; and

(B) Has agreed to accept transfer of the individual and to provide appropriate medical treatment;

(iii) The transferring hospital sends to the receiving facility all medical records (or copies thereof) related to the emergency condition which the individual has presented that are available at the time of the transfer, including available history, records related to the individual's emergency medical condition, observations of signs or symptoms, preliminary diagnosis, results of diagnostic studies or telephone reports of the studies, treatment provided, results of any tests and the informed written consent or certification (or copy thereof) required under paragraph (d)(1)(ii) of this section, and the name and address of any on-call physician (described in paragraph (f) of this section) who has refused or failed to appear within a reasonable time to provide necessary stabilizing treatment. Other records (e.g., test results not yet available or historical records not readily available from the hospital's files) must be sent as soon as practicable after transfer; and

(iv) The transfer is effected through qualified personnel and transportation equipment, as required, including the use of necessary and medically appropriate life support measures during the transfer.

(3) A participating hospital may not penalize or take adverse action against a physician or a qualified medical person described in paragraph (d)(1)(ii)(C) of this section because the physician or qualified medical person refuses to authorize the transfer of an individual with an emergency medical condition that has not been stabilized, or against any hospital employee because the employee reports a violation of a requirement of this section.

(e) *Recipient hospital responsibilities.* A participating hospital that has specialized capabilities or facilities (including, but not limited to, facilities such as burn units, shock-trauma units, neonatal intensive care units, or (with respect to rural areas) regional referral centers) may not refuse to accept from a referring hospital within the boundaries of the United States an appropriate transfer of an individual who requires such specialized capabilities or facilities if the receiving hospital has the capacity to treat the individual.

(f) *Termination of provider agreement.* If a hospital fails to meet the requirements of paragraph (a) through (e) of this section, HCFA may terminate the provider agreement in accordance with § 489.53.

(g) *Consultation with Peer Review Organizations (PROs)*—(1) *General.* Except as provided in paragraph (g)(3) of this section, in cases where a medical opinion is necessary to determine a physician's or hospital's liability under sectjon 1867(d)(1) of the Act, HCFA requests the appropriate PRO (with a contract under Part B of title XI of the Act) to review the alleged section 1867(d) violation and provide a report on its findings in accordance with paragraph (g)(2)(iv) and (v) of this section. HCFA provides to the PRO all information relevant to the case and within its possession or control. HCFA, in consultation with the OIG, also provides to the PRO a list of relevant questions to which the PRO must respond in its report.

(2) *Notice of review and opportunity for discussion and additional information.* The PRO shall provide the physician and hospital reasonable notice of its review, a reasonable opportunity for discussion, and an opportunity for the physician and hospital to submit additional information before issuing its report. When a PRO receives a request for consultation under paragraph (g)(1) of this section, the following provisions apply—

(i) The PRO reviews the case before the 15th calendar day and makes its tentative findings.

(ii) Within 15 calendar days of receiving the case, the PRO gives written notice, sent by certified mail, return receipt requested, to the physician or the hospital (or both if applicable).

(iii) (A) The written notice must contain the following information:

(*1*) The name of each individual who may have been the subject of the alleged violation.

(*2*) The date on which each alleged violation occurred.

(*3*) An invitation to meet, either by telephone or in person, to discuss the case with the PRO, and to submit additional information to the PRO within 30 calendar days of receipt of the notice, and a statement that these rights will be waived if the invitation is not

accepted. The PRO must receive the information and hold the meeting within the 30-day period.

(4) A copy of the regulations at 42 CFR 489.24.

(B) For purposes of paragraph (g)(2)(iii)(A) of this section, the date of receipt is presumed to be 5 days after the certified mail date on the notice, unless there is a reasonable showing to the contrary.

(iv) The physician or hospital (or both where applicable) may request a meeting with the PRO. This meeting is not designed to be a formal adversarial hearing or a mechanism for discovery by the physician or hospital. The meeting is intended to afford the physician and/or the hospital a full and fair opportunity to present the views of the physician and/or hospital regarding the case. The following provisions apply to that meeting:

(A) The physician and/or hospital has the right to have legal counsel present during that meeting. However, the PRO may control the scope, extent, and manner of any questioning or any other presentation by the attorney. The PRO may also have legal counsel present.

(B) The PRO makes arrangements so that, if requested by HCFA or the OIG, a verbatim transcript of the meeting may be generated. If HCFA or OIG requests a transcript, the affected physician and/or the affected hospital may request that HCFA provide a copy of the transcript.

(C) The PRO affords the physician and/or the hospital an opportunity to present, with the assistance of counsel, expert testimony in either oral or written form on the medical issues presented. However, the PRO may reasonably limit the number of witnesses and length of such testimony if such testimony is irrelevant or repetitive. The physician and/or hospital, directly or through counsel, may disclose patient records to potential expert witnesses without violating any non-disclosure requirements set forth in part 476 of this chapter.

(D) The PRO is not obligated to consider any additional information provided by the physician and/or the hospital after the meeting, unless, before the end of the meeting, the PRO requests that the physician and/or hospital submit additional information to support the claims. The PRO then allows the physician and/or the hospital an additional period of time, not to exceed 5 calendar days from the meeting, to submit the relevant information to the PRO.

