

required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by August 3, 2007. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this rule for the purposes of judicial review, nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2)).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Intergovernmental relations, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: May 22, 2007.

Russell L. Wright, Jr.,

Acting Regional Administrator, Region 4.

[FR Doc. E7-10696 Filed 6-1-07; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

42 CFR Part 136

Center for Medicare & Medicaid Services

42 CFR Part 489

[CMS-2206-F]

RIN 0917-AA02

Section 506 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003—Limitation on Charges for Services Furnished by Medicare Participating Inpatient Hospitals to Individuals Eligible for Care Purchased by Indian Health Programs

AGENCY: Indian Health Service (IHS), Center elsewhere for Medicare & Medicaid Services (CMS), Health and Human Services (HHS).

ACTION: Final rule.

SUMMARY: The Secretary of the Department of Health and Human Services (HHS) hereby issues this final rule establishing regulations required by section 506 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA), (Pub. L. 108-173). Section 506 of the MMA amended section 1866 (a)(1) of the Social Security Act to add subparagraph (U) which requires hospitals that furnish inpatient hospital services payable under Medicare to participate in the contract health services program (CHS) of the Indian Health Service (IHS) operated by the IHS, Tribes, and Tribal organizations, and to participate in programs operated by urban Indian organizations that are funded by IHS (collectively referred to as I/T/Us) for any medical care purchased by those programs. Section 506 also requires such participation to be in accordance with the admission practices, payment methodology, and payment rates set forth in regulations established by the Secretary, including acceptance of no more than such payment rates as payment in full.

DATES: These final regulations are effective July 5, 2007.

FOR FURTHER INFORMATION CONTACT: Carl Harper, Director, Office of Resource Access and Partnerships, IHS, 801 Thompson Avenue, Twinbrook Metro Plaza Suite 360, Rockville, Maryland 20852, telephone (301) 443-2694. Dorothy Dupree, Director, Tribal Affairs Group, OEA, CMS, 7500 Security Boulevard, Mail Stop: C1-13-11, Baltimore, Maryland 21244, telephone (410) 786-1942. (These are not toll free numbers.)

SUPPLEMENTARY INFORMATION:

I. Background

On April 28, 2006, IHS and CMS published proposed rules in the **Federal Register** (71 FR 25124) as mandated by section 506(c) of the MMA, which requires the Secretary to publish rules implementing the requirements of section 506 of the MMA. Under that statutory provision, hospitals that furnish inpatient hospital services payable under Medicare are required to participate both in the contract health service (CHS) program of IHS operated by IHS, Tribes, and Tribal organizations, and in programs operated by urban Indian organizations (I/T/Us) that are funded by the IHS, for medical care purchased by those programs. Section 506 also requires such participation to be in accordance with the admission practices, payment methodology, and

payment rates set forth in regulations established by the Secretary, including acceptance of no more than such rate as payment in full. The proposed rule provided interested persons until June 27, 2006 to submit written comments.

II. Provisions of the Proposed Regulations

a. The Proposed Rule

We proposed to amend the IHS regulations at 42 CFR part 136, by adding a new subpart D to describe the payment methodology and other requirements for Medicare-participating hospitals and critical access hospitals (CAHs) that furnish inpatient services, either directly or under arrangement, to individuals who are authorized to receive services from such hospitals under a CHS program of the IHS, Tribes, and Tribal organizations, and IHS-funded programs operated by urban Indian organizations (collectively, I/T/U programs). As provided in the statute, we also proposed to amend CMS regulations at 42 CFR part 489 to require Medicare-participating hospitals and critical access hospitals (CAHs) that furnish inpatient hospital services to individuals who are eligible for and authorized to receive items and services covered by such I/T/U programs to accept no more than the payment methodology under 42 CFR part 136, subpart D as payment in full for such items and services. The proposed rule did not include additional regulation of admission practices.

