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Wednesday, February 27, 2002

## Part IV

# Department of Health and Human Services

Centers for Medicare and Medicaid Services

## 42 CFR Parts 410 and 414

Medicare Program; Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Nonemergency Ambulance Services; Final Rule

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

## 42 CFR Parts 410 and 414

[HCFA-1002-FC]

RIN 0938-AK30

## Medicare Program; Fee Schedule for Payment of Ambulance Services and Revisions to the Physician Certification Requirements for Coverage of Nonemergency Ambulance Services

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS. **ACTION:** Final rule with comment period.

SUMMARY: This final rule establishes a fee schedule for the payment of ambulance services under the Medicare program, implementing section 1834(l) of the Social Security Act. As required by that section, the proposed rule on which this final fee schedule for ambulance services is based was the product of a negotiated rulemaking process that was carried out consistent with the Federal Advisory Committee Act and the Negotiated Rulemaking Act of 1990. The fee schedule described in this final rule will replace the current retrospective reasonable cost payment system for providers and the reasonable charge system for suppliers of ambulance services. In addition, this final rule requires that ambulance suppliers accept Medicare assignment; codifies the establishment of new Health Care Common Procedure Coding System (HCPCS) codes to be reported on claims for ambulance services; establishes increased payment under the fee schedule for ambulance services furnished in rural areas based on the location of the beneficiary at the time the beneficiary is placed on board the ambulance; and revises the certification requirements for coverage of nonemergency ambulance services. DATES: Effective date: April 1, 2002.

Comment date: We will consider comments on portions of the regulation with respect to the following sections of the Medicare, Medicaid, and State Child Health Insurance Program Benefits Improvement and Protection Act (BIPA), Pub. L. 106–554: the provisions implementing the portion of section 205 relating to cost reimbursement for ambulance services furnished by certain critical access hospitals (CAHs) (§ 414.601 and § 414.610(a)); the provisions implementing section 221, establishing the rate for rural ambulance

mileage greater than 17 miles and up to 50 miles (§ 414.610(c)(5)); the provisions implementing section 423 with regard to immediate payment of the full ambulance services fee schedule amount for in-county ground mileage under certain circumstances (§414.615(g)), if we receive them at the appropriate address, as provided below, no later than 5 p.m. on April 29, 2002. ADDRESSES: Mail written comments (an original and 3 copies) to the following address only: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1002-FC, PO Box 8013, Baltimore, MD 21244-8013.

To ensure that mailed comments are received in time for us to consider them, please allow for possible delays in delivering them.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses: Room 443–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or, Room C5–14–03, 7500 Security Boulevard, Baltimore, MD 21244–8013.

Comments mailed to the above addresses may be delayed and received too late for us to consider them.

Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code CMS–1002–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 C5–12–08 at 7500 Security Blvd, Baltimore, MD, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. Please call (410) 786– 7197 to view these comments.

For information on ordering copies of the **Federal Register** containing this document and electronic access, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Glenn McGuirk, (410) 786–5723. SUPPLEMENTARY INFORMATION: Copies: To order copies of the Federal Register containing this document, send your request to: New Orders, Superintendent of Documents, PO 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) 512–1800 or by faxing to (202) 512-2250. The cost for each copy is \$9. As an alternative, you

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## I. Background

The Medicare program pays for transportation services for Medicare beneficiaries when other means of transportation are contraindicated. Ambulance services are divided into different levels of ground (including water) and air ambulance services based on the medically necessary treatment provided during transport. These services include the levels of service listed below, which we define later in this rule.

For Ground:

- Basic Life Support (BLS)
- Advanced Life Support, Level 1 (ALS1)
- Advanced Life Support, Level 2 (ALS2)
- Specialty Care Transport (SCT)Paramedic ALS Intercept (PI)
- *For Air:*
- Fixed Wing Air Ambulance (FW)
- Rotary Wing Air Ambulance (RW) Currently payment levels for

ambulance services depend, in part, upon the entity that furnishes the services. Providers (hospitals, including critical access hospitals, skilled nursing facilities, and home health agencies) are paid on a retrospective reasonable cost basis. Suppliers, which are entities that are independent of any provider, are paid on a reasonable charge basis. This final rule establishes a fee schedule payment system for all such services.

## A. History of Medicare Ambulance Services

1. Original Statutory Coverage of Ambulance Services

Under section 1861(s)(7) of the Social Security Act (the Act), Medicare part B (Supplementary Medical Insurance) covers and pays for ambulance services, to the extent prescribed in regulations, when the use of other methods of transportation would be contraindicated. The House Ways and Means Committee and Senate Finance Committee Reports that accompanied the 1965 Social Security Amendments suggest that the Congress intended that (1) the ambulance benefit cover transportation services only if other means of transportation are contraindicated by the beneficiary's medical condition, and (2) only ambulance service to local facilities be covered unless necessary services are not available locally, in which case, transportation to the nearest facility furnishing those services is covered (H.R. Rep. No. 213, 89th Cong., 1st Sess. 37 and S. Rep. No. 404, 89th Cong., 1st Sess., Pt I, 43 (1965)). The reports indicate that transportation may also be provided from one hospital to another, to the beneficiary's home, or to an extended care facility.

2. Medicare Regulations for Ambulance Services

Our regulations relating to ambulance services are located at 42 CFR part 410, subpart B. Section 410.10(i) lists ambulance services as one of the covered medical and other health services under Medicare part B. Ambulance services are subject to basic conditions and limitations set forth at § 410.12 and to specific conditions and limitations included at § 410.40.

On January 25, 1999, we published a final rule with comment period (64 FR 3637) to revise and update Medicare policy concerning ambulance services. It identified destinations to which ambulance services are covered, established requirements for the vehicles and staff used to furnish ambulance services, and clarified coverage of nonemergency ambulance services for Medicare beneficiaries. This rule also implemented section 4531(c) of the Balanced Budget Act of 1997 (BBA), Pub. L. 105-33, concerning Medicare coverage for paramedic intercept services in rural communities.

We published a final rule on March 15, 2000 (65 FR 13911) responding to public comments received on the January 25, 1999 final rule with comment period regarding Medicare coverage of, and payment for, paramedic intercept ambulance services in rural communities. It also implemented section 412 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (BBRA), Pub. L. 106–113, by adding a new definition of a rural area.

## 3. Negotiated Rulemaking Process

Section 1834(l)(1) of the Act provides that the ambulance fee schedule be established through the negotiated rulemaking process described in the Negotiated Rulemaking Act of 1990 (Pub. L. 101–648, 5 U.S.C. 581–590). Negotiations were conducted by a committee chartered under the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2). The Negotiated

Rulemaking Committee on the Medicare Ambulance Services Fee Schedule (the Committee) consisted of individuals associated with national organizations that represent interests that are likely to be significantly affected by the fee schedule. There was a public solicitation through the Federal Register on January 22, 1999 (64 FR 3474) for participation in the negotiated rulemaking process. (Additional information about the negotiations can be found in the January 22, 1999 Federal Register notice or may be accessed at our Internet Web site at http://www.hcfa.gov/medicare/ ambmain.htm.)

The Committee discussed various issues related to the ambulance fee schedule and a consensus Committee Statement was signed on February 14, 2000.

### 4. Proposed Rule

In our proposed rule, we discussed the negotiated rulemaking procedure used to formulate our policy for the ambulance fee schedule and proposed additions to part 414 based on recommendations of the Committee. We discussed operational and regional variations, cost of living differences, services furnished in rural areas, and mileage. The structure of the fee schedule, the ambulance inflation factor, and phase-in methodology were also discussed.

In addition, we proposed changes unrelated to the Committee's consensus statement on matters including coverage of ambulance services, physician certification requirements, payment during the first year, and billing method. We discussed local or State law related to ambulance services, mandatory assignment, and miscellaneous payment policies, including multiple patients, pronouncement of death, multiple arrivals, and BLS services furnished in an ALS vehicle.

We presented our methodology for determining the conversion factor (CF) and for implementing the fee schedule. We discussed expenditure control for ambulance services and adjustments to account for inflation. Finally, to seek input on the desirability and flexibility of developing a code set to describe patients' conditions, we included an addendum containing a list of medical conditions.

In accordance with the negotiated rulemaking procedures, we proposed the following additions to part 414 based on the recommendations of the Committee.

1. Definitions and levels of services. In part 414, we proposed to add subpart H, § 414.605 to define several levels of ground ambulance services ranging from BLS to specialty care transport. (Note that the term "ground" refers to both land and water transportation. The definitions and RVUs for each of the levels of service were described in § 414.605, "Definitions.") Also, we proposed that the rate per ground mile for all ground ambulance services would be the same for each level of service.

We stated in the proposed rule that there would be two levels of air ambulance services to distinguish fixed wing from rotary wing (helicopter) aircraft. In addition, to recognize the operational cost differences of the two types of aircraft, there would be two distinct payment amounts for air ambulance mileage. The air ambulance services mileage rate would be calculated per actual loaded (patient onboard) miles flown, expressed in statute miles (that is, ground, not nautical, miles.)

The Committee used an industry consensus document, described below, as the basis for defining the levels of ambulance service.

During 1990, the development of a training blueprint and the evaluation of current levels of training and certification for prehospital providers were identified as priority needs for national emergency medical services (EMS). As a result, the National EMS Training Blueprint Project was formed.

In May 1993, representatives of EMS organizations adopted the National EMS **Education and Practice Blueprint** consensus document (Blueprint). As stated in the National EMS Education and Practice Blueprint, Executive Summary, printed September 1993, "The Blueprint divides the major areas of prehospital instruction and/or core performance into 16 'core elements.'" For each core element, the Blueprint recommends that there be four levels of prehospital EMS providers 'corresponding to various knowledge and skills in each of the core elements." At the "First Responder" level, personnel use a limited amount of equipment to perform initial assessments and interventions. The "EMT-Basic" has the knowledge and skill of the First Responder, but is also qualified to function as the minimum staff for an ambulance. "EMT-Intermediate" personnel has the knowledge and skills identified at the First Responder and EMT-Basic levels, but is also qualified to perform essential advanced techniques and to administer a limited number of medications. The "EMT-Paramedic," in addition to having the competencies of an EMT-

Intermediate, has enhanced skills and can administer additional interventions and medications.

Since the release of the Blueprint, a consensus panel of EMS educators has recommended that the Department of Transportation, National Highway Traffic and Safety Administration (DOT/ NHTSA) revise the document. DOT/ NHTSA has accepted the recommendation of the panel and expects to release a revised Blueprint or an equivalent document in the near future.

To request a copy of the National Emergency Medical Services Education and Practice Blueprint, please fax your request to: NHTSA/EMS Division, (202) 366–7721. Please include your name and address. Because of staffing and resource limitations NHTSA will forward the requested document via regular mail.