(v) Within 60 calendar days of receiving the case, the PRO must submit to HCFA a report on the PRO's findings. HCFA provides copies to the OIG and to the affected physician and/or the affected hospital. The report must contain the name of the physician and/or the hospital, the name of the individual, and the dates and times the individual arrived at and was transferred (or discharged) from the hospital. The report provides expert medical opinion regarding whether the individual involved had an emergency medical condition, whether the individual's emergency medical condition was stabilized, whether the individual was transferred appropriately, and whether there were any medical utilization or quality of care issues involved in the case.

(vi) The report required under paragraph (g)(2)(v) of this section should not state an opinion or conclusion as to whether section 1867 of the Act or § 489.24 has been violated.

(3) If a delay would jeopardize the health or safety of individuals or when there was no screening examination, the PRO review described in this section is not required before the OIG may impose civil monetary penalties or an exclusion in accordance with section 1867(d)(1) of the Act and 42 CFR part 1003 of this title.

(4) If the PRO determines after a preliminary review that there was an appropriate medical screening examination and the individual did not have an emergency medical condition, as defined by paragraph (b) of this section, then the PRO may, at its discretion, return the case to HCFA and not meet the requirements of paragraph (g) except for those in paragraph (g)(2)(v).

(h) *Release of PRO assessments.* Upon request, HCFA may release a PRO assessment to the physician and/or hospital, or the affected individual, or his or her representative. The PRO physician's identity is confidential unless he or she consents to its release. (See §§ 476.132 and 476.133 of this chapter.)

§ 489.25 Special requirements concerning CHAMPUS and CHAMPVA programs.

For inpatient services, a hospital that participates in the Medicare program must participate in any health plan contracted under 10 U.S.C. 1079 or 1086 (Civilian Health and Medical Program of the Uniformed Services) and under 38 U.S.C. 613 (Civilian Health and Medical Program of the Veterans Administration) and accept the CHAMPUS/CHAMPVA-determined allowable amount as payment in full, less applicable deductible, patient cost-share, and noncovered items. Hospitals must meet the requirements of 32 CFR part 199 concerning program benefits under the Department of Defense. This section applies to inpatient services furnished to beneficiaries admitted on or after January 1, 1987.

§ 489.26 Special requirements concerning veterans.

For inpatient services, a hospital that participates in the Medicare program must admit any veteran whose admission is authorized by the Department of Veterans Affairs under 38 U.S.C. 603 and must meet the requirements of 38 CFR part 17 concerning admissions practices and payment methodology and amounts. This section applies to services furnished to veterans admitted on and after July 1, 1987.

§ 489.27 Beneficiary notice of discharge rights.

A hospital that participates in the Medicare program must furnish each Medicare beneficiary, or an individual acting on his or her behalf, the notice of discharge rights HCFA supplies to the hospital to implement section 1886(a)(1)(M) of the Act. The hospital must furnish the statement at or about the time of admission. The hospital must be able to demonstrate compliance with this requirement. This provision is effective with admissions beginning on or after July 22, 1994.

Subpart E—Termination of Agreement and Reinstatement After Termination

4. In § 489.53, the introductory text of paragraph (a) is republished, paragraphs (a) (10), (11), and (12) are added, and paragraphs (b) and (c)(2) are revised to read as follows:

§ 489.53 Termination by HCFA.

(a) *Basis for termination of agreement with any provider.* HCFA may terminate the agreement with any provider if HCFA finds that any of the following failings is attributable to that provider:

* * * * *

(10) In the case of a hospital or a rural primary care hospital as defined in section 1861(mm)(1) of the Act that has reason to believe it may have received an individual transferred by another hospital in violation of § 489.24(d), the hospital failed to report the incident to HCFA or the State survey agency.

(11) In the case of a hospital requested to furnish inpatient services to CHAMPUS or CHAMPVA beneficiaries or to veterans, it failed to comply with § 489.25 or § 489.26, respectively.

(12) It failed to furnish the notice of discharge rights as required by § 489.27.

(b) *Termination of provider agreement.* (1) In the case of a hospital or rural primary care hospital that has

an emergency department as defined in § 489.24(b), HCFA may terminate the provider agreement if—

(i) The hospital fails to comply with the requirements of § 489.24 (a) through (e), which require the hospital to examine, treat or transfer emergency medical condition cases appropriately, and require that hospitals with specialized capabilities or facilities accept an appropriate transfer; or

(ii) The hospital fails to comply with § 489.20 (m), (q), and (r), which require the hospital to report suspected violations of § 489.24(d), to post conspicuously in emergency departments or in a place or places likely to be noticed by all individuals entering the emergency departments, as well as those individuals waiting for examination and treatment in areas other than traditional emergency departments, (that is, entrance, admitting area, waiting room, treatment area), signs specifying rights of individuals under this subpart, to post conspicuously information indicating whether or not the hospital participates in the Medicaid program, and to maintain medical and other records related to transferred individuals for a period of 5 years, a list of on-call physicians for individuals with emergency medical conditions, and a central log on each individual who comes to the emergency department seeking assistance.

(2) In the case of a SNF, HCFA terminates a SNF's provider agreement if it determines that—

(i) The SNF no longer meets the requirements for long term care facilities specified in part 483, subpart B of this chapter; and

(ii) The SNF's deficiencies pose immediate jeopardy to patients' health and safety.

(c) *Notice of termination.*

* * * * *

(2) *Exception.*

(i) For a SNF with deficiencies that pose immediate jeopardy to patients' health and safety, HCFA gives notice of termination at least 2 days before the effective date of termination of the provider agreement.