b. Summary of Changes in the Final Rule

In reviewing several comments, IHS and CMS determined that the payment methodology in the proposed rule was not adequately explained. Therefore, we are clarifying the payment methodologies established by this regulation to include more detail. For hospital services that would be paid under prospective payment systems (PPS) by the Medicare program, the basic payment methodology under this rule is based on the applicable PPS. For example, inpatient hospital services of acute care hospitals, psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals will be paid based on the same four Medicare PPS systems as would be used to pay for similar hospital services to the hospitals' Medicare patients, as described under 42 CFR part 412, while outpatient hospital services and skilled nursing facility services (SNF) will be paid based on their Medicare PPS systems, as described under 42 CFR part 419 (outpatient) and 42 CFR part 413

(SNF) respectively. The basic payment methodology under this rule for Medicare-participating hospitals that furnish inpatient services but are exempt from PPS and currently receive reasonable cost reimbursement under the Medicare program (for example, critical access hospitals (CAHs), children's hospitals, cancer hospitals, and certain other hospitals reimbursed by Medicare under special arrangements), is based on 42 CFR part 413, which addresses reasonable cost reimbursement.

In addition, based on the comments received, IHS and CMS determined that the requirement that providers participate in IHS and Tribal CHS programs and IHS-funded urban Indian organization programs was not clear in the proposed rule and additional guidance was needed. Therefore, we clarified that hospitals participating in Medicare that furnish inpatient hospital services will be required to accept the payment methodology and no more than the rates established under 42 CFR part 136, subpart D as payment in full for such services. This change also clarifies that such hospitals may not refuse service to an individual on the basis that the individual may be eligible for payment under such CHS and IHS-funded urban Indian programs. We did not include additional prohibitions on discrimination in admission practices because such requirements are already covered and enforced by the HHS Office for Civil Rights under existing regulations at 45 CFR part 80.

III. Analysis of and Responses to Public Comments

The IHS received 35 comments from Tribes, Tribal organizations, hospital associations, CAHs, and individuals. The IHS, in partnership with CMS, carefully reviewed the submissions by individuals, groups, Indian, and non-Indian organizations. We did not consider 4 of these comments, because they were received after the closing date. Of the 31 timely comments, 26 comments supported the proposed regulation. Several comments requested clarification of certain sections of the rule.

Comment: We received 10 comments that expressed serious concern regarding the long delay in publication of the proposed rule and requested expedited publication of a final rule.

Response: The development of this final rule has been a long and careful process, involving consultation with the Tribes through the CMS Tribal Technical Advisory Group, and close collaboration between IHS and CMS. An incidental benefit of this process has

been greater understanding by all parties of the service delivery and payment processes that are at issue in this rule.

Comment: A number of the comments from Tribes and Tribal organizations expressed concerns that affected Indian health programs would need training to fully implement and monitor the participation and payment requirements.

Response: IHS is authorized to provide technical assistance regarding implementation of this final rule. Tribal program representatives can contact Mr. Carl Harper at the phone number listed in the contact information.

Comment: One commenter expressed concern that American Indian/Alaska Native (AI/AN) populations have many complications and co-morbidities that do not exist to the same extent in the patient population as a whole, including diabetes, cardiovascular disease, injury, trauma, and alcoholism. The commenter suggested that costs to treat this population are higher and suggested IHS would be paying less for its patient population than Medicare actually pays for services furnished to a comparable population.

Response: Patients who are more seriously ill tend to require a higher level of hospital resources than patients who are less seriously ill even though they may be admitted to the hospital for the same reason. Recognizing this, Medicare payments can be higher for patients in certain diagnostic-related groups (DRGs) based on a secondary diagnosis that could indicate specific complications or co-morbidities. Also, the DRG groupings take into consideration co-morbidity factors, and payment adjustments that would be available to reflect the higher costs of disproportionate share hospital adjustments and outlier payments are provided for exceptionally high cost cases, all of which would address high costs of this patient population. As a result, IHS payment under this rule will reflect the serious health issues faced by its patient population.