We proposed the following seven levels of ambulance services.

a. Basic Life Support (BLS)—When medically necessary, the provision of basic life support (BLS) services as defined in the National Emergency Medical Services EMS Education and Practice Blueprint for the Emergency Medical Technician-Basic (EMT-Basic) including the establishment of a peripheral intravenous (IV) line.

b. Advanced Life Support, Level 1 (ALS1)—When medically necessary, this is the provision of an assessment by an advanced life support (ALS) ambulance provider or supplier or the furnishing of one or more ALS interventions. An ALS assessment is performed by an ALS crew and results in the determination that the beneficiary's condition requires an ALS level of care, even if no other ALS intervention is performed. An ALS provider or supplier is defined as a provider or supplier whose staff includes an individual trained to the level of the EMT-Intermediate or Paramedic as defined in the National EMS Education and Practice Blueprint. An ALS intervention is defined as a procedure beyond the scope of an EMT-Basic as defined in the National EMS Education and Practice Blueprint. These definitions are discussed later in the "Discussion of Public Comments on the Proposed Rule" section.

c. Advanced Life Support, Level 2 (ALS2)—When medically necessary, the administration of at least three different medications or the provision of one or more of the following ALS procedures:

• Manual defibrillation/ cardioversion.

- Endotracheal intubation.
- Central venous line.
- Cardiac pacing.

- Chest decompression.
- Surgical airway.
- Intraosseous line.

d. Specialty Care Transport (SCT)— When medically necessary, for a critically injured or ill beneficiary, a level of interhospital service furnished beyond the scope of the paramedic as defined in the National EMS Education and Practice Blueprint. This is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area (for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training).

e. Paramedic ALS Intercept (PI)— These services are defined in § 410.40(c) "Paramedic ALS Intercept Services". These are ALS services furnished by an entity that does not provide the ambulance transport. Under limited circumstances, Medicare payment may be made for these services. (To obtain additional information about paramedic ALS intercept services, please refer to the March 15, 2000 final rule (65 FR 13911).)

*f. Fixed Wing Air Ambulance (FW)*— We proposed that fixed wing air ambulance services would be covered when the point from which the beneficiary is transported to the nearest hospital with appropriate facilities is inaccessible by land vehicle, or great distances or other obstacles (for example, heavy traffic) and the beneficiary's medical condition is not appropriate for transport by either BLS or ALS ground ambulance.

g. Rotary Wing Air Ambulance (RW)— We proposed that rotary wing (helicopter) air ambulance services are covered when the point from which the beneficiary is transported to the nearest hospital with appropriate facilities is inaccessible by ground vehicle, or great distances or other obstacles (for example, heavy traffic) and the beneficiary's medical condition is not appropriate for transport by either BLS or ALS ground ambulance.

#### B. Current Payment System

The Medicare program pays for ambulance services on a reasonable cost basis when furnished by a provider and on a reasonable charge basis when furnished by a supplier. (For purposes of this discussion, the term "provider" means all Medicare-participating institutional providers that submit claims for Medicare ambulance services (hospitals, including critical access hospitals (CAHs); skilled nursing facilities (SNFs); and home health agencies (HHAs).) The term "supplier" means an entity that is other than a provider. See § 400.202.) The reasonable charge methodology bases payment for ambulance services furnished by ambulance suppliers on the lowest of the customary, prevailing, actual, or inflation indexed charge (IIC).

The following describes the current reasonable charge billing methods for ambulance services:

• Method 1: A single, all-inclusive charge reflecting all services, supplies, and mileage.

• Method 2: One charge reflecting all services and supplies (base rate) with a separate charge for mileage.

• Method 3: One charge for all services and mileage, with a separate charge for supplies.

• Method 4: Separate charges for services, mileage, and supplies.

#### C. Organization of the Preamble

The headings for the discussion of various policy issues in this final rule correspond to the headings used in the September 2000 proposed rule. For the convenience of the reader, the analysis of comments and their responses are integrated with the discussion of each issue.

#### D. Recent Legislation

We do not intend for the aggregate amount of payments under the ambulance fee schedule to be lower than the aggregate amount of payments under the current system. Consequently, as described below, we will adjust the conversion factor (CF) and air ambulance rates if actual experience under the fee schedule is different from the assumptions used to determine the initial CF and air ambulance rates.

We estimate that total spending (the sum of Medicare program payments and beneficiary copayments) for ambulance services over the next five years will be:

Payments (\$ billion)
2.7
2.8
2.9
3.0
3.1

These estimates are based on the assumption that the ambulance inflation factor will be 2.2 percent for 2002 and 2.5 percent for years 2003 through 2006, that the ratio of services furnished at the various levels of intensity (for example, BLS versus ALS1 versus ALS2, etc.) will not change and that there will be an increase in Medicare beneficiary enrollment of 0.9, 0.8, 0.9, 1.3 and 1.0 percent in the years 2002 through 2006, respectively. To the extent that any of these assumptions are different from actual experience, actual payments will be higher or lower than these estimates.

As we indicated in the proposed rule, we will monitor payment data and evaluate whether the assumptions used to establish the original CF (for example, the ratio of the volume of BLS services to ALS services) are accurate. If the actual proportions among the different levels of service are different from the projected amounts, we will adjust the CF accordingly and apply this adjusted CF prospectively. Similarly, if the level of low charge billing is significantly different from the assumed level, we will also adjust the CF and apply such an adjusted CF prospectively.

Over the past 20 years, the Congress has been moving towards fee schedules and prospective payment systems for Medicare payment. In the case of ambulance services, the reasonable charge methodology has resulted in a wide variation of payment rates for the same service. In addition, this payment methodology is administratively burdensome, requiring substantial recordkeeping for historical charge data. The Congress, under the BBA, mandated the establishment of a national fee schedule for payment of ambulance services.

#### 1. Balanced Budget Act of 1997 (BBA)

Section 4531(b)(2) of the BBA added a new section 1834(l) to the Social Security Act (the Act). Section 1834(l) of the Act requires the establishment of a national fee schedule for payment of ambulance services under Medicare part B through negotiated rulemaking. This section also requires that in establishing the ambulance fee schedule, we will—

• Establish mechanisms to control increases in expenditures for ambulance services as a benefit under part B of the Medicare program;

• Establish definitions for ambulance services that link payments to the types of services furnished;

• Consider appropriate regional and operational differences;

• Consider adjustments to payment rates to account for inflation and other relevant factors;

• Phase in the fee schedule in an efficient and fair manner; and,

• Require that payment for ambulance services be made only on an assignment-related basis.

In addition, the BBA requires that ambulance services covered under Medicare be paid based on the lower of the actual billed charge or the ambulance fee schedule amount. The law also provides, in a paragraph entitled "Savings," that total payments during the first year of the ambulance fee schedule may be no more than what would have been paid if the ambulance fee schedule were not in effect. In addition, we are implementing the provisions of a regulation proposed in June 1997 that we would have made final prior to the fee schedule, but decided instead to implement coincident with the fee schedule, as discussed below.

Section 4531(c) of BBA 1997 provided for payment of paramedic advanced life support (ALS) intercept services directly to the entity furnishing those services under limited circumstances. Paramedic ALS intercept services are ALS services delivered by paramedics that operate separately from the agency that provides the ambulance transport. This type of service is most often provided for an emergency ambulance transport in which a local volunteer ambulance that can provide only basic life support (BLS) level service is dispatched to transport a beneficiary. If the beneficiary needs ALS services such as EKG monitoring, chest decompression, or IV therapy, another entity dispatches a paramedic to meet the BLS ambulance at the scene or once the ambulance is on the way to the hospital. The ALS paramedics then provide their services to the beneficiary. One statutory criteria for payment is that the service must be furnished in a rural area. Other criteria (for example, the transporting entity must be volunteer) limited the application of this provision. The program defined a rural area as one that was outside any area defined by the Office of Management and Budget as a Metropolitan Statistical Area, (MSA) or New England County Metropolitan Area (NECMA).

2. Balanced Budget Refinement Act of 1999

Section 412 of the BBRA provided a new definition for the term "rural" in the context of the Medicare coverage provision for paramedic ALS intercept services. The BBRA states that, effective for services furnished on or after January 1, 2000:

"An area shall be treated as a rural area if it is designated as a rural area by any law or regulation of the State or if it is located in a rural census tract of a metropolitan statistical area (as determined under the most recent Goldsmith modification, originally published in the **Federal Register** on February 27, 1992 (57 FR 6725)."

This definition applies only to the Medicare paramedic ALS intercept benefit implemented at § 410.40(c). This is a very limited benefit and to date we know of only one State (New York) with areas that meet the statutory requirements. (See the March 15, 2000 final rule on "Coverage of, and Payment for, Paramedic Intercept Ambulance Services" (65 FR 13911).) For all other ambulance services, the definition of "rural" specified in this final rule will apply.

3. The Medicare, Medicaid, and State Child Health Insurance Program Benefits Improvement and Protection Act of 2000 (BIPA)

BIPA provided the following changes to the ambulance fee schedule that have been incorporated into this rule.

a. Critical Access Hospital (CAH)

The proposed rule would have applied the ambulance fee schedule to all entities furnishing ambulance services to Medicare beneficiaries. Section 205 of BIPA provided that CAHs, or entities owned and operated by them, are paid for ambulance services based on reasonable cost if there is no other ambulance provider or supplier within a 35-mile drive. As a result, these entities are exempt from the ambulance fee schedule described in this final rule. These entities are also exempt from the current cost-per-trip inflation cap applicable to providers. This cap, established by section 4531(a)(1) of the BBA, limits increases in the cost per trip of ambulance services from one year to the next by the consumer price index for all urban consumers, reduced by 1 percentage point. Implementation of section 205 of BIPA requires us to establish a process for a CAH to qualify for this exemption. Such a process was addressed in a separate final rule, "Medicare Program; Changes to the Hospital Inpatient **Prospective Payment Systems and Rates** and Costs of Graduate Medical Education; Fiscal Year 2002 Rates, Etc.; Final Rules," published August 1, 2001 (66 FR 39828). The payment policy component is addressed in this rule.

*Comment:* Some commenters believe that we should pay all CAHs based on cost payment for ambulance services because, in their view, section 1834(g) of the Act requires that CAHs be paid on a reasonable cost basis for all services, not just their services to inpatients and outpatients.

*Response:* The Congress, in section 205 of BIPA, specifically provides that ambulance services furnished on or after December 21, 2000 by a CAH or an entity owned and operated by a CAH be paid on a reasonable cost basis if the CAH or entity is the only provider or supplier located within a 35-mile drive of the CAH or entity. BIPA did not grant CMS broad authority to pay other CAHs on a cost basis. Therefore, CAHs that do not fall within the ambit of section 205

of BIPA will be paid under the ambulance fee schedule.

#### b. Rural Ambulance Mileage

The proposed rule would have established payment for rural mileage greater than 17 miles at the same rate as mileage within urban areas. Section 221 of BIPA provided that the payment rate for rural ambulance mileage greater than 17 miles and up to 50 miles be increased by not less than one-half of the additional payment per mile established for the first 17 miles of a rural ambulance trip. We are establishing this rate at one-half of the additional payment per mile established for the first 17 miles of a rural ambulance trip. This amount is the minimum that is required by the plain language of the law and is not discretionary. We believe that proposed rulemaking, which would be necessary to set the amount at a level higher than the minimum, is impracticable in this instance for timely implementation the law. This is consistent with the amount established by the Congress for the period prior to April 1, 2002. We are waiving proposed rulemaking for this provision and will implement it as a final rule with comment period. Therefore, we will accept public comments on this policy.