(ii) If HCFA finds that a hospital is in violation of § 489.24 (a) through (e), and HCFA determines that the violation poses immediate and serious jeopardy to the health and safety of the individuals presenting themselves to the hospital for emergency services, HCFA:

(A) Gives a preliminary notice of termination notifying the hospital that it will be terminated in 23 days if it does not correct or refute the identified deficiencies;

(B) Gives a final notice of termination and concurrent notice to the public at least 2 and not more than 4 days before the effective date of termination of the provider agreement.

* * * * *

C. Part 1003 is amended as follows:

PART 1003—CIVIL MONEY PENALTIES AND ASSESSMENTS

1. The authority citation for part 1003 is revised to read as follows:

Authority: 42 U.S.C. 1302, 1320a–7, 1320a–7a, 1320b–10, 1395u(j), 1395u(k), 1395dd(d)(1), 11131(c) and 11137(b)(2).

2. In § 1003.100, the introductory language in paragraph (b) is republished, paragraphs (b)(1) introductory text, (b)(1)(iv) and (b)(1)(v) are revised, and a new paragraph (b)(1)(vi) is added to read as follows:

§ 1003.100 Basis and purpose.

* * * * *

(b) *Purpose.* This part—

(1) Provides for the imposition of civil monetary penalties and, as applicable, assessments against persons who—

* * * * *

(iv) Fail to report information concerning medical malpractice payments or who improperly disclose, use or permit access to information reported under part B of title IV of Public Law 99–660, and regulations specified in 45 CFR part 60;

(v) Misuse certain Medicare and Social Security program words, letters, symbols and emblems; or

(vi) Violate a requirement of section 1867 of the Act or § 489.24 of this title;

* * * * *

3. Section 1003.101 is amended by adding definitions for the terms "participating hospital" and "responsible physician," and by revising the definition of "respondent" to read as follows:

§ 1003.101 Definitions.

For purposes of this part:

* * * * *

Participating hospital means (1) a hospital or (2) a rural primary care hospital as defined in section 1861(mm)(1) of the Act that has entered into a Medicare provider agreement under section 1866 of the Act.

* * * * *

Respondent means the person upon whom the Department has imposed, or proposes to impose, a penalty, assessment or exclusion.

Responsible physician means a physician who is responsible for the examination, treatment, or transfer of an individual who comes to a participating hospital's emergency department seeking assistance and includes a physician on call for the care of such individual.

* * * * *

4. Section 1003.102 is amended by redesignating paragraph (c) as paragraph (d), adding a new paragraph (c), and revising redesignated paragraph (d) to read as follows:

§ 1003.102 Basis for civil money penalties and assessment.

* * * * *

(c) (1) The Office of the Inspector General (OIG) may impose a penalty for violations of section 1867 of the Act or § 489.24 of this title against—

(i) Any participating hospital with an emergency department that—

(A) Knowingly violates the statute on or after August 1, 1986 or;

(B) Negligently violates the statute on or after May 1, 1991; and

(ii) Any responsible physician who—

(A) Knowingly violates the statute on or after August 1, 1986;

(B) Negligently violates the statute on or after May 1, 1991;

(C) Signs a certification under section 1867(c)(1)(A) of the Act if the physician knew or should have known that the benefits of transfer to another facility did not outweigh the risks of such a transfer; or

(D) Misrepresents an individual's condition or other information, including a hospital's obligations under this section.

(2) For purposes of this section, a responsible physician or hospital "knowingly" violates section 1867 of the Act if the responsible physician or hospital recklessly disregards, or deliberately ignores a material fact.

(d) (1) In any case in which it is determined that more than one person was responsible for presenting or causing to be presented a claim as described in paragraph (a) of this section, each such person may be held liable for the penalty prescribed by this part, and an assessment may be imposed against any one such person or jointly and severally against two or more such persons, but the aggregate amount of the assessments collected may not exceed the amount that could be assessed if only one person was responsible.

(2) In any case in which it is determined that more than one person was responsible for presenting or causing to be presented a request for payment or for giving false or misleading information as described in paragraph (b) of this section, each such person may be held liable for the penalty prescribed by this part.

(3) In any case in which it is determined that more than one person was responsible for failing to report information that is required to be reported on a medical malpractice payment, or for improperly disclosing, using, or permitting access to information, as described in paragraphs (b)(5) and (b)(6) of this section, each such person may be held liable for the penalty prescribed by this part.

(4) In any case in which it is determined that more than one responsible physician violated the provisions of section 1867 of the Act or of § 489.24 of this title, a penalty may be imposed against each responsible physician.

(5) Under this section, a principal is liable for penalties and assessments for the actions of his or her agent acting within the scope of the agency.

5. Section 1003.103 is amended by revising paragraph (a), and adding a new paragraph (e) to read as follows:

§ 1003.103 Amount of penalty.

(a) Except as provided in paragraphs (b), (c), (d), and (e) of this section, the OIG may impose a penalty of not more than $2,000 for each item or service that is subject to a determination under § 1003.102.

* * * * *

(e) For violations of section 1867 of the Act or § 489.24 of this title, the OIG may impose—

(1) Against each participating hospital with an emergency department, a penalty of not more than—

(i) $25,000 for each knowing violation occurring on or after August 1, 1986 and before December 22, 1987;

(ii) $50,000 for each knowing violation occurring on or after December 22, 1987; and

(iii) $50,000 for each negligent violation occurring on or after May 1, 1991, except that if the participating hospital has fewer than 100 State-licensed, Medicare-certified beds on the date the penalty is imposed, the penalty will not exceed $25,000; and

(2) Against each responsible physician, a penalty of not more than—

(i) $25,000 for each knowing violation occurring on or after August 1, 1986 and before December 22, 1987;

(ii) $50,000 for each knowing violation occurring on or after December 22, 1987; and

(iii) $50,000 for each negligent violation occurring on or after May 1, 1991.