Comment: One commenter expressed concern that the CHS program payments are not always timely and should be paid in accordance with Medicare timeline requirements.

Response: This regulation addresses practices, payment methodologies, and rates of payment that are not already addressed under current laws or regulations. The time frame for paying claims authorized by IHS under the CHS program is already governed by section 220 of the Indian Health Care Improvement Act (IHCIA).

Comment: One commenter expressed concern that payment for services should be absolute for services rendered, not at the service unit's discretion. In addition, this commenter suggested IHS set the timeline for notification of emergency services at a minimum of 30 days following services rendered.

Response: Payment for services is based on a medical priority system which is based on the availability of funds as established under 42 CFR part 136, subpart C. Under subpart C of title 42, notification of emergency services must be provided within 72 hours after the beginning of treatment or admission to a health care facility. The timeline for notification of emergency services for the elderly and disabled is currently set at 30 days in accordance with section 406 of the IHCIA.

Comment: One commenter expressed concern that the proposed rule places an additional burden on hospitals by capping rates paid to public and private non-IHS funded hospitals, with no additional responsibility or accountability placed on I/T/U programs regarding payments to such hospitals.

Response: This rule would provide for rates that hospitals accept under the Medicare program. We do not believe these rates place an additional burden on hospitals.

Comment: One commenter asked whether the payment rates required under this rule would apply to claims for services furnished by long-term care hospitals, independent inpatient rehabilitation facilities, and inpatient psychiatric facilities to individuals who were authorized for the service by an I/T/U program.

Response: Long-term care hospitals, independent inpatient rehabilitation facilities, and inpatient psychiatric facilities are covered by these rules because they meet the criteria of section 506 of the MMA: They are covered by the definition of "hospital" in section 1861(e) or (f), as applicable, of the Social Security Act and they furnish inpatient hospital services. They will be paid based upon their respective Medicare PPS systems.

Comment: A commenter asked whether agents will be precluded from charging the I/T/U for the records needed for payment determination or quality assurance in cases in which a facility is using an outside agent to manage its medical records and patient information.

Response: Under section 136.30(j), additional payment would not be available for the cost of copying of medical records to an outside agent who

manages medical records and patient information.

Comment: One commenter expressed concern that the proposed rule does not clearly define what it means to “participate” in programs operated by IHS, Tribes, Tribal organizations, or urban Indian (I/T/U) programs.

Response: Participation in I/T/U programs means that all hospitals covered by this rule must accept the admission practices, payment methodology, and no more than the rates of payment established under this rule as payment in full for items and services purchased by I/T/U programs for individuals eligible for and referred by such programs. To clarify that acceptance of these requirements is mandatory for participation in Medicare, IHS has revised the proposed rule in two ways. First, subsections (a) and (b) of 42 CFR 136.30 have been amended to clarify which entities are affected by the rule and the services that will be covered. Second, 42 CFR 489.29 has also been amended to be consistent with 42 CFR part 136, subpart D. Paragraph (b) has been added to 42 CFR 489.29 to clarify that hospitals cannot deny services to an individual on the basis that payment for such services is authorized by an I/T/U program. However, the rule does not provide additional regulation of discrimination in admission practices because such requirements are already covered and enforced by the HHS Office for Civil Rights under existing regulations at 45 CFR part 80.

Comment: One commenter asked whether hospitals which are not reimbursed on a reasonable cost basis will be reimbursed based on the Medicare DRGs or other prospective payment rate.