#### c. Inflation Factor

The proposed rule would have increased the per trip payments for services furnished in 2001 over the per trip payments for these services furnished in 2000 by an amount equal to the change in the CPI-U reduced by one percent. Section 423 of BIPA provided that the ambulance inflation factor for services furnished during the period July 1, 2001 through December 31, 2001 be equal to 4.7 percent, an increase of two percentage points over the rate in the proposed rule. We have implemented this provision without proposed rulemaking because it was self-implementing, not discretionary for CMS, and did not require us to interpret the law. For that reason, we find notice and comment rulemaking unnecessary.

#### d. Ground Ambulance Mileage

The proposed rule would have paid for all ground ambulance mileage during a four-year transition period based on a blend of the current payment rate and the fee schedule rate. Section 423 provided that there will be no phased-in blended payment for mileage for ambulance suppliers paid by carriers in those States in which, prior to the fee schedule, the carrier's payment to all suppliers did not include separate payment for all in-county ambulance mileage. Mileage paid by these carriers in these States will be paid based on the full fee schedule amount. This provision does not apply to providers. Because the law does not permit CMS to exercise any discretion in implementing the policy, we find notice and comment rulemaking unnecessary. Therefore, we are waiving proposed rulemaking for this provision and will implement it as a final rule with comment. Therefore, we will accept public comments on this policy.

### E. Components of Ambulance Fee Schedule Payment Amounts

Ambulances may be ground, water or air. We proposed that the payment amount for each ambulance service paid under the ambulance fee schedule would be the sum of a base payment amount and a mileage rate. The base payment amount for each air ambulance service paid under the ambulance fee schedule would be the product of two primary factors: (1) A nationally uniform unadjusted base rate; and (2) a geographic adjustment factor for an ambulance fee schedule area.

We proposed that the base payment amount for each ground or water ambulance service paid under the ambulance fee schedule would be the product of three factors—

(1) A nationally uniform relative value for the service;

(2) A geographic adjustment factor for an ambulance fee schedule area; and

(3) A nationally uniform conversion factor (CF) for the service. We are proceeding with these proposals in this final rule. A detailed description of these factors is discussed in this final rule.

Relative value units (RVUs) measure the value of ambulance services relative to the value of a base level ambulance service. Thus, if the value of the resources necessary to furnish service B is twice the value of the resources needed to furnish service A, service B will have twice as many RVUs as service A. RVUs are multiplied by a CF expressed as a dollar value to produce a payment amount. The RVUs represent, on average, the relative resources associated with the various levels of ambulance services. RVUs for each level of service were established by the Committee

Because the fee schedule is based on the relative values of different levels of ground ambulance services relative to a basic life support ground ambulance service, a factor is needed to convert the relative value to a dollar amount which is the national base payment rate. In order to determine the CF, the general approach is first to determine the total amount of money available and divide that total by the total number of relative value units that we estimate will be in the fee schedule for the base year. As we describe in more detail below, we used 1998 Medicare ambulance claims data to determine the total RVUs in this calculation.

Section 1834(1)(3) of the Act states that, in establishing the ambulance fee schedule, the Secretary must ensure that the aggregate amount of payment made for ambulance services in calendar year (CY) 2000 (originally expected to be the first year of the fee schedule) does not exceed the aggregate amount of payment that would have been made absent the fee schedule. In the January 22, 1999 notice concerning the meetings of the Committee, we stated that we were postponing final agency action, pending establishment of the ambulance fee schedule, on a proposal to base payment on the level of service (ALS or BLS) actually needed by the beneficiary. We stated our position that the savings that would have been realized through implementation of that policy in 1998 should not be lost to the Medicare program. We estimated that \$65 million in program savings would have been realized in 1998 if this policy had been in effect at that time.

Section 4531(b)(3) of the BBA, which added section 1834(l)(3) to the Act, provided that the fee schedule was to be effective for ambulance services furnished on or after January 1, 2000. However, because of other statutory obligations, the scope of systems changes required to implement the ambulance fee schedule, and the need to ensure that our computerized systems were compliant with the Year 2000 (Y2K) requirements, we could not meet this statutory deadline.

In the September 12, 2000 proposed rule, we indicated our intention to implement the fee schedule beginning January 1, 2001. However, although the proposed rule was largely based on an agreement reached as part of a negotiated rulemaking process with representatives of the ambulance industry and other interests, we received over 340 public comments. We did not have sufficient time to carefully consider all comments and publish a final rule in time to implement the fee schedule by January 1, 2001. This final rule establishes an implementation date of April 1, 2002. Our objective is to have the ambulance fee schedule become effective as soon as we can, in this case, April 1, 2002.

#### F. Negotiated Rulemaking Process

Section 1834(l)(1) of the Act provided that the ambulance fee schedule be

established through the negotiated rulemaking process described in the Negotiated Rulemaking Act of 1990 (Pub. L. 101–648, 5 U.S.C. 581–590). Prior to using negotiated rulemaking under the Negotiated Rulemaking Act, the head of an agency must generally consider whether the following conditions exist:

• There is a need for a rule.

• There are a number of identifiable interests that will be significantly affected by the rule.

• There is a reasonable likelihood that a committee can be convened with a balanced representation of persons who—

+ Can adequately represent the interests identified; and,

+ Are willing to negotiate in good faith to reach a consensus on the proposed rule.

• There is a reasonable likelihood that a committee will reach a consensus on the proposed rule within a fixed timeframe.

• The negotiated rulemaking procedure will not unreasonably delay the notice of proposed rulemaking and the issuance of a final rule.

• The agency has adequate resources and is willing to commit its resources, including technical assistance, to the committee.

• The agency, to the maximum extent possible consistent with the legal obligations of the agency, will use the consensus of the committee as the basis for the rule proposed by the agency for notice and comment.

Negotiations were conducted by a committee chartered under the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2). We used the services of an impartial convener to help identify interests that would be significantly affected by the proposed rule (including residents of rural areas) and the names of organizations who were willing and qualified to represent those interests. The Negotiated Rulemaking Committee on the Medicare Ambulance Services Fee Schedule (the Committee) consisted of individuals associated with national organizations that represent interests that were likely to be significantly affected by the fee schedule. (Additional information about the negotiations can be found in the January 22, 1999 Federal Register notice or may be accessed at our Internet Web site at http://www.hcfa.gov/medicare/ ambmain.htm.)

To the extent that the proposed rule accurately reflects the Committee Statement, signed on February 14, 2000, each member of the Committee has agreed not to comment on those issues on which consensus was reached.

## *G.* Interaction With the Proposed Rule Published on June 17, 1997

On June 17, 1997, we published a proposed rule (62 FR 32715) in the Federal Register to revise and update the Medicare ambulance services regulations at § 410.40. Specifically, we proposed: To base Medicare payment on the level of ambulance service required to treat the beneficiary's condition; to clarify and revise the policy on coverage of nonemergency ambulance services; and to set national vehicle, staff, billing, and reporting requirements. As noted above, section 1834(1)(2) of the Act provides, in part, that in establishing the ambulance fee schedule, the Secretary establish definitions for ambulance services that link payments to the types of services furnished. One of the provisions of the June 17, 1997 proposed rule would have defined ambulance services as either BLS or ALS and linked Medicare payment to the type of service required by the beneficiary's condition. We received a large number of comments on this provision, and, in general, commenters were very concerned about our proposal.

## II. Discussion of Public Comments on the Proposed Rule

In response to the publication of the September 2000 proposed rule, we received approximately 340 comments. We received comments from, among others, national ambulance organizations, emergency physician groups and State emergency programs. The majority of the comments addressed issues related to medical condition descriptions lists, physician certification, and definitions of services.

As stated previously, the headings for the policy issues in this final rule correspond to the headings used in the September 2000 proposed rule. For the convenience of the reader, the analysis of comments and their responses are integrated with the discussion of each issue.

## A. Proposals Based on Negotiated Rulemaking

In our proposed rule, published September 12, 2000, we discussed the negotiated rulemaking procedures used to formulate our policy for the ambulance fee schedule.

*Comment:* One commenter stated that we should reconvene the Committee to consider the comments received in response to the proposed rule and also reconvene the Committee annually to consider all future adjustments.

*Response:* We have decided not to reconvene the Committee. We have

adhered to the Committee's recommendations in all cases in which the Committee addressed an issue. Furthermore, some issues were excluded from the negotiation process, and therefore, were not within the purview of the Committee. Also, we believe that reconvening the Committee would significantly postpone the implementation of the regulation.

*Comment:* Commenters from various regions stated that their organizations were not represented on the Committee.

Some commenters believe that the North American Association of Public Utility Models (NAPUM) should have been included as a participant in the negotiated rulemaking process. NAPUM could have shared its Public Utility Model EMS system in the development of the ambulance fee schedule.

Another commenter stated that the fixed wing air ambulance organizations were not properly represented at the negotiated rulemaking meetings and, therefore, the payment rates for fixed wing air mileage are inadequate.

*Response:* There was a public solicitation through the **Federal Register** (January 22, 1999) for participation in the negotiated rulemaking process. All interested parties who responded to this public notice were given due consideration by the neutral convener whom we retained for this purpose. Also, the Association of Air Medical Services (AAMS), which has approximately 130 members that are fixed wing providers, represented the air ambulance industry.

In the proposed rule, we proposed the following additions to part 414 based on the recommendations of the Committee.

## 1. Definitions and Levels of Services

In part 414, we proposed to add subpart H, § 414.605 that would define several levels of ground ambulance services ranging from BLS to specialty care transport (SCT). (Note that the term "ground" refers to both land and water transportation. The definitions and RVUs for each of the levels of service are described in § 414.605, "Definitions.") Also, this section proposed that the mileage rate paid under the fee schedule per ground mile would be the same for each level of ground ambulance service.

In the course of establishing national standards for ALS and BLS during 1990, the development of a training blueprint and the evaluation of current levels of prehospital provider training and certification were identified by the national emergency medical services (EMS) industry as a priority need for EMS. As a result, the National EMS Training Blueprint Project was formed.

In May 1993, representatives of EMS organizations adopted the Blueprint consensus document. This consensus document was used as the basis for defining the levels of service. As stated in the Blueprint, Executive Summary, printed September 1993, "The Blueprint divides the major areas of prehospital instruction and/or core performance into 16 'core elements.' "For each core element, the Blueprint recommended that there be four levels of prehospital EMS providers "corresponding to various knowledge and skills in each of the core elements." At the First Responder level, personnel use a limited amount of equipment to perform initial assessments and interventions.

The EMT-Basic has the knowledge and skill of the First Responder, but is also qualified to function as the minimum staff for an ambulance. EMT-Intermediate personnel has the knowledge and skills identified at the First Responder and EMT-Basic levels, but is also qualified to perform essential advanced techniques and to administer a limited number of medications. The EMT-Paramedic, in addition to having the competencies of an EMT-Intermediate, has enhanced skills and can administer additional interventions and medications.