6. Section 1003.105 is revised to read as follows:

§ 1003.105 Exclusion from participation in Medicare and State health care programs.

(a) (1) Except as set forth in paragraph (b) of this section, the following persons may be subject, in lieu of or in addition to any penalty or assessment, to an exclusion from participation in Medicare for a period of time determined under § 1003.107. The OIG will also direct each appropriate State agency to exclude the person from each health care program for the same period of time—

(i) Any person who is subject to a penalty or assessment under § 1003.102 (a) or (b)(1) through (b)(4).

(ii) Any responsible physician who—

(A) Knowingly violates section 1867 of the Act or § 489.24 of this title on or after December 22, 1987, but before July 1, 1990;

(B) Knowingly and willfully, or negligently, violates section 1867 of the Act or § 489.24 of this title on or after July 1, 1990 but before May 1, 1991; or

(C) Commits a gross and flagrant, or repeated, violation of section 1867 of the Act or § 489.24 of this title on or after May 1, 1991. For purposes of this section, a gross and flagrant violation is one that presents an imminent danger to the health, safety or well-being of the individual who seeks emergency examination and treatment or places that individual unnecessarily in a high-risk situation.

(2) Nothing in this section will be construed to limit the Department's authority to impose an exclusion without imposing a penalty.

(b)(1) With respect to determinations under § 1003.102 (b)(2) or (b)(3), or with respect to violations occurring on or after December 22, 1987 and before July 1, 1990 under § 1003.105(a)(1)(ii), a physician may not be excluded if the OIG determines that he or she is the sole community physician or the sole source of essential specialized services in a community.

(2)(i) With respect to any exclusion based on liability for a penalty or assessment under § 1003.102 (a), (b)(1), or (b)(4), the OIG will consider an application from a State agency for a waiver if the person is the sole community physician or the sole source of essential specialized services in a community. With respect to any exclusion imposed under § 1003.105(a)(1)(ii), the OIG will consider an application from a State agency for a waiver if the physician's exclusion from the State health care program would deny beneficiaries access to medical care or would otherwise cause hardship to beneficiaries.

(ii) If a waiver is granted, it is applicable only to the State health care program for which the State requested the waiver.

(iii) If the OIG subsequently obtains information that the basis for a waiver no longer exists, or the State agency submits evidence that the basis for the waiver no longer exists, the waiver will cease and the person will be excluded from the State health care program for the remainder of the period that the person is excluded from Medicare.

(iv) The OIG notifies the State agency whether its request for a waiver has been granted or denied.

(v) The decision to deny a waiver is not subject to administrative or judicial review.

(3) For purposes of this section, the definitions contained in § 1001.2 of this chapter for "sole community physician" and "sole source of essential specialized services in a community" apply.

(c) When the Inspector General proposes to exclude a nursing facility from the Medicare and Medicaid programs, he or she will, at the same time he or she notifies the respondent, notify the appropriate State licensing authority, the State Office of Aging, the long-term care ombudsman, and the State Medicaid agency of the Inspector General's intention to exclude the facility.

7. Section 1003.106 is amended by adding a heading to paragraph (a), adding paragraph (a)(4), and revising the introductory text of paragraph (b) to read as follows:

§ 1003.106 Determinations regarding the amount of the penalty and assessment.

(a) Amount of penalty.

* * * * *

(4) In determining the amount of any penalty in accordance with § 1003.102(c), the OIG takes into account—

(i) The degree of culpability of the respondent;

(ii) The seriousness of the condition of the individual seeking emergency medical treatment;

(iii) The prior history of offenses of the respondent in failing to provide appropriate emergency medical screening, stabilization and treatment of individuals coming to a hospital's emergency department or to effect an appropriate transfer;

(iv) The respondent's financial condition;

(v) The nature and circumstances of the violation; and

(vi) Such other matters as justice may require.

(b) *Determining the amount of the penalty or assessment.* As guidelines for

taking into account the factors listed in paragraph (a)(1) of this section, the following circumstances are to be considered—

* * * * *

8. Section 1003.107 is revised to read as follows:

§ 1003.107 Determinations regarding exclusion.

(a) In determining whether to exclude a person under this part and the duration of any exclusion, the Department considers the circumstances described in § 1003.106(a).

(b) With respect to determinations to exclude a person under §§ 1003.102(a) or (b)(1) through (b)(4), the Department considers those circumstances described in § 1003.106(b). Where there are aggravating circumstances with respect to such determinations, the person should be excluded.

(c) In determining whether to exclude a physician under §§ 1003.102(b)(2) or (b)(3) or, with respect to a violation occurring on or after December 22, 1987 and before July 1, 1990, under § 1003.105(a)(1)(ii), the Department also considers the access of beneficiaries to physicians' services.

(d) Except as set forth in paragraph (e), the guidelines set forth in this section are not binding. Nothing in this section limits the authority of the Department to settle any issue or case as provided by § 1003.126.

(e) An exclusion based on a determination under §§ 1003.102(b)(2) or (b)(3) or, with respect to a violation occurring on or after December 22, 1987 and before July 1, 1990, under § 1003.105(a)(1)(ii), may not exceed 5 years.