Response: We have clarified the payment methodology in the final rule in response to this comment. We are clarifying that, for hospital services that would be paid under prospective payment systems (PPS) by the Medicare program, the basic payment methodology under this rule is based on the applicable PPS. For example, inpatient services furnished by acute care hospitals, psychiatric hospitals, rehabilitation hospitals, and long-term care hospitals will be paid based on their respective PPS used in the Medicare program to pay for similar hospital services to the hospitals’ Medicare patients, as described under 42 CFR part 412, while outpatient hospital services and skilled nursing facility (SNF) services will be paid based on their Medicare PPS, as described under 42 CFR part 419 (outpatient) and 42 CFR part 413 (SNF)

respectively. Under the basic payment methodology of this rule for Medicare-participating hospitals that furnish inpatient services but are exempt from PPS and currently receive reasonable cost reimbursement under the Medicare program (for example, CAHs, children’s hospitals, cancer hospitals, and certain other hospitals reimbursed by Medicare under special arrangements), I/T/Us will reimburse such hospitals for claims in accordance with 42 CFR part 413, which addresses reasonable cost reimbursement. In other words, hospitals reimbursed by Medicare on a reasonable cost basis will not be paid by use of DRGs or other case classification systems used under the various Medicare PPS payment methods. To clarify what hospitals can expect to receive as reimbursements, IHS has created two basic payment determinations under section 136.30(c) in the final rule; one for PPS based payments and one for payments based on reasonable costs.

Comment: Two commenters recommended that payment adjustments for organ acquisition costs, blood clotting factors, new technology services, and disproportionate share be included in the interim payment calculations in order to provide for an appropriate level of reimbursement.

Response: IHS agrees that payment adjustments for the types of services listed above should be included in the payment calculations in order to provide for an appropriate level of reimbursement. Payment adjustments for disproportionate share and new medical technology already are included in the PPS methodology under subparts F and G of part 412. Moreover, to ensure that hospitals receiving PPS payment include these payment adjustments, IHS will use the Medicare PRICER system (or a similar system) in calculating final payment. The system includes adjustments such as those above. For items not adjusted within the system, the IHS fiscal intermediary will be instructed to use standard payments calculated by CMS (for example, payments based on the Average Sales Price (ASP) for hemophilia clotting factors). To clarify that such payments will be added to the basic rate calculation, IHS has added a new section 136.30(d) to the rule.

Comment: Several commenters expressed concern that the interim payment rates will have a financial impact on CAHs. Another commenter expressed concern about the per diem mechanism used to make interim payments to CAHs because there is no requirement to follow Medicare regulations by the I/T/U.

Response: The economic financial impact study conducted by an IHS fiscal intermediary demonstrates that the interim payment rates will have limited financial impact on rural and small rural hospitals as explained in section VI of this final rule, Regulatory Impact Statement. Moreover, in revising the proposed adoption of the Medicare payment methodologies in section 136.30(c) of the final rule, IHS has identified two basic determinations for payment. Payments to CAHs are covered under section 136.30(c)(2). IHS will follow payment guidance based on the reasonable cost methodology under 42 CFR 413.70, “Payment for services of a CAH”. As with other payments based on reasonable cost, payments to CAHs will be based on the interim payment rate established under 42 CFR part 413, subpart E.

Comment: One commenter asked whether the final rule will be applied to claims which are received after the effective date, regardless of the date of service, or only to claims with a date of service after the effective date.

Response: The requirements of the final rule will apply to claims with a date of service on or after the effective date of the final regulation.

Comment: A commenter asked whether contracts will become invalidated by this regulation or remain in effect until they expire in situations in which a hospital contract is currently in place with IHS, which has rates that are not based on Medicare or are not less than Medicare rates.

Response: Medicare-participating hospitals that furnish inpatient services must accept the rate methodology established under this regulation as a condition of participation in the Medicare program. Current hospital contract rates that are lower than the rates established by this regulation will continue to apply in accordance with section 136.30(c).

Comment: One commenter asked if the Medicare timely filing guidelines will be waived and/or modified for claims when the I/T/U (1) is not the primary payor and the patient has alternate resources or, (2) delayed in sending out a timely purchase order.