After the release of the Blueprint, a consensus panel of EMS educators had recommended that DOT/NHTSA revise the document. The Department of Transportation, National Highway Traffic and Safety Administration (DOT/ NHTSA) has accepted the recommendation of the panel and is expected to release a revised Blueprint or an equivalent document in the near future.

To request a copy of the National Emergency Medical Services Education and Practice Blueprint, please fax your request to: NHTSA/EMS Division, (202) 366–7721. Please include your name and address. Because of staffing and resource limitations, NHTSA will forward the requested document via regular mail.

#### Levels of Ambulance Services

Payment for all ambulance services under the fee schedule will be based on a base rate payment. In addition, there will be a separate payment for mileage.

In the proposed rule, we stated that there would be two levels of air ambulance services to distinguish fixed wing from rotary wing (helicopter) aircraft. In addition, to recognize the operational cost differences of the two types of aircraft, there would be two distinct payment amounts for air ambulance mileage. The air ambulance services mileage rate would be calculated per actual loaded (patient on board) miles flown, expressed in statute miles (that is, ground, not nautical, miles).

In the proposed rule, we proposed the seven levels of ambulance services shown below. We expressed the qualifications for staff at the various levels in terms of the Blueprint. As just noted, we are revising the proposed qualifications to indicate that the vehicle staffing will comply with existing State and local laws for each level of service.

a. *Basic Life Support (BLS)*—In the proposed rule, we stated that, when medically necessary, the provision of basic life support (BLS) services is defined in the National Emergency Medicine Services (EMS) Education and Practice Blueprint for the Emergency Medical Technician-Basic (EMT-Basic) including the establishment of a peripheral intravenous (IV) line.

b. Advanced Life Support, Level 1 (ALS1)—In the proposed rule, we stated that, when medically necessary, this level of service requires the provision of an assessment by an advanced life support (ALS) ambulance provider or supplier and the furnishing of one or more ALS interventions. An ALS assessment is performed by an ALS crew and results in the determination that the beneficiary's condition requires an ALS level of care, even if no other ALS intervention is performed. The proposed rule also stated that an ALS provider or supplier is defined as a provider trained to the level of the EMT-Intermediate or Paramedic as defined in the National EMS Education and Practice Blueprint. We proposed to define an ALS intervention as a procedure beyond the scope of an EMT-Basic as defined in the National EMS Education and Practice Blueprint.

c. Advanced Life Support, Level 2 (ALS2)—In the proposed rule, we stated that this level of service is defined by, when medically necessary, the administration of at least three different medications or the provision of one or more of the following ALS procedures:

• Manual defibrillation/ cardioversion.

- Endotracheal intubation.
- Central venous line.
- Cardiac pacing.
- Chest decompression.
- Surgical airway.
- Intraosseous line.

*d. Specialty Care Transport (SCT)*—In the proposed rule, we stated that this level of service is defined by, when medically necessary, for a critically injured or ill beneficiary, a level of interhospital service furnished beyond the scope of the paramedic as defined in the National EMS Education and Practice Blueprint. We stated that this service would be necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area (for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training).

e. Paramedic ALS Intercept (PI)—In the proposed rule, we stated that these services would be defined in § 410.40(c) "Paramedic ALS Intercept Services." These are ALS services furnished by an entity that does not provide the ambulance transport. Under limited circumstances, Medicare payment may be made directly to the entity furnishing paramedic services. (To obtain additional information about paramedic ALS intercept services, please refer to the March 15, 2000 final rule (65 FR 13911).)

f. Fixed Wing Air Ambulance (FW)— In the proposed rule, we stated that fixed wing air ambulance services would be covered when the point from which the beneficiary is transported to the nearest hospital with appropriate facilities is inaccessible by land vehicle, or great distances or other obstacles (for example, heavy traffic) and the beneficiary's medical condition is not appropriate for transport by either BLS or ALS ground ambulance.

g. Rotary Wing Air Ambulance (RW)— In the proposed rule, we stated that rotary wing (helicopter) air ambulance services would be covered when the point from which the beneficiary is transported to the nearest hospital with appropriate facilities is inaccessible by ground vehicle, or great distances or other obstacles (for example, heavy traffic) and the beneficiary's medical condition is not appropriate for transport by either BLS or ALS ground ambulance.

*Comment:* In the context of determining when payment would be made at the ALS rate versus the BLS rate, some commenters disagreed with the definitions provided in the National **Emergency Medical Services Education** and Practice Blueprint (the Blueprint), stating that State definitions and standards differed from this document. Some States license as paramedics individuals who have not completed all of the hours or modules required by the Department of Transportation's National Standard Paramedic Curriculum. Technically, these individuals would not be "trained to the level" of a paramedic as defined in the Blueprint and the resulting National Standard Paramedic Curriculum. Commenters suggested that the definition of a

paramedic should be a person who is licensed by the State at an ALS level, regardless of whether the level of the training of the person meets the definition of "paramedic" as described in the Blueprint or National Standard Paramedic Curriculum.

Several commenters also noted that the definition of BLS is confusing regarding establishment of a peripheral intravenous (IV) line. They further commented that, in many States, BLS personnel are not permitted by State law to establish IV lines. To clarify the definition, the commenters recommended that we make it clear that, when an IV line is established by an ALS crew, this is an ALS intervention that qualifies the trip as an ALS transport.

*Response:* As a basis for defining the levels of service in the proposed rule, we incorporated the knowledge and skills outlined in the Blueprint. After considering the observations made by commenters and recognizing that the Department of Transportation, National Highway Traffic and Safety Administration has agreed to revise the Blueprint in the near future, we concluded that the knowledge and skill levels outlined in the Blueprint may be contrary to some existing State training standards and requirements. We have chosen instead, to rely on vehicle staffing requirements contained in existing State and local laws. Therefore, we are revising § 414.605 to indicate that payment will be made at the ALS1 level if the service furnished is beyond the skill level of an EMT-Basic in accordance with State and local laws.

*Comment:* Several commenters noted that the definition of ALS1 differed from that in the Committee Statement. Specifically, the conjunction used in the Committee Statement between "assessment by an advanced life support (ALS) ambulance provider or supplier" and "the furnishing of one or more ALS interventions" was "and/or" rather than "and." In addition, commenters pointed out that the ALS2 definition differed slightly between the preamble of the proposed rule and the proposed regulation text. For ALS2, commenters addressed the Committee Statement definition which was based on the supplier's provision of "three different medications or the provision of one or more of the following ALS procedures:

• Manual defibrillation/ cardioversion.

- Endotracheal intubation.
- Central venous line.
- Cardiac pacing.
- Chest decompression.
- Surgical airway.

Intraosseous line."

The proposed definition at § 414.605 stated "three different medications *and* the provision of one or more of the following ALS procedures:

Manual defibrillation/

cardioversion.

- Endotracheal intubation.
- Central venous line.
- Cardiac pacing.
- Chest decompression.
- Surgical airway.
- Intraosseous line."

*Response:* We agree with the commenters that the conjunction was inconsistent with the Committee Statement and, therefore, we are revising the regulation text to be consistent with the Committee Statement. We note, however, that we are using the conjunction "or" because this term carries the same meaning as "and/or."

Comment: Many commenters stated that the proposed definition of ALS assessment is confusing. The definition states that the ALS assessment is one "performed by an ALS crew that results in the determination that the beneficiary's condition requires an ALS level of care." The commenters stated that, in order to be consistent with the Committee Statement, the definition should state that an ALS assessment is one performed by an ALS crew to determine whether the beneficiary's condition requires an ALS level of care. Some commenters suggested that the definition should be revised as follows: "'Advanced Life Support (ALS) assessment' is an assessment of a beneficiary with a medical condition requiring assessment by an ALS crew to determine whether ALS interventions are needed or may be needed during transport.'

Response: We agree, and we have clarified the definition of ALS assessment accordingly. We are also clarifying that the ALS assessment is relevant only in an emergency case. While the Committee Statement is silent on this point, we believe that the ALS assessment would not be required in non-emergency or scheduled situations.

*Comment:* Many commenters stated that we should provide payment for all drugs, both low and high cost. Commenters stated that we had refused to negotiate on the issue of a separate payment for drugs in addition to and apart from the fee schedule payment for the ambulance transport, on the grounds that all drug costs should be included in the base rate. The commenters believe that this position fails to take into account the fact that many ambulance systems are now being forced to pay for drugs that were previously paid for outside of the Medicare payment. These costs, they argue, were not captured in the aggregate ambulance payment amount which we calculated and upon which we would calculate the CF. Therefore, they argue, these costs would not be reflected in the base rates. One way drugs were paid for in the past outside the Medicare ambulance benefit was that a hospital would restock the ambulance without charge for any drugs that had been used. Commenters argue that, if hospitals do not continue restocking, ambulance suppliers will have to bear the cost of these drugs from a base rate that the commenters believe is already too low. The commenters believe that we should allow separate payments for drugs in addition to the ambulance fee schedule payment.

*Response:* Medicare's drug benefit does not permit a discrete payment for drugs furnished on board an ambulance. Drugs in ambulances have been included in ambulance payment only because they have been considered to be ambulance supplies. The law permits payment for a drug furnished on board an ambulance only if the drug is considered an element of the ambulance service. At the same time, the law does not permit payment under the ambulance benefit other than through the ambulance fee schedule.

As noted above, the BBA required that total payments during the first year of the fee schedule be no more than what would have been paid if the ambulance fee schedule were not in effect. The law provides no means to increase program payments for ambulance services that use new high-cost drugs. It provides only the inflation factor to increase rates under the ambulance fee schedule. With this constraint in mind, the Committee considered, within the structure of the fee schedule, establishing a separate RVU for drugs provided as ambulance supplies above a certain threshold cost. However, the Committee rejected this option. Therefore, payment for these items is included in the base rates for all levels of service.

*Comment:* Commenters questioned whether oxygen, saline and aspirin are considered medications for purposes of meeting the alternate criterion for the ALS2 level of service that the ambulance supplier provide three different medications.

*Response:* The proposed definition for an ALS2 level of service provides that this level of service is defined by, when medically necessary, the administration of at least three different medications or the provision of one or more of the following ALS procedures:

• Manual defibrillation/ cardioversion.

- Endotracheal intubation.
- Central venous line.
- Cardiac pacing.
- Chest decompression.
- Surgical airway.
- Intraosseous line.

Only medications requiring a higher level of skill to administer are considered medications for purposes of this definition. We are clarifying in the final rule that payment at the ALS2 level requires the administration of at least three medications by intravenous push/bolus or by continuous infusion, excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (for example, Dextrose, Normal Saline, Ringer's Lactate). Therefore, oxygen, saline and aspirin are not considered as medications for the purpose of determining whether an ALS2 level of care has been furnished.

*Comment:* Many commenters wanted to know whether three doses of the same medication on one transport warrant classifying the service as an ALS2 service.