9. Section 1003.108 is revised to read as follows:

§ 1003.108 Penalty, assessment, and exclusion not exclusive.

Penalties, assessments, and exclusions imposed under this part are in addition to any other penalties prescribed by law.

10. Section 1003.109 is amended by revising paragraphs (a) introductory text and (a)(4) through (6), and by adding paragraphs (a)(7) and (c) to read as follows:

§ 1003.109 Notice of proposed determination.

(a) If the Inspector General proposes a penalty and, when applicable, assessment, or proposes to exclude a respondent from participation in Medicare or any State health care program, as applicable, in accordance with this part, he or she must deliver or send by certified mail, return receipt requested, to the respondent, written notice of his or her intent to impose a penalty, assessment and exclusion, as applicable. The notice includes—

* * * * *

(4) The amount of the proposed penalty, assessment and the period of proposed exclusion (where applicable);

(5) Any circumstances described in § 1003.106 that were considered when determining the amount of the proposed penalty and assessment and the period of exclusion;

(6) Instructions for responding to the notice, including—

(i) A specific statement of respondent's right to a hearing, and

(ii) A statement that failure to request a hearing within 60 days permits the imposition of the proposed penalty, assessment and exclusion without right of appeal; and

(7) In the case of a notice sent to a respondent who has an agreement under section 1866 of the Act, the notice also indicates that the imposition of an exclusion may result in the termination of the provider's agreement in accordance with section 1866(b)(2)(C) of the Act.

* * * * *

(c) If the respondent fails, within the time permitted, to exercise his or her right to a hearing under this section, any exclusion, penalty, or assessment becomes final.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

Dated: May 27, 1994.

Bruce C. Vladeck,

Administrator, Health Care Financing Administration.

Dated: May 27, 1994.

June G. Brown,

Inspector General, Department of Health and Human Services.

Dated: June 13,1994.

Donna E. Shalala,

Secretary.

Appendix I—An Important Message From Medicare; Your Rights While You Are a Medicare Hospital Patient

• You have the right to receive all the hospital care that is necessary for the proper diagnosis and treatment of your illness or injury. According to Federal law, your discharge date must be determined solely by your medical needs, not by "Diagnosis Related Groups" (DRGs) or Medicare payments.

• You have the right to be fully informed about decisions affecting your Medicare coverage and payment for your hospital stay and for any post-hospital services.

• You have the right to request a review by a Peer Review Organization (PRO) of any written Notice of Noncoverage that you receive from the hospital stating that Medicare will no longer pay for your hospital care. PROs are groups of doctors who are paid by the Federal Government to review medical necessity, appropriateness and quality of hospital treatment furnished to Medicare patients. The phone number and address of the PRO for your area are:

Talk to Your Doctor About Your Stay in the Hospital

You and your doctor know more about your condition and your health needs than anyone else. Decisions about your medical treatment should be made between you and your doctor. If you have any questions about your medical treatment, your need for continued hospital care, your discharge, or your need for possible post-hospital care, don't hesitate to ask your doctor. The hospital's patient representative or social worker will also help you with your questions and concerns about hospital services.

If You Think You Are Being Asked To Leave the Hospital Too Soon

• Ask a hospital representative for a written notice of explanation immediately, if you have not already received one. This notice is called a Notice of Noncoverage. You must have this Notice of Noncoverage if you wish to exercise your right to request a review by the PRO.

• The Notice of Noncoverage will state either that your doctor or the PRO agrees with the hospital's decision that Medicare will no longer pay for your hospital care.

—If the hospital and your doctor agree, the PRO does not review your case before a Notice of Noncoverage is issued. But the PRO will respond to your request for a review of your Notice of Noncoverage and seek your opinion. You cannot be made to pay for your hospital care until the PRO makes its decision, if you request the review by noon of the first work day after you receive the Notice of Noncoverage.

—If the hospital and your doctor disagree, the hospital may request the PRO to review your case. If it does make such a request, the hospital is required to send you a notice to that effect. In this situation the PRO must agree with the hospital or the hospital cannot issue a Notice of Noncoverage. You may request that the PRO reconsider your case after you receive a Notice of Noncoverage, but since the PRO has already reviewed your case once, you may have to pay for at least one day of hospital care before the PRO completes this reconsideration.

If you do not request a review, the hospital may bill you for all the costs of your stay beginning with the third day after you receive the Notice of Noncoverage. The hospital, however, cannot charge you for care unless it provides you with a Notice of Noncoverage.

How To Request a Review of the Notice of Noncoverage

• If the *Notice of Noncoverage* states that your physician agrees with the hospital's decision.

—You must make your request for review to the PRO by noon of the first work day after

you receive the *Notice of Noncoverage* by contacting the PRO by phone or in writing.
—The PRO must ask for your views about your case before making its decision. The PRO will inform you by phone or in writing of its decision on the review.
—If the PRO agrees with the *Notice of Noncoverage*, you may be billed for all costs of your stay beginning at noon of the day you receive the PRO's decision.
—Thus, you will not be responsible for the cost of hospital care before you receive the PRO's decision.

• If the *Notice of Noncoverage* states that the PRO agrees with the hospital's decision:

—You should make your request for reconsideration to the PRO immediately upon receipt of the *Notice of Noncoverage* by contacting the PRO by phone or in writing.
—The PRO can take up to three working days from receipt of your request to complete the review. The PRO will inform you in writing of its decision on the review.
—Since the PRO has already reviewed your case once, prior to the issuance of the *Notice of Noncoverage*, the hospital is permitted to begin billing you the cost of your stay beginning with the third calendar day after you receive your *Notice of Noncoverage* even if the PRO has not completed its review.
—Thus, if the PRO continues to agree with the *Notice of Noncoverage*, you may have to pay for at least one day of hospital care.