Response: Under 42 CFR 136.61, as applied in this rule, the I/T/U program is the payor of last resort for individuals eligible for any alternate resources. The timely filing period under 42 CFR 424.44 and provisions of the Medicare Claims Processing Manual will apply to all claims submitted to an I/T/U program for payment.

Comment: One commenter asked the IHS to remove the Health Insurance Portability and Accountability Act

(HIPAA) requirement for electronic claim submission.

Response: If the I/T/U program accepts paper claims, this is still an acceptable format for claims submission. However, if non-I/T/U providers generally submit their claims electronically to other payers, they should also do so for I/T/U payers that accept electronic claims. HIPAA requires electronic claims to be filed using the standard 837 format.

IV. Collection of Information Requirements

This document does not impose any new information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35). **Note:** The burden requirements in section 136.30(h)(1) for submitting a claim form are currently approved under OMB approval number 0938-0279.

V. Regulatory Impact Statement

The IHS has examined the impact of this final rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4), and Executive Order 13132.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). This action is not a significant regulatory action under Executive Order 12866. Further regulatory evaluation is not necessary because the economic impact will be minimal.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. Individuals and States are not included in the definition of a small entity.

The I/T/Us have entered into contracts with many public and private non-I/T Medicare-participating hospitals at rates less than or equal to the rate proposed in this rule. IHS intends to continue existing contracts with these hospitals; however, to the extent that I/T/Us are not able to negotiate a contract with a hospital, payment rates established by this rule will apply. This action will alleviate the need for and administrative burden of negotiating rates through individual contracts by IHS as well as the Medicare-participating hospitals.

The IHS conducted a study to determine the financial impact the interim payment rates, as proposed by this regulation, would have on public and private non-I/T/U hospitals. As part of this study, IHS compared the interim rates to the rates that IHS has negotiated per contracts with public and private non-I/T/U hospitals. For FY 2003, of the 387 hospitals that IHS does business with, IHS has negotiated contracts with 48 percent of these hospitals. Based on IHS data, the findings revealed the overall negative impact on these public and private non-I/T/U hospitals would be less than 1 percent. Of the 387 hospitals in the study, 105 are rural hospitals. Out of the 105 rural hospitals, 84 are small rural hospitals (less than 100 beds). By comparing the interim rate to full billed charges, (that is, what IHS pays if a contract is not negotiated) revealed a negative financial impact of 8 percent on these rural hospitals. Further analysis of the inpatient bed utilization by hospital revealed IHS represents less than 2 percent of the rural and small rural hospitals total business meaning that 98 percent of the hospitals' income comes from other sources. For these reasons, IHS has determined that the rates proposed by these regulations will not have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601 et seq.

In addition, section 1102(b) of the Act requires IHS to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, IHS defines a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. For the reasons provided above, IHS has determined that this rule will not have a significant impact on the operations of a substantial number of small rural hospitals. Section 202 of the Unfunded

Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose requirements mandate expenditure in any 1 year by State, local, or Tribal governments, in the aggregate, or by the private sector, of \$120 million. This proposal would not impose substantial Federal mandates on State, local or Tribal governments or private sector.

Executive Order 13132 establishes certain requirements that an Agency must meet when it promulgates a final rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. It has been determined that this action would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government, and therefore would not have Federalism implications.

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

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance)

List of Subjects

42 CFR Part 136

American Indian, Alaska Natives, Health, Medicare.

42 CFR Part 489

Health facilities, Medicare, Reporting and recordkeeping requirements.

Dated: November 2, 2006.

Charles W. Grim,

Assistant Surgeon General, Director, Indian Health Service.

Dated: November 16, 2006.

Leslie V. Norwalk,

Acting Administrator, Centers for Medicare & Medicaid Services.

Dated: April 18, 2007.

Michael O. Leavitt,

Secretary.