*Response:* Three separate administrations of the same medically necessary medication (of the kind specified in the criteria for ALS2) during a single transport qualifies for payment at the ALS2 level.

*Comment:* Many commenters requested clarification regarding SCT. In particular, the commenters asked that we further define the phrase "paramedics with additional training." A commenter suggested that we include a reference to any State or local standards or protocols that define SCT training above and beyond the paramedic curriculum and a reference to a curriculum approved by the medical director of an EMS or ambulance system and shared with the carrier.

*Response:* As indicated in the response concerning the Blueprint, above, we are revising § 414.605 to indicate that vehicle staffing must be in compliance with existing State and local laws. We now define "paramedics with additional training" in terms of State or local authority that governs the licensing and certification of EMS personnel in the State in which a paramedic is licensed. It seems possible, even likely that there is no comparable definition in every State.

*Comment:* Some commenters asked whether the code for the SCT level service may be used as a code for a trip from a facility to an air ambulance and from the air ambulance to the final facility destination.

*Response:* Yes, the SCT level of service may be used in transporting a

beneficiary from the hospital to an air ambulance and then from the air ambulance to the second hospital, if the SCT criteria are met.

*Comment:* Some commenters believe that paramedic intercept services will suffer because of the failure in the fee schedule to recognize paramedic intercept in States other than New York as a cost-effective means of the delivery of prehospital care. Commenters stated that it is important to provide adequate payment for paramedic intercept in all areas of the country.

*Response:* As described in the regulations in § 410.40(c) (and also in Program Memorandum B–00–01 issued in January, 2000), under the Medicare statute, payment may be made directly to the intercept supplier for intercept services only if—

(a) The intercept service is provided in a rural area under a contract with one or more volunteer ambulance services;

(b) The volunteer ambulance supplier is certified to provide ambulance services;

(c) The volunteer ambulance supplier provides services only at the BLS level at the time of the intercept; and

(d) The volunteer ambulance supplier is prohibited by State law from billing anyone for the service furnished. The entity providing the intercept services must also be qualified to provide services under Medicare and must bill all patients receiving its intercept services.

At this time, to the best of our knowledge, only the State of New York has areas that meet these four criteria. In all other areas, the BLS level ambulance supplier must bill the program for an appropriate level of service. If the paramedic intercept supplier wants to receive payment, it would have to make an agreement with the volunteer supplier regarding payment.

*Comment:* One commenter asked whether the new levels of ALS2 and SCT under the fee schedule would be blended with the current ALS emergency code payment rates during the transition period.

*Response:* For both ALS2 and SCT, the "old" portion of the blended amount is the allowance for ALS emergency services.

## 2. Emergency Response Adjustment Factor

We proposed to add § 414.610(c)(1) to state that, for the BLS and ALS1 levels of service, an ambulance service that qualifies as an emergency response service would be assigned higher RVUs to recognize the additional costs incurred in responding immediately to an emergency medical condition. An immediate response is one in which the ambulance supplier begins as quickly as possible to take the steps necessary to respond to the call. No emergency response adjustment factor applies to PI, ALS2, SCT, FW, or RW.

*Comment:* Some commenters stated that the definition of "emergency response" for purposes of the fee schedule in the implementing instructions (Program Memorandum AB–00–88) is inconsistent with the definition in the proposed rule and with the definition in the Committee Statement. The definition in AB–00–88 is:

An emergency response is one that, at the time the ambulance supplier is called, is provided after the sudden onset of a medical condition manifesting itself by acute symptoms of sufficient severity such that the absence of immediate medical attention could reasonably be expected to result in placing the beneficiary's health in serious jeopardy; in impairment to bodily functions; or in serious dysfunction to any bodily organ or part. The definition in the Committee Statement is:

For the BLS and ALS1 levels of service, an ambulance service that qualifies as an emergency response will be assigned a higher relative value to recognize the additional costs incurred in responding immediately to an emergency medical condition. An immediate response is one in which the ambulance provider begins as quickly as possible to take the steps necessary to respond to the call. There is no emergency modifier for PI, ALS2, or SCT.

*Response:* We agree with the commenter, and we will be changing the definition of "emergency response" in the final regulation to conform to the definition in the Committee Statement with one exception. We have decided to delete from the Committee Statement's definition the phrase "emergency medical condition" because the purpose of the higher payment for the emergency medical condition is to recognize the additional cost required in order to be prepared to respond immediately to a call (for example, from a "911" service) when it is received without regard to the condition of the beneficiary. The nature of the beneficiary's condition is considered in determining whether an ambulance transport was medically necessary and in determining the level of service (for example, BLS-Emergency, ALS1-Emergency or ALS2). However, the emergency rate is paid based on the immediate response to the 911-type call and not based on the services furnished

to the beneficiary. Therefore, we are revising the definition as follows:

Emergency response means responding immediately at the BLS or ALS1 level of service to a 911 call or the equivalent in areas without a 911 call system. An immediate response is one in which the ambulance supplier begins as quickly as possible to take the steps necessary to respond to the call.

We note that the definition of "emergency response" here is intended only to describe the circumstances under which higher payment would be made for services and its use is limited to this context. It would have no effect on other program definitions of "emergency."

#### 3. Operational Variations

We proposed to add § 414.610(a), which would state that the ambulance fee schedule applies to all entities that furnish ambulance services, regardless of type. All public or private, for profit or not-for-profit, volunteer, governmentaffiliated, institutionally-affiliated or owned, or wholly independent supplier ambulance companies, however organized, would be paid according to this ambulance fee schedule, with the exception of CAHs as discussed above.

#### 4. Regional Variations

#### a. Cost of living differences

In our proposed rule, we proposed that the payment for ambulance services would be adjusted to reflect the varying costs of conducting business in different regions of the country. We stated that we would adjust the payment by a geographic adjustment factor (GAF) equal to the practice expense (PE) portion of the geographic practice cost index (GPCI) for the Medicare physician fee schedule. (For purposes of this document, we use the abbreviation "GPCI" to mean the PE portion of the GPCI.) The GPCI is an index that reflects the relative costs of certain components of a physician's cost of doing business (for example, employee salaries, rent, and miscellaneous expenses) in one area of the country as compared to another. The geographic areas would be the same as those used for the physician fee schedule. (A detailed discussion of the physician fee schedule areas can be found in the July 2, 1996 proposed rule (61 FR 34615) and the November 22, 1996 final rule (61 FR 59494).)

We proposed that the GPCI would be applied to 70 percent of the base payment rate for ground ambulance services; this percentage approximates the portion of ground ambulance service costs that are represented by salaries. Similarly, we proposed that the GPCI would be applied to 50 percent of the base payment rate for air ambulance services. The GPCI would not be applied to the mileage payment rate. In addition, the applicable GPCI would be based on the geographic location at which the beneficiary is placed on board the ambulance.

We proposed to use the most recent GPCI; the physician fee schedule law requires that the GPCI be updated every 3 years. The latest revision became effective January 1, 2001. The updated data were published in the November 1, 2000 final rule on the physician fee schedule (65 FR 65585).

*Comment:* A few commenters stated that the practice expense portion of the physician fee schedule GPCI does not properly reflect the cost of living when calculating payment for ambulance services.

*Response:* We proposed using the practice expense portion of the GPCI, as described in the physician fee schedule final rule published in the Federal Register on November 1, 2000 (65 FR 65585). We based our proposal on the Committee Statement that using the PE of the GPCI is the most appropriate means available to measure the geographic differences in the costs of providing ambulance services. The components of the PE portion of the GPCI (for example, personnel and supplies) are similar to the components of ambulance services and the geographical variations in these costs for ambulances would therefore be similar to the cost variations for physician practices. Also, based on data available to the Committee, it recommended, and we agree, that the labor share of the costs of ambulance services is approximately 70 percent of the ground and 50 percent of the air ambulance cost. Therefore, the GPCI will apply to only 70 percent of the ground and 50 percent of the air ambulance base rates. We are not adjusting the mileage rates.

*Comment:* Some commenters believe that both legs of a round trip should be paid on the basis of the initial point of pick-up of the beneficiary, and that both legs of a scheduled round trip crossing GPCI or State lines should be billed to the carrier with jurisdiction for the initial point of pick-up. The commenters state that, given the proposed rule, suppliers may have to bill different carriers for each of two legs on the same round trip. Also, beneficiaries are likely to be confused by bills which indicate different charges for each leg of a round trip, if it does not begin in a rural area. Finally, rural suppliers could lose the rural adjustment for the second leg of a round trip. Some commenters also believe the

point of pick-up is not the best criterion for establishing level of payment. There were some commenters who felt that the GPCI should be matched to the location of the ambulance company. Also, some commenters wanted clarification on trips originating in another carrier jurisdiction.

Response: The Committee determined that the most equitable way to apply the GPCI, as well as the rural adjustment payment, was by the point of pick-up and not by the destination, location of the ambulance company, or where the ambulance is garaged. One concern identified by the Committee with using the location of the company or the place where the ambulance is garaged was the relative ease of moving the location of the company or garage to achieve higher payment. A second issue was that any individual trip in a rural area would likely be longer and prevent an ambulance from furnishing an additional trip, thereby reducing utilization, whether the ambulance was garaged in an urban or rural area. Considering each leg of a round trip separately gives effect to the Committee's determinations. Moreover, considering each leg separately achieves administrative simplicity and greater administrative accuracy in making payments.

*Comment:* One commenter suggested that the Medicare hospital area wage index be used in place of the GPCI, since many of the ambulance providers are hospital-based.

*Response:* The Committee decided to use the GPCI, not the hospital area wage index. As stated above, the components of the ambulance service are more similar to the components of the PE portion of the GPCI than they are to the components of the hospital wage index. Also, fewer than 15 percent of ambulance services furnished to Medicare beneficiaries are hospitalbased, so we do not see the hospital wage index as more appropriate than the GPCI. Thus, we will continue to use the practice expense GPCIs from the physician fee schedule.

#### b. Services furnished in rural areas

We proposed to add § 414.610(c)(1)(v), which stated that, for ground ambulance services in rural areas, a 50 percent increase is applied to the mileage rate for each of the first 17 miles; the regular (urban) mileage allowance applies to every mile over 17 miles. For air ambulance services, we stated, in rural areas, that a 50 percent increase is applied to the total payment for air services, both mileage and base rate. We proposed the 50 percent rural increase for the first 17 miles in consideration of the circumstances of isolated, essential ambulance suppliers (that is, when there is only one ambulance service in a given geographic area) which may not furnish many trips over the course of a typical month because of a small rural population. While we recognize that this methodology is not sufficiently precise to limit the rural bonus payment to only those rural ambulances that are isolated, essential, low-volume (the definition of rural we are proposing is not as precise as other alternatives), we proposed an adjustment to increase the rate of payment for mileage if the location at which the beneficiary is placed on board the ambulance is located in a rural area. We proposed to define a rural area to be an area outside a Metropolitan Statistical Area (MSA) or a New England County Metropolitan Area, or an area within an MSA identified as rural, using the Goldsmith modification.