Note: The process described above is called "immediate review." If you miss the deadline for this immediate review while you are in the hospital, you may still request a review of Medicare's decision to no longer pay for your care at any point during your hospital stay or after you have left the hospital. The *Notice of Noncoverage* will tell you how to request this review.

Post-Hospital Care

When your doctor determines that you no longer need all the specialized services provided in a hospital, but you still require medical care, he or she may discharge you to a skilled nursing facility or home care. The discharge planner at the hospital will help arrange for the services you may need after your discharge. Medicare and supplemental insurance policies have limited coverage for skilled nursing facility care and home health care. Therefore, you should find out which services will or will not be covered and how payment will be made. Consult with your doctor, hospital discharge planner, patient representative, and your family in making preparations for care after you leave the hospital. Don't hesitate to ask questions.

Acknowledge of Receipt—My signature only acknowledges my receipt of this Message from (name of hospital) on (date) and does not waive any of my rights to request a review or make me liable for any payment.

Signature of beneficiary or person acting on behalf of beneficiary

Date of receipt

Appendix II—Posting of Signs

Section 6018(a)(2) of the Omnibus Budget Reconciliation Act of 1989 (OBRA '89), effective July 1, 1990, requires hospitals and rural primary care hospitals with emergency departments to post signs which specify the rights (under section 1867 of the Social Security Act) of women in labor and individuals with emergency medical conditions to examination and treatment.

To comply with these requirements:

• At a minimum, the signs must specify the rights of unstable individuals with emergency conditions and women in labor who come to the emergency department for health care services;

• It must indicate whether the facility participates in the Medicaid program;

• The wording of the sign must be clear and in simple terms understandable by the population serviced;

• Print the signs in English and other major languages that are common to the population of the area serviced;

• The letters within the signs must be clearly readable at a distance of at least 20 feet or the expected vantage point of the emergency department patrons; and

• Post signs in a place or places likely to be noticed by all individuals entering the emergency department, as well as those individuals waiting for examination and treatment (e.g., entrance, admitting area, waiting room, treatment area).

The sample on the following page, which may be adapted for your use, contains sufficient information to satisfy these requirements. It does not, however, satisfy the visibility requirement.

Appendix III—It's the Law! If You Have a Medical Emergency or Are in Labor

You have the right to receive, within the capabilities of this hospital's staff and facilities:

• An appropriate medical Screening Examination.

• Necessary Stabilizing Treatment (including treatment for an unborn child) and if necessary.

• An appropriate Transfer to another facility even if you cannot pay or do not have medical insurance or you are not entitled to Medicare or Medicaid.

This hospital (does/does not) participate in the Medicaid program.

[FR Doc. 94–14926 Filed 6–16–94; 1:43 pm]
BILLING CODE 4120–01–P

FEDERAL EMERGENCY MANAGEMENT AGENCY

44 CFR Part 65

[Docket No. FEMA–7096]

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Interim rule.

SUMMARY: This interim rule lists communities where modification of the base (100-year) flood elevations is appropriate because of new scientific or technical data. New flood insurance premium rates will be calculated from the modified base (100-year) flood elevations for new buildings and their contents.

DATES: These modified base flood elevations are currently in effect on the dates listed in the table and revise the Flood Insurance Rate Map(s) in effect prior to this determination for each listed community.

From the date of the second publication of these changes in a newspaper of local circulation, any person has ninety (90) days in which to request through the community that the Associate Director, Mitigation Directorate, reconsider the changes. The modified elevations may be changed during the 90-day period.

ADDRESSES: The modified base (100-year) flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Michael K. Buckley, P.E., Chief, Hazard Identification Branch, Mitigation Directorate, 500 C Street, SW., Washington, DC 20472, (202) 646–2756.

SUPPLEMENTARY INFORMATION: The modified base (100-year) flood elevations are not listed for each community in this interim rule. However, the address of the Chief Executive Officer of the community where the modified base (100-year) flood elevation determinations are available for inspection is provided.

Any request for reconsideration must be based upon knowledge of changed conditions, or upon new scientific or technical data.

The modifications are made pursuant to Section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 et seq., and with 44 CFR Part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified base (100-year) flood elevations are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified elevations, together with the floodplain management criteria

required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities.

The changes in base flood elevations are in accordance with 44 CFR 65.4.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Associate Director, Mitigation Directorate, certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified base (100-year) flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification

This proposed rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

Accordingly, 44 CFR Part 65 is amended to read as follows:

PART 65—[AMENDED]