■ The Indian Health Service is amending 42 CFR Chapter I as set forth below:

PART 136—INDIAN HEALTH

■ 1. The authority citation for part 136 continues to read as follows:

Authority: 25 U.S.C. 13; 42 U.S.C. 1395cc(a)(1)(U), 42 U.S.C. 2001 and 2003, unless otherwise noted.

■ 2. Add new subpart D consisting of §§ 136.30 through 136.32, to read as follows:

Subpart D—Limitation on Charges for Services Furnished by Medicare-Participating Hospitals to Indians

Sec.

136.30 Payment to Medicare-participating hospitals for authorized Contract Health Services.

136.31 Authorization by urban Indian organization.

136.32 Disallowance.

Subpart D—Limitation on Charges for Services Furnished by Medicare-Participating Hospitals to Indians

§ 136.30 Payment to Medicare-participating hospitals for authorized Contract Health Services.

(a) *Scope.* All Medicare-participating hospitals, which are defined for purposes of this subpart to include all departments and provider-based facilities of hospitals (as defined in sections 1861(e) and (f) of the Social Security Act) and critical access hospitals (as defined in section 1861(mm)(1) of the Social Security Act), that furnish inpatient services must accept no more than the rates of payment under the methodology described in this section as payment in full for all items and services authorized by IHS, Tribal, and urban Indian organization entities, as described in paragraph (b) of this section.

(b) *Applicability.* The payment methodology under this section applies to all levels of care furnished by a Medicare-participating hospital, whether provided as inpatient, outpatient, skilled nursing facility care, as other services of a department, subunit, distinct part, or other component of a hospital (including services furnished directly by the hospital or under arrangements) that is authorized under part 136, subpart C by a contract health service (CHS) program of the Indian Health Service (IHS); or authorized by a Tribe or Tribal organization carrying out a CHS program of the IHS under the Indian Self-Determination and Education Assistance Act, as amended, Pub. L. 93-638, 25 U.S.C. 450 *et seq.*; or authorized for purchase under § 136.31 by an urban Indian organization (as that term is defined in 25 U.S.C. 1603(h)) (hereafter "I/T/U").

(c) *Basic determination.* (1) Payment for hospital services that the Medicare program would pay under a prospective payment system (PPS) will be based on that PPS. For example, payment for inpatient hospital services shall be made per discharge based on the

applicable PPS used by the Medicare program to pay for similar hospital services under 42 CFR part 412.

Payment for outpatient hospital services shall be made based on a PPS used in the Medicare program to pay for similar hospital services under 42 CFR part 419. Payment for skilled nursing facility (SNF) services shall be based on a PPS used in the Medicare program to pay for similar SNF services under 42 CFR part 413.

(2) For Medicare participating hospitals that furnish inpatient services but are exempt from PPS and receive reimbursement based on reasonable costs (for example, critical access hospitals (CAHs), children's hospitals, cancer hospitals, and certain other hospitals reimbursed by Medicare under special arrangements), including provider subunits exempt from PPS, payment shall be made per discharge based on the reasonable cost methods established under 42 CFR part 413, except that the interim payment rate under 42 CFR part 413, subpart E shall constitute payment in full for authorized charges.

(d) *Other payments.* In addition to the amount payable under paragraph (c)(1) of this section for authorized inpatient services, payments shall include an amount to cover: The organ acquisition costs incurred by hospitals with approved transplantation centers; direct medical education costs; units of blood clotting factor furnished to an eligible patient who is a hemophiliac; and the costs of qualified non-physician anesthetists, to the extent such costs would be payable if the services had been covered by Medicare. Payment under this subsection shall be made on a per discharge basis and will be based on standard payments established by the Centers for Medicare & Medicaid Services (CMS) or its fiscal intermediaries.