The Goldsmith modification evolved from an outreach grant program sponsored by the Office of Rural Health Policy of the Health Resources and Services Administration (HRSA) of the Department of Health and Human Services. This program was created to establish an operational definition of rural populations lacking easy geographic access to health services in large counties with metropolitan cities. Using 1980 census data, Dr. Harold F. Goldsmith and his associates created a methodology for identifying rural census tracts located within a large metropolitan county of at least 1,225 square miles. However, these census tracts are so isolated by distance or physical features that they are more rural than urban in character. Additional information regarding the Goldsmith modification can be found on the Internet at *http://* www.ruralhealth.hrsa.gov/ Goldsmith.htm.

We could not easily adopt and implement, within the constraints necessary to implement the fee schedule timely, a methodology for recognizing geographic population density disparities other than MSA/non-MSA. However, we will consider alternative methodologies that may more appropriately address payment to isolated, low-volume rural ambulance suppliers. Thus, the rural adjustment in this rule is a temporary proxy to recognize the higher costs of certain low-volume rural suppliers.

Several difficult issues will need to be resolved to establish more precise criteria for suppliers that should receive the rural adjustment. Examples of such issues include: (1) Appropriately identifying an ambulance supplier as rural; (2) identifying the supplier's total ambulance volume (because Medicare has a record only of its Medicare services); and (3) identifying whether the supplier is isolated, because some suppliers might not furnish services to Medicare beneficiaries (thus, Medicare would have no record of their existence) and one of these suppliers might be located near an otherwise "isolated" supplier. Addressing these issues in some cases will require the collection of data that are currently unavailable. We intend to work with the industry and with the Office of Rural Health Policy to identify and collect pertinent data as soon as possible.

We stated in our proposed rule that the application of the rural adjustment would be determined by the geographic location at which the beneficiary is placed on board the ambulance. Under the proposed rule, the rural adjustment would have been made using the following methodology:

• Ground—A 50 percent add-on applied to only the mileage payment rate for the first 17 loaded miles and a 25 percent add-on applied to only the mileage payment rate for miles 18 through 50.

• Air—A 50 percent add-on applied to the base rate and to all of the loaded mileage.

*Comment:* Several commenters expressed concern that there should be a more precise definition of low-volume rural ambulance suppliers and that the rural payment rate should be higher. They suggested that we could use data from the Office of Rural Health (ORH) or the Administration on Aging that would give a more precise determination than the MSA/non-MSA classification. Another commenter suggested using any areas that are designated as rural by the State. One commenter suggested that until a better rural adjustment is implemented, rural suppliers and providers should be paid under their current payment methodologies.

*Response*: We are exploring alternative means for identifying lowvolume rural suppliers. We are exploring data from other sources, including the ORH, which has sponsored a study, Rural-Urban Commuting Areas (RUCA). This study was performed by the University of Washington Rural Health Research Center. We anticipate that a more precise definition of low-volume rural suppliers will reduce the number of suppliers who qualify for the higher rural payment, allowing us to better target the payment increases to these suppliers while adhering to the aggregate payment limit provided in the law. We do not have the legal authority to exempt rural ambulance services from the fee schedule and pay them under the current methodology with the exception of certain CAHs. (See discussion of section 205 of BIPA.) In addition, BIPA provided that the payment rate for rural ambulance mileage greater than 17 miles and up to 50 miles be increased by not less than one-half of the additional payment per mile established for the first 17 miles of a rural ambulance trip.

*Comment:* A few commenters suggested that we adopt a more precise means of identifying rural areas for the fee schedule, using zip codes rather than MSAs as the basis for identification.

*Response:* We are currently using zip codes to identify areas. However, we identify all zip codes as urban or rural, based on whether the zip code is located in an MSA or not, including the Goldsmith modifications. The zip code is the basis for determining point of pick-up and the payment of claims. As stated above, we are examining other alternatives for identifying rural and urban areas more precisely.

*Comment:* Some commenters asked if the rural modifier applies if the supplier bills less than \$5 for mileage.

*Response:* The law requires that payment be based on the lower of the fee schedule amount or the actual charge. If the supplier/provider's charge for mileage is less than the rural mileage fee schedule amount, then payment is based on the lower actual billed amount.

*Comment:* One commenter suggested that we double the payment to small, rural hospital ambulance providers in the following categories: sole community provider hospitals, hospitals eligible for the CAH program, and hospitals under 100 beds.

*Response:* The Committee Statement does not include such a provision, and we would point out that, because of the requirements of section 1834(l)(3) of the Act, increased payments under such a provision would need to be offset by reduced payments to other ambulance providers and suppliers. Moreover, there is no authority to exempt these small rural hospitals from the fee schedule except as provided by the Congress in section 205 of BIPA. That section provides that only CAHs that are the only ambulance service provider/ supplier within a 35-mile drive will be exempt from the fee schedule and will be paid based on their reasonable cost.

#### 5. Mileage

We proposed adding §414.610(c)(1)(iii) that would state that

mileage would be paid separately from the base rate. The payment for mileage reflects the costs attributable to the use of the ambulance vehicle (for example, maintenance and depreciation) which increase as the vehicle's mileage increases. Based on the Committee's agreement, the mileage rates for the base year 1998 would be as follows: \$5 per mile for ground ambulance, \$6 per mile for fixed wing ambulance, and \$16 per mile for rotary wing ambulance. These rates will be adjusted by the ambulance inflation factor. However, payment for some mileage in rural areas is made at a higher rate as discussed in section II.A.4.b. of this final rule.

6. Structure of the Fee Schedule for Ambulance Services

We proposed in § 414.610(a) that the fee schedule payment for ambulance services would equal a base rate payment plus payments for mileage and applicable adjustment factors. (See Table 1 for a description of the structure of the ambulance fee schedule.)

### 7. Ambulance Inflation Factor

We proposed adding § 414.615, "Transition methodology for implementing the ambulance fee schedule," which would state that the ambulance fee schedule would include the ambulance inflation factor specified in section 1834(l)(3) of the Act (recently amended by BIPA) and discussed below.

## 8. Phase-in Methodology

We proposed adding § 414.615 that would provide for a 4-year transition period, as the result of the Committee agreement. (The phase-in schedule is described in section IV of this preamble.)

### B. Proposed Changes Not Based on Negotiated Rulemaking

In the September 12, 2000 proposed rule, we proposed changes to certain policies that were not within the scope of the negotiated rulemaking process. These proposed changes were as follows:

## 1. Coverage of Ambulance Services

In § 410.40(b), we proposed revising the introductory language to provide a cross-reference to § 414.605 for a description of the specific levels of services. We proposed to revise paragraph § 410.40(d)(1) to state that transportation includes fixed wing and rotary wing ambulances. Also, we proposed revising § 410.40(d)(3) by adding two options to document medical necessity.

## 2. Physician Certification Requirements

On January 25, 1999, we published a final rule (64 FR 3637) that updated Medicare coverage policy concerning ambulance services. That final rule provided the documentation requirements for coverage of nonemergency ambulance services for Medicare beneficiaries. The rule requires ambulance suppliers to obtain, from the beneficiary's attending physician, a written order certifying the medical necessity of nonemergency scheduled and unscheduled ambulance transports. The final rule became effective February 24, 1999.

Our present regulations (at §§ 410.40(d)(2) and 410.40(d)(3)) set forth the requirements for scheduled and unscheduled nonemergency ambulance transports. The regulations require ambulance suppliers to obtain, from the beneficiary's attending physician, a written physician statement certifying the medical necessity of requested ambulance transports.

Section 410.40(d)(3)(i) specifies that, in cases when a beneficiary living in a facility and under the direct care of a physician requires nonemergency, unscheduled transport, the physician's certification can be obtained up to 48 hours after transport. After publication of this rule, we were made aware of instances in which ambulance suppliers, despite having provided ambulance transports, were experiencing difficulty in obtaining the necessary physician certification statements within the required 48-hour timeframe.

While we still believe that the 48-hour timeframe is the appropriate standard, we recognize that there may be instances when, not through fault of their own, it may not be possible for the ambulance suppliers to meet the requirement. Therefore, we have determined that there is a need to revise and clarify this requirement (as described in § 410.40, "Coverage of ambulance services," paragraph (d)(3)).

We proposed that, before submitting a claim, the ambulance supplier must obtain—

(1) A signed physician certification statement from the attending physician; or

(2) If the ambulance supplier is unable to obtain a signed physician certification statement from the attending physician, a signed physician certification must be obtained from either the physician, physician assistant, nurse practitioner, clinical nurse specialist, registered nurse, or discharge planner who is employed by the hospital or facility where the beneficiary is being treated and who has personal knowledge of the beneficiary's condition at the time the transport is ordered or the service was furnished (the term "physician certification statement" will also be applicable to statements signed by other authorized individuals); or

(3) If the supplier is unable to obtain the required statement as described in (1) and (2) above within 21 calendar days following the date of service, the ambulance supplier must document its attempts to obtain the physician certification statement and may then submit the claim. Acceptable documentation must include a signed return receipt from the U.S. Postal Service or similar delivery service. A signed return receipt will serve as documentation that the ambulance supplier attempted to obtain the required physician certification statement from the beneficiary's attending physician.

In all cases, the appropriate documentation must be kept on file and, upon request, presented to the carrier or intermediary. It is important to note that the presence of the signed physician certification statement does not necessarily demonstrate that the transport was medically necessary. The ambulance supplier must meet all coverage criteria in order for payment to be made.

Comment: Several commenters. including a national ambulance association and an association representing medical professionals, state that the proposed regulation permits physician certification statements to be signed by physician assistants (PA), nurse practitioners (NP), and clinical nurse specialists (CNS), but only if employed by the facility in which the beneficiary is being treated. The commenters state, however, that, in most cases, practitioners are employed not by the facility but by the attending physician. The commenters recommended that the requirements of § 410.40(d)(3)(iii) be revised to specify that, in keeping with Medicare regulations, the PA, NP, or CNS may also be employed by the attending physician.

*Response:* We agree with the commenters and are revising § 410.40(d)(3)(iii) to clarify that the PA, NP, or CNS may be employed either by the facility or by the beneficiary's attending physician.

*Comment:* Many commenters recommended that we revise § 410.40(d)(3)(iv) to conform to Program Memorandum B–00–09 that clarified the circumstances under which a physician certification is required for both scheduled and unscheduled transports.

Response: Program Memorandum B-00–09 was issued in response to an inquiry that specifically addressed the 48-hour time requirement set forth in § 410.40(d)(3)(i). The program memorandum specifies that, in cases where a beneficiary who is living in a facility and who is under the direct care of a physician requires nonemergency, unscheduled transport, the physician's certification can be obtained 48 hours after transport has been provided. Based on comments, we are, however, revising the regulation to clarify that §410.40(d)(3) is applicable to nonrepetitive, nonemergency, scheduled ambulance services. In specifying that the rule applies to nonrepetitive transports, we are aware that § 410.40(d)(2), as currently written, contains a requirement that suppliers obtain the required documentation no earlier than 60 days before the date the service is furnished. We are revising §410.40(d)(2) to clarify that the 60-day requirement is applicable only to repetitive transports, not nonrepetitive ones.