1. The authority citation for Part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 65.4 [Amended]

2. The tables published under the authority of § 65.4 are amended as follows:

State and county	Location	Dates and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
Iowa: Story	City of Ames	April 22, 1994, April 29, 1994, The Daily Tribune.	The Honorable Larry Curtis, Mayor, City of Ames, P.O. Box 811, Ames, Iowa 50010.	March 3, 1994.	190254
Louisiana: St. Tammany Parish.	Unincorporated areas.	April 7, 1994, April 14, 1994, Farmer Newspaper.	The Honorable Kevin Davis, President, St. Tammany Parish, Police Jury, P.O. Box 628, Covington, Louisiana 70434.	February 22, 1994.	225205
North Dakota: Cass	City of Fargo	April 19, 1994, April 26, 1994, The Forum.	The Honorable Jon G. Lindgren, Mayor, City of Fargo, City Hall, 200 North Third Street, Fargo, North Dakota 28102.	April 12, 1994.	385364
Texas: Bexar	Unincorporated areas.	April 14, 1994, April 21, 1994, San Antonio Express News.	The Honorable Cyndi Krier, Bexar County Judge, Bexar County Courthouse, 100 Dolorosa, San Antonio, Texas 78205.	February 2, 1994.	480035
Texas: Dallas and Denton.	City of Carrollton	April 21, 1994, April 28, 1994, The Metrocrest News.	The Honorable Milburn Gravley, Mayor, City of Carrollton, P.O. Box 110535, Carrollton, Texas 75011–0535.	March 9, 1994.	480167
Texas: Dallas	City of Dallas	April 12, 1994, April 19, 1994, Daily Commercial Record.	The Honorable Steve Bartlett, Mayor, City of Dallas, Office of the Mayor and City Council, 1500 Madrilla, 5E North, Dallas, Texas 75201.	February 17, 1994.	480171
Texas: Williamson	City of Georgetown	April 20, 1994, April 27, 1994, Williamson County Sun.	Mr. David Hall, Floodplain Administrator, City of Georgetown, P.O. Box 409, Georgetown, Texas 78627.	January 24, 1994.	480668
Texas: Harris	Unincorporated areas.	April 1, 1994, April 8, 1994, Houston Chronicle.	The Honorable Jon Lindsay, Harris County Judge, Ninth Floor Courtroom, 1001 Preston, Houston, Texas 77002.	March 11, 1994.	480287
Texas: Tarrant	City of Keller	April 19, 1994, April 26, 1994, The Keller Citizen.	The Honorable John Buchanan, Mayor, City of Keller, P.O. Box 770, Keller, Texas 76244.	March 11, 1994.	480602

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance")

Dated: June 16, 1994.

Richard T. Moore,

Associate Director for Mitigation.

[FR Doc. 94–15156 Filed 6–21–94; 8:45 am]

BILLING CODE 6718–03–M

44 CFR Part 65

Changes in Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: Modified base (100-year) flood elevations are finalized for the communities listed below. These modified elevations will be used to calculate flood insurance premium rates for new buildings and their contents

EFFECTIVE DATE: The effective dates for these modified base (100-year) flood elevations are indicated on the following table and revise the Flood Insurance Rate Map(s) in effect for each listed community prior to this date.

ADDRESSES: The modified base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the following table.

FOR FURTHER INFORMATION CONTACT: Michael K. Buckley, P.E., Chief, Hazard Identification Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646–2756.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes the final determinations listed below of the final determinations of modified base (100-year) flood elevations for each community listed. These modified elevations have been published in newspapers of local circulation and ninety (90) days have elapsed since that publication. The Associate Director has resolved any appeals resulting from this notification.

The modified base (100-year) flood elevations are not listed for each community in this notice. However, this rule includes the address of the Chief Executive Officer of the community where the modified base (100-year) flood elevation determinations are available for inspection.

The modifications are made pursuant to Section 206 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 et seq., and with 44 CFR Part 65.

For rating purposes, the currently effective community number is shown and must be used for all new policies and renewals.

The modified base (100-year) flood elevations are the basis for the floodplain management measures that the community is required to either adopt or to show evidence of being already in effect in order to qualify or to remain qualified for participation in the National Flood Insurance Program (NFIP).

These modified elevations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own, or pursuant to policies established by other Federal, State, or regional entities.

These modified elevations are used to meet the floodplain management requirements of the NFIP and are also used to calculate the appropriate flood insurance premium rates for new buildings built after these elevations are made final, and for the contents in these buildings.

The changes in base (100-year) elevations are in accordance with 44 CFR 65.4.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Associate Director, Mitigation Directorate, certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because modified base (100-year) flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are required to maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification

This proposed rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 65

Flood insurance, Floodplains, Reporting and recordkeeping requirements.

Accordingly, 44 CFR Part 65 is amended to read as follows:

PART 65—[AMENDED]

1. The authority citation for Part 65 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 65.4 [Amended]

2. The tables published under the authority of § 65.4 are amended as follows:

State and county	Location	Dates and name of newspaper where notice was published	Chief executive officer of community	Effective date of modification	Community No.
Oklahoma: Oklahoma (FEMA docket No. 7087).	City of Oklahoma	December 10, 1993, December 17, 1993, The Daily Oklahoman.	The Honorable Ronald J. Norick, Mayor, City of Oklahoma City, 200 North Walker, Suite 302, Oklahoma City, Oklahoma 73102.	November 18, 1993.	405378
Texas: Tarrant (FEMA docket No. 7087).	City of North Richland Hills.	December 2, 1993, December 9, 1993, Mid-Cities News.	The Honorable Tommy Brown, Mayor, City of North Richland Hills, P.O. Box 820609, North Richland Hills, Texas 76182.	November 19, 1993.	480607
Texas: Collin (FEMA docket No. 7087).	City of Plano	December 24, 1993, December 31, 1993, The Dallas Morning News.	The Honorable James N. Muns, Mayor, City of Plano, P.O. Box 860358, Plano, Texas 75086–0358.	December 13, 1993.	480140
Texas: Wichita (FEMA docket No. 7087).	City of Wichita Falls	January 19, 1994, January 26, 1994, Wichita Falls Times Record News.	The Honorable Mike Lam, Mayor, City of Wichita Falls, P.O. Box 1431, Wichita Falls, Texas 76307.	December 20, 1993.	480662

(Catalog of Federal Domestic Assistance No. 83.100, "Flood Insurance")

Dated: June 16, 1994.