(e) *Basic payment calculation.* The calculation of the payment by I/T/Us will be based on determinations made under paragraphs (c) and (d) of this section consistent with CMS instructions to its fiscal intermediaries at the time the claim is processed. Adjustments will be made to correct billing or claims processing errors, including when fraud is detected. I/T/Us shall pay the providing hospital the full PPS based rate, or the interim reasonable cost rate, without reduction for any co-payments, coinsurance, and deductibles required by the Medicare program from the patient.

(f) *Exceptions to payment calculation.* Notwithstanding paragraph (e) of this section, if an amount has been negotiated with the hospital or its agent

by the I/T/U, the I/T/U will pay the lesser of: The amount determined under paragraph (e) of this section or the amount negotiated with the hospital or its agent, including but not limited to capitated contracts or contracts per Federal law requirements;

(g) *Coordination of benefits and limitation on recovery.* If an I/T/U has authorized payment for items and services provided to an individual who is eligible for benefits under Medicare, Medicaid, or another third party payor—

(1) The I/T/U shall be the payor of last resort under § 136.61;

(2) If there are any third party payers, the I/T/U will pay the amount for which the patient is being held responsible after the provider of services has coordinated benefits and all other alternative resources have been considered and paid, including applicable co-payments, deductibles, and coinsurance that are owed by the patient; and

(3) The maximum payment by the I/T/U will be only that portion of the payment amount determined under this section not covered by any other payor; and

(4) The I/T/U payment will not exceed the rate calculated in accordance with paragraph (e) of this section or the contracted amount (plus applicable cost sharing), whichever is less; and

(5) When payment is made by Medicaid it is considered payment in full and there will be no additional payment made by the I/T/U to the amount paid by Medicaid (except for applicable cost sharing).

(h) *Claims processing.* For a hospital to be eligible for payment under this section, the hospital or its agent must submit the claim for authorized services—

(1) On a UB92 paper claim form (until abolished, or on an officially adopted successor form) or the HIPAA 837 electronic claims format ANSI X12N, version 4010A1 (until abolished, or on an officially adopted successor form) and include the hospital's Medicare provider number/National Provider Identifier; and

(2) To the I/T/U, agent, or fiscal intermediary identified by the I/T/U in the agreement between the I/T/U and the hospital or in the authorization for services provided by the I/T/U; and

(3) Within a time period equivalent to the timely filing period for Medicare claims under 42 CFR 424.44 and provisions of the Medicare Claims Processing Manual applicable to the type of item or service provided.

(i) *Authorized services.* Payment shall be made only for those items and

services authorized by an I/T/U consistent with part 136 of this title or section 503(a) of the Indian Health Care Improvement Act (IHCIA), Public Law 94-437, as amended, 25 U.S.C. 1653(a).

(j) *No additional charges.* A payment made in accordance with this section shall constitute payment in full and the hospital or its agent may not impose any additional charge—

(1) On the individual for I/T/U authorized items and services; or

(2) For information requested by the I/T/U or its agent or fiscal intermediary for the purposes of payment determinations or quality assurance.

§ 136.31 Authorization by urban Indian organization.

An urban Indian organization may authorize for purchase items and services for an eligible urban Indian (as those terms are defined in 25 U.S.C. 1603(f) and (h)) according to section 503 of the IHCIA and applicable regulations. Services and items furnished by Medicare-participating inpatient hospitals shall be subject to the payment methodology set forth in § 136.30.

§ 136.32 Disallowance.

(a) If it is determined that a hospital has submitted inaccurate information for payment, such as admission, discharge or billing data, an I/T/U may as appropriate—

(1) Deny payment (in whole or in part) with respect to any such services, and;

(2) Disallow costs previously paid, including any payments made under any methodology authorized under this subpart. The recovery of payments made in error may be taken by any method authorized by law.

(b) For cost based payments previously issued under this subpart, if it is determined that actual costs fall significantly below the computed rate actually paid, the computed rate may be retrospectively adjusted. The recovery of overpayments made as a result of the adjusted rate may be taken by any method authorized by law.