*Comment:* Many commenters, including a national ambulance association, expressed a concern that carriers may be interpreting the revised definition of "bed confined" to mean that the beneficiary be bed-confined even in cases where the medical condition of the beneficiary would otherwise indicate that transportation by means other than ambulance would be contraindicated. The commenters recommended that § 410.40(d)(1) be revised as follows:

For nonemergency transportation, transportation by ambulance is appropriate if the beneficiary is bedconfined or if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. In determining whether a beneficiary is bed-confined, the following criteria must be met:

(i) The beneficiary is unable to get up from the bed without assistance.

(ii) The beneficiary is unable to ambulate.

(iii) The beneficiary is unable to sit in a chair or wheelchair.

*Response:* In the June 17, 1997 proposed rule (62 FR 32719), these three criteria were developed to define bedconfinement. These criteria identify individuals who may need ambulance services: we identified as bed-confined only those individuals who are "completely confined to bed and unable to tolerate any activity out of bed." Subsequent instructional guidelines

(PM AB-99-53, AB-99-83, AB-00-103) were issued in an effort to clarify that the bed-confined criteria are not meant to be the sole criteria in determining medical necessity; bed-confinement is one factor to be considered. It is important that all factors relating to the beneficiary's condition are considered in evaluating whether the medical necessity criteria for ambulance services have been met. As always, it is the responsibility of the ambulance supplier to furnish complete and accurate documentation of the beneficiary's condition to demonstrate that the ambulance service being furnished meets the medical necessity criteria.

It is not our intent either to require that the bed-confined condition be met in every case in order for an ambulance transport to be covered or to mandate coverage of an ambulance transport solely because a beneficiary is bedconfined.

We agree with the commenters that our proposed revision was unclear. We are revising proposed 410.40(d)(1). In addition to the identifying criteria on bed-confinement, the final rule will now state that:

For nonemergency ambulance transportation, transportation by ambulance is appropriate if the beneficiary is bedconfined and it is documented that the beneficiary's medical condition is such that other methods of transportation are contraindicated, or if his or her medical condition, regardless of bed-confinement, is such that transportation by ambulance is medically required. In determining whether a beneficiary is bed-confined, the following criteria must be met: \* \* \*

#### 3. Payment During the First Year

As explained below in more detail, we stated that we would use the universe of claims paid in 1998 (reduced by the \$65 million savings that would have been realized through implementation of the BLS and ALS definitions proposed in the June 17, 1997 proposed rule (62 FR 32718)) to establish the CF and would index the 1998 dollars to CY 2002 dollars using the compounded inflation factors derived from section 1834(l)(3) of the Act. (The transition and the inflation factors are described in § 414.615.)

#### 4. Billing Method

In proposed § 414.610, we stated that, after the transition period, we would bundle into the base rate payment all items and services furnished within the ambulance benefit. This would eliminate billing on an itemized basis for any items and services related to the ambulance service (for example, oxygen, drugs, extra attendants, and EKG testing). In addition, only the base rate code and the mileage code would be used to bill Medicare. (This decision was made in accordance with section 1834(l)(7) of the Act, which gives us the authority to specify a uniform coding system, as well as with section 1834(l)(2)(B) of the Act.) During the transition period, suppliers who currently use billing methods 3 or 4 may continue to bill for supplies separately (see section I.B. for a description of these billing methods).

## 5. Local or State Ordinances

In proposed § 414.610, we stated that, regardless of any local or State ordinances that contain provisions on ambulance staffing or furnishing of all ambulance services by ALS suppliers, we would pay the appropriate ambulance fee schedule rate for the services that are actually required by the condition of the beneficiary. We proposed this policy pursuant to the Medicare statutory requirement (see section 1834(l)(2)(B) of the Act) to use definitions of services that link payments to the types of services furnished.

#### 6. Mandatory Assignment

In proposed § 414.610, we stated that, effective January 1, 2001, all payments for ambulance services must be made on an assignment-related basis, as mandated by section 1834(l)(6) of the Act. Ambulance suppliers must accept the Medicare allowed charge as payment in full and not bill the beneficiary any amount other than unmet Part B deductible or coinsurance amounts. There is no transitional period for mandatory assignment.

*Comment:* One commenter asked whether the fee schedule and mandatory assignment apply when Medicare is the secondary payer.

*Response:* Yes, both the ambulance fee schedule and mandatory assignment apply when Medicare is the secondary payer.

*Comment:* Several commenters objected to the requirement of mandatory assignment for claims when the fee schedule is implemented. They claim that because the rates in some areas are so low, some ambulance suppliers will go out of business without balance billing. One commenter indicated that we have the discretion to delay implementation of mandatory assignment until the end of the phasein period. The commenter also requested clarification that mandatory assignment pertains only to services that are covered by Medicare.

*Response:* Mandatory assignment is required by section 1834(l)(6) of the Act.

We do not agree that there is discretion to delay its implementation until the fee schedule is fully phased-in. The implementation date given in the proposed rule will be changed to coincide with the actual implementation of the fee schedule. Historically, ninety-five percent of ambulance services have been submitted under assignment, and, while the fee schedule redistributes payments, we do not anticipate that the assignment requirement is a major issue nationally. It is correct that mandatory assignment pertains only to Medicare covered services.

*Comment:* Some commenters asked whether the provider/supplier may bill the beneficiary for the non-covered charges for transportation to a facility beyond the nearest appropriate facility, or whether mandatory assignment prevents the provider/supplier from billing for this additional mileage.

*Response:* Mandatory assignment does not preclude billing for this additional mileage. Mandatory assignment refers only to services that are covered by the Medicare program.

*Comment:* Some commenters asked about the correlation between "Medicare+Choice" (M+C) plan payments and the ambulance fee schedule. The commenters asked if the amount paid by M+C plans is affected by the fee schedule amounts and if the liability of M+C enrollees is affected by the mandatory assignment requirement for the fee schedule.

*Response:* For ambulance services that are under contract with the plan, Medicare rates do not affect the payment amounts by the M+C or the enrollee's copay. For ambulance services that are not under contract (for example, out-of-area emergency transports), the M+C is liable for the Medicare allowance in that area less any copay that the beneficiary pays pursuant to the M+C plan's rule for coinsurance.

#### 7. Miscellaneous Payment Policies

The following payment policies were in effect before publication of the proposed rule; however, we used the proposed rule as an opportunity to clarify them.

## a. Multiple Patients

Occasionally, an ambulance will transport more than one patient at a time. (For example, this may happen at the scene of a traffic accident.) In this case, we proposed to prorate the payment as determined by the ambulance fee schedule among all of the patients in the ambulance. If two patients were transported at one time, and one was a Medicare beneficiary and the other was not, we would make payment based on one-half of the ambulance fee schedule amount for the level of medically appropriate service furnished to the Medicare beneficiary. The Medicare Part B coinsurance, deductible, and assignment rules would apply to this prorated payment.

Similarly, if both patients were Medicare beneficiaries, payment for each beneficiary would be made based on half of the ambulance fee schedule amount for the level of medically appropriate services furnished to each beneficiary. The Medicare Part B coinsurance, deductible, and assignment rules would apply to these prorated amounts.

*Comment:* Some commenters disagree with our paying only the rate for one trip if two patients are transported. The commenters contend that it is not true that transporting two or more patients in the same vehicle costs no more than transporting one patient. Additional time will be required to load and unload each patient. Each patient will require specific individual care. The supplier will also incur additional liability for each patient for whom it is responsible. The commenters believe that one mileage fee should be paid, but that two base rates should be paid.

*Response:* With respect to multiple patient transports, we agree with the commenters that there would be, on average, a higher cost for multiple patient transports than for those with only a single patient onboard. While commenters stated that an extra attendant would be onboard and additional supplies would be used for multiple patients, we do not believe this would always be true. Therefore, if two patients are transported simultaneously, for each Medicare beneficiary we will allow 75 percent of the payment allowance for the base rate applicable to the level of care furnished to that beneficiary. If three or more patients are transported simultaneously, then the payment allowance for the Medicare beneficiary (or each of them) is equal to 60 percent of the service payment allowance applicable for the level of care furnished to the beneficiary. However, a single payment allowance for mileage would continue to be prorated by the number of patients onboard. Also, we are establishing a modifier to identify these claims.

#### b. Pronouncement of Death

In the proposed rule, we stated that there are three rules that apply to ambulance services and the pronouncement of death. First, if the beneficiary was pronounced dead by an individual who is licensed to pronounce death in that State prior to the time that the ambulance is called, no payment would be made. Second, if the beneficiary is pronounced dead after the ambulance is called but before the ambulance arrives at the scene, payment for an ambulance trip would be made at the BLS rate, but no mileage would be paid. Third, if the beneficiary is pronounced dead after being loaded into the ambulance, payment would be made following the usual rules (that is, the same level of payment would be made as if the beneficiary had not died).

*Comment:* Some commenters suggested that we pay at the ALS rate if the crew attempts to resuscitate, even though they may fail. Also, some commenters believe that the pronouncement of death needs to be clarified further, so that unnecessary transportation will be limited.

*Response:* Program payment may be made only for medically necessary ambulance transports. There is no basis for us to pay under the ambulance benefit for services such as attempts to resuscitate, if no ambulance transport occurs. In this final rule, we are setting forth the following criteria to apply in the pronouncement of death:

• If the beneficiary is pronounced dead by an individual who is authorized by the State to pronounce death prior to the time the ambulance is called, no payment will be made.

• If the beneficiary is pronounced dead by an individual who is authorized by the State to pronounce death prior to the arrival of the ambulance, but after it is called, a BLS base rate payment will be made (except for air, as noted in the comment and response below). No payment for mileage will be made.

• If the beneficiary is pronounced dead by an individual who is authorized by the State to pronounce death during the transport of the ambulance, the same payment rules apply as if the beneficiary were alive.

*Comment:* Some commenters suggested that, in the case where a beneficiary dies while an air ambulance is enroute to the scene, we pay air ambulance at the air base rate, not the BLS ground rate.

*Response:* We agree with the commenters. We will not pay mileage because there is no transport, but we will pay the applicable air base rate.

#### c. Multiple Arrivals

We stated in the proposed rule that, when multiple units respond to a call for services, we would pay the entity that provides the transportation for the beneficiary. The transporting entity would bill for all services furnished, as stated in current policy. For example, if BLS and ALS entities respond to a call and the BLS entity furnishes the transportation after an ALS assessment is furnished, the BLS entity would bill using the ALS1 rate. We would pay the BLS entity at the ALS1 rate. The BLS entity and the ALS entity would have to negotiate between themselves payment for the ALS assessment.

*Comment:* Some commenters stated that the discussion of multiple arrivals in the proposed rule is confusing. They state that, although the issue was not discussed by the Committee, our discussion appears to be inconsistent with the industry's understanding that the ALS level of service may be billed only if an ALS supplier/provider is involved in the actual transportation.