Richard T. Moore,

Associate Director for Mitigation.

[FR Doc. 94–15157 Filed 6–21–94; 8:45 am]

BILLING CODE 6718–03–M

44 CFR Part 67

Final Flood Elevation Determinations

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Final rule.

SUMMARY: Base (100-year) flood elevations and modified base (100-year) flood elevations are made final for the communities listed below. The base (100-year) flood elevations and modified base flood elevations are the basis for the floodplain management measures that each community is required either to adopt or to show evidence of being already in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

EFFECTIVE DATES: The date of issuance of the Flood Insurance Rate Map (FIRM) showing base flood elevations and modified base flood elevations for each community. This date may be obtained by contacting the office where the FIRM is available for inspection as indicated on the table below.

ADDRESSES: The final base flood elevations for each community are available for inspection at the office of the Chief Executive Officer of each community. The respective addresses are listed in the table below.

FOR FURTHER INFORMATION CONTACT: Michael K. Buckley, P.E., Chief, Hazard Identification Branch, Mitigation Directorate, 500 C Street SW., Washington, DC 20472, (202) 646–2756.

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency makes final determinations listed below of base flood elevations and modified base flood elevations for each community listed. The proposed base flood elevations and proposed modified base flood elevations were published in newspapers of local circulation and an opportunity for the community or individuals to appeal the proposed determinations to or through the community was provided for a period of ninety (90) days. The proposed base flood elevations and proposed modified base flood elevations were also published in the **Federal Register**.

This final rule is issued in accordance with Section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR Part 67.

FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR Part 60.

Interested lessees and owners of real property are encouraged to review the proof Flood Insurance Study and FIRM available at the address cited below for each community.

The base flood elevations and modified base flood elevations are made final in the communities listed below. Elevations at selected locations in each community are shown.

National Environmental Policy Act

This rule is categorically excluded from the requirements of 44 CFR Part 10, Environmental Consideration. No environmental impact assessment has been prepared.

Regulatory Flexibility Act

The Associate Director, Mitigation Directorate, certifies that this rule is exempt from the requirements of the Regulatory Flexibility Act because final or modified base flood elevations are required by the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and are required to establish and maintain community eligibility in the NFIP. No regulatory flexibility analysis has been prepared.

Regulatory Classification

This proposed rule is not a significant regulatory action under the criteria of Section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 12612, Federalism

This rule involves no policies that have federalism implications under Executive Order 12612, Federalism, dated October 26, 1987.

Executive Order 12778, Civil Justice Reform

This rule meets the applicable standards of Section 2(b)(2) of Executive Order 12778.

List of Subjects in 44 CFR Part 67

Administrative practice and procedure, Flood insurance, Reporting and recordkeeping requirements.

Accordingly, 44 CFR Part 67 is amended to read as follows:

PART 67—[AMENDED]

1. The authority citation for Part 67 continues to read as follows:

Authority: 42 U.S.C. 4001 et seq.; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp., p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp., p. 376.

§ 67.11 [Amended]

2. The tables published under the authority of § 67.11 are amended as follows:

PROPOSED BASE (100-YEAR) FLOOD ELEVATIONS

Source of flooding and location	#Depth in feet above ground. *Elevation in feet (NGVD)
ARKANSAS	
Maumelle (city), Pulaski County (FEMA Docket No. 7088)	
Arkansas River:	
Approximately 0.9 mile upstream of the I–430 bridge and approximately 1,300 feet east and 400 feet south of the intersection of Crystal Hill Road and Counts Massie Road	*263
Approximately 4,900 feet west of the intersection of Orchid Drive and Masters Place Cove	*266
Approximately 4,200 feet west of the intersection of Odom Boulevard (south) and Naylor Drive	*268
White Oak Bayou:	
Approximately 2,700 feet east of the intersection of Maumelle Boulevard and Palmer Drive	*262
Approximately 2,000 feet east of the intersection of Murphy Drive and Hyman Drive	*262
Maps are available for review at City Hall, 550 Edgewood Drive, Maumelle, Arkansas.	
IOWA	
Fairfield (city), Jefferson County (FEMA Docket No. 7088)	
Crow Creek:	
Approximately 900 feet upstream of the confluence of Kaghaghee Creek	*693
Approximately 1,950 feet upstream of the confluence of Kaghaghee Creek	*695
Maps are available for review at the City Hall, City of Fairfield, 118 South Main Street, Fairfield, Iowa.	
TEXAS	
Carrollton (City), Dallas, Denton, and Collin Counties (FEMA Docket No. 7082)	
Stream 6D–5:	
Approximately 300 feet upstream of the confluence with Hutton Branch	*494
Approximately 0.6 mile upstream of Carmel Drive	*546
Elm Fork of Trinity River:	
Just downstream of Beltline Road	*440
Approximately 200 feet upstream of the confluence of Denton Creek	*446
Maps are available for inspection at the City of Engineering Department, 1945 Jackson Road, Carrollton, Texas.	
Jacksonville (city), Cherokee County (FEMA Docket No. 7088)	
Keys Creek:	