■ The Centers for Medicare & Medicaid Services is amending 42 CFR Chapter IV, as set forth below:

PART 489—PROVIDER AGREEMENTS AND SUPPLIER APPROVAL

■ 3. The authority citation for part 489 continues to read as follows:

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

Subpart B—Essentials of Provider Agreements

■ 4. A new § 489.29 is added to subpart B to read as follows:

§ 489.29 Special requirements concerning beneficiaries served by the Indian Health Service, Tribal health programs, and urban Indian organization health programs.

(a) Hospitals (as defined in sections 1861(e) and (f) of the Social Security Act) and critical access hospitals (as defined in section 1861(mm)(1) of the Social Security Act) that participate in the Medicare program and furnish inpatient hospital services must accept the payment methodology and no more than the rates of payment established under 42 CFR part 136, subpart D as payment in full for the following programs:

(1) A contract health service (CHS) program under 42 CFR part 136, subpart C, of the Indian Health Service (IHS);

(2) A CHS program under 42 CFR part 136, subpart C, carried out by an Indian Tribe or Tribal organization pursuant to the Indian Self-Determination and Education Assistance Act, as amended, Public Law 93-638, 25 U.S.C. 450 *et seq.*; and

(3) A program funded through a grant or contract by the IHS and operated by an urban Indian organization under which items and services are purchased for an eligible urban Indian (as those terms are defined in 25 U.S.C. 1603 (f) and (h)).

(b) Hospitals and critical access hospitals may not refuse service to an individual on the basis that the payment for such service is authorized under programs described in paragraph (a) of this section.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 300

[Docket No. 070215036-7107-02; I.D. 012307A]

RIN 0648-AU79

International Fisheries; Pacific Tuna Fisheries; Restrictions for 2007 Purse Seine and Longline Fisheries in the Eastern Tropical Pacific Ocean

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Department of Commerce.

ACTION: Final rule.

SUMMARY: NMFS publishes this final rule to implement the 2007 management measures to reduce overfishing of the eastern tropical Pacific Ocean (ETP) tuna stocks in 2007, consistent with recommendations by the Inter-American Tropical Tuna Commission (IATTC) that have been approved by the Department of State (DOS) under the Tuna Conventions Act. The U.S. purse seine fishery for yellowfin, bigeye, and skipjack tunas in the ETP will be closed for a 6-week period beginning August 1, 2007, through September 11, 2007. The longline fishery for bigeye tuna will close when a 500 metric ton (mt) limit has been reached. These actions are taken to limit fishing mortality caused by purse seine fishing and longline fishing in the ETP and contribute to long-term conservation of the tuna stocks at levels that support healthy fisheries.

DATES: The 2007 purse seine fishery closure for yellowfin, bigeye, and skipjack tunas is effective on 12:00 a.m. Pacific Time, August 1, 2007, through 11:59 p.m. Pacific Time, September 11, 2007. For 2007, NMFS will close the bigeye longline fishery through appropriate procedures to ensure that the bigeye longline tuna catch does not exceed 500 mt.

ADDRESSES: Copies of the regulatory impact review/final regulatory flexibility analysis (FRFA) may be obtained from the Southwest Regional Administrator, Southwest Region, NMFS, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802-4213.

FOR FURTHER INFORMATION CONTACT: J. Allison Routt, Sustainable Fisheries Division, Southwest Region, NMFS, (562) 980-4030.

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SUPPLEMENTARY INFORMATION: The United States is a member of the IATTC, which was established by international agreement through the Convention for the Establishment of an Inter-American Tropical Tuna Commission (Convention), which was signed in 1949. The IATTC was established to ensure the effective international conservation and management of highly migratory species of fish in the ETP. For the purposes of these closures, the ETP is defined to include the waters bounded by the coast of the Americas, the 40° N. and 40° S. parallels, and the 150° W. meridian. The IATTC has maintained a scientific research and