*Response:* According to the definition of "ALS assessment" that we are promulgating in this final rule, an assessment may result in the determination that no ALS level service is required and, in that instance, an ALS1–Emergency level payment may be made to the transporting BLS ambulance supplier even if no ALS paramedic rides onboard.

*Comment:* One commenter stated that when two ALS ambulances respond, the ambulance fee schedule payment should be divided between them according to the services each provided.

*Response:* We have always construed the Medicare law as permitting payment for services only to the entity that provides the services, in this case, ambulance transport. Any suppliers that furnish services other than the transport must look to the transporting supplier for payment for other services. As described above, there is a limited provision of the law for paramedic intercept services under which the Congress permitted payment to be made directly to the entity furnishing the intercept service, but only under special circumstances provided in the regulations in § 410.40(c). However, a provider (for example, a hospital or skilled nursing facility) may furnish ambulance services under arrangements in accordance with section 1861(w) of the Act. In this case, the provider may bill for the ambulance service, even if another supplier furnished the transport, if the service is furnished pursuant to an arrangement between the two entities in accordance with the law.

## d. BLS Services in an ALS Vehicle

The proposed rule stated that effective with implementation of the fee schedule, claims would be paid at the BLS level where an ALS vehicle is used but no ALS level of service is furnished. Claims would be filed using the appropriate BLS code. Like the other rules describing levels of service, these rules would be applicable on the effective date of this rule; there would be no transitional period for the rule.

Comment: Several commenters stated that our decision to pay at the BLS rate for the use of an ALS vehicle when no ALS service is furnished has the effect of not recognizing all-ALS mandates by local authorities (situations where the local government mandates that all ambulances within its jurisdiction be equipped to provide an ALS level of service). The commenters stated that this policy, which will result in an immediate budget savings for Medicare of approximately \$70 million in 2002, should be phased in on the same schedule as the other regulatory changes. The commenters believe that we should apply the transition provisions in the negotiated rule to all payment changes, including those stemming from our decision to pay BLS rates when BLS services are provided using an ALS vehicle. Because we did not propose to phase in this policy (that is, we are not continuing to pay at the ALS level under the old portion of the transition payment), the commenters believe that many emergency medical systems will be threatened and Medicare beneficiaries will be at risk of not having access to emergency and other medical transportation services.

Response: While we continue to believe that BLS services should be paid at the BLS rate, even when an ALS vehicle is used, we agree with the comment to phase in the implementation of this policy. Therefore, when an ALS vehicle is used to furnish non-emergency BLS services only, the "old" portion of the blended rate will be at the "old" ALS nonemergency payment level and the "new" portion of the blended rate will be at the BLS fee schedule amount.

In addition, we are revising the definition of an ALS assessment needed to qualify for an ALS1-Emergency level of payment from the proposed definition. An emergency ambulance trip may be paid as an ALS1-Emergency even when the only ALS service furnished is an ALS assessment. This revision in the final rule will increase the trips paid at the ALS1-Emergency level, rather than at the BLS-Emergency level. Where the only ALS service furnished is an ALS assessment for an emergency, the "old" portion of the blended rate will be at the ALS emergency rate. We have also increased the amount of spending upon which the CF is based by the amount of savings that had been attributed to this policy.

## III. Methodology for Determining the Conversion Factor

As discussed in the September 12, 2000 proposed rule (65 FR 55078), our approach to determining the conversion factor (CF) was:

(1) To use the most recent complete year of ambulance claims;

(2) To translate those claims into the format that would have been used under the fee schedule; and

(3) To calculate the CF, that, when applied to the RVUs for each level of service, results in the same total program payment for those claims, less \$67 million that would have been saved if the fee schedule legislation had not been passed. (Under the final rule, as discussed in section III.D, we have decided not to subtract this amount in calculation of the CF.)

We would then inflate this CF in accordance with the inflation factor prescribed in the statute. (See section 1834(l)(3) of the Act, as amended by section 423 of BIPA.) We used 1998 as the base year because this was the most recent complete year for which claims data were available. For claims processed by carriers (that is, claims from independent ambulance suppliers), we used allowed charge data. For claims processed by fiscal intermediaries (FIs) for provider-based ambulance services, we used the submitted charges on the Medicare claims multiplied by the cost-to-charge ratio applicable to the ambulance costs for each provider.

We modified the claims data in several ways to calculate the proposed fee schedule and its impact. First, we separated all claims into two groups:

Carrier-processed claims for ambulance services (8 million in 1998).
FI processed claims for ambulance

services (900,000 in 1998).

#### A. Carrier-Processed Claims

We had to adjust some of the 1998 claims for purposes of the proposed ambulance fee schedule calculation. Some of the claims did not report mileage and, because mileage will be required for each ambulance service under the fee schedule, an adjustment had to be made for the missing miles (see above). In other cases, the billing codes under the old system did not translate directly into services that would be paid under the proposed fee schedule. Below is a more detailed explanation of the adjustments that were made to the 1998 base year data in order to accommodate missing data.

#### 1. Mileage

Approximately 1.1 million claims for ground ambulance services did not

show any mileage. The proposed fee schedule for ambulance services will provide a payment for the trip and a payment per statute mile for the loaded mileage traveled. Therefore, in calculating the proposed CF, we added mileage to those claims that did not report mileage. We did so by assigning the mode value (that is, the number of miles billed most often) per trip in urban areas (1.0 miles) and the mode value or mileage per trip in rural areas (1.0 miles).

Current billing instructions provide that only one ambulance trip may be billed per line on a claim. Because billing rules prohibit more than one trip to be reported on a line, we assumed any number greater than one was an error. Therefore, we did not count multiple trips billed on the same line of a claim. This reduced the total trip count processed by carriers by approximately 1 percent. This reduction of about 1 percent in the number of trips resulted in an increase of about 1 percent in the average allowed charge per trip.

*Comment:* Some commenters stated that some billers do not bill for mileage and will continue not to bill mileage after the fee schedule is implemented. Commenters stated that in other cases a supplier's submitted charge for mileage is lower than the fee schedule rural mileage rate and asked that the Medicare carrier automatically increase the supplier's charge by 50 percent before comparing the submitted charge to the fee schedule rural mileage rate. (This comparison is made because the law requires that payment be based on the lower of the actual submitted charge or the fee schedule amount.) Also, commenters stated that some billers have a lower charge for mileage that would offset their higher charge for the ambulance base rate service, but that this will not be considered when we process the claim for the base rate for purposes of the fee schedule.

*Response:* In the process of setting the conversion factor (CF), we found over one million claims that should have reported mileage but did not. As stated above, we assigned a value of 1 mile to each of these claims. This was the mode value of mileage for both urban and rural ambulance claims. The average value was 7 miles for urban and 17 miles for rural claims. Assuming 1 mile each for claims without mileage results in a higher CF than would have resulted if we used the average number of miles. We will monitor claims data after the fee schedule is initially implemented and recalibrate the CF to reflect actual, as opposed to projected, billing practices.

With respect to comments that we take into account suppliers that have high service charges but low mileage charges, we do not believe that this result is necessary or practical. Section 1833(a)(1)(R) of the Act states that CMS pays the lower of "the actual charge for the services" or fee schedule. While some commenters argued that we should be comparing total charges (that is, base rate plus mileage) rather than looking at the service and mileage separately, we believe comparing the components of the charge is equally consistent with the law. Moreover, the entire Medicare claims processing system is set up to process claims on an individual line-item basis. To change the claims processing system would jeopardize timely implementation of the fee schedule.

*Comment:* Many commenters suggested that the urban/rural designation for round trips should be based on the original point of pick-up, rather than from each point of pick-up.

*Response:* Each trip consisting of a point of pick-up and a destination is considered to be a trip on its own and must be billed, processed and paid individually.

*Comment:* One commenter presented this hypothetical: beneficiary becomes ill on a cruise near Alaska. Beneficiary is airlifted. The nearest facility cannot adequately care for the beneficiary. The nearest facility that can adequately attend to the beneficiary is in Anchorage, Alaska. The beneficiary lives in the continental United States. The beneficiary requests to be sent to Seattle, Washington. Can this be done?

*Response:* The program covers mileage only to the nearest facility equipped to treat the beneficiary. Any additional mileage is not covered by Medicare. However, the beneficiary may arrange with the ambulance supplier to pay the difference.

### 2. Billing Codes

We determined that the billing codes that represent items and services included under the ambulance fee schedule are all billing codes submitted by ambulance suppliers in the range of Health Care Common Procedure Coding System (HCPCS) A0030 through A0999 (excluding HCPCS code A0888, which is not covered by Medicare) and Common Procedural Terminology– Fourth Edition (CPT–4) <sup>1</sup> codes 93005 and 93041. HCPCS billing codes A0030 through A0999 represent ambulance services, supplies, and equipment that are covered by the ambulance fee schedule, and CPT codes 93005 and 93041 represent electrocardiogram (EKG) services that may be billed by ambulance suppliers. In addition, we incorporated all HCPCS billing codes in the range of A4000 through Z9999; these services could have been paid by a carrier to an ambulance supplier only if they represented items and services covered under the Medicare ambulance benefit. We excluded all other CPT billing codes in the range of 00001 through 99999 (except the two EKG codes listed above) because they represent services not covered by the ambulance fee schedule.

Next, we adjusted all billing codes that represented an ALS vehicle when no ALS service was furnished. We removed the actual allowed charges on these claims and replaced them with the charges that would have been allowed by the carrier for the corresponding BLS level of service (that is, emergency for emergency and nonemergency for nonemergency).

*Comment:* Ševeral commenters stated that our decision to pay at the BLS rate for the use of an ALS vehicle when no ALS service is furnished has the effect of not recognizing all-ALS mandates by local authorities (situations where the local government mandates that all ambulances within its jurisdiction be equipped to provide an ALS level of service). The commenters stated that this reduction in the amount of spending used to set the CF was inappropriate.

*Response:* While we continue to believe that BLS services should be paid at the BLS rate, even when an ALS vehicle is used, we have decided to increase the amount of spending upon which the CF is based by the amount of savings that had been attributed to this policy.

## 3. Crosswalking the Old Billing Codes to the New Billing Codes

We converted the old billing codes in the base year data to the new billing codes as they will be under the final fee schedule. The old BLS codes convert directly to the final BLS codes. The old air ambulance codes (fixed wing and helicopter) convert to the final air ambulance codes. The old water ambulance code converts to the final BLS-Emergency code. The old mileage codes distinguished ALS miles from BLS miles; both of these old codes will convert to the single proposed mileage code. Codes used to report air mileage will convert to the final codes for fixed and rotary wing mileage, respectively. All air miles will be reported in statute miles. As mentioned earlier, we

<sup>&</sup>lt;sup>1</sup>CPT codes and descriptions only are copyright 2001 of the American Medical Association. All Rights Reserved. Applicable FARS/DFARS Apply.

converted the codes for an ALS vehicle when no ALS services were furnished to the corresponding BLS codes. The conversion of the remaining old ALS codes (for example, when ALS services were furnished) to final ALS codes is less straightforward because there are more levels of ALS service under the final fee schedule than currently exist. All nonemergency ALS codes convert to the ALS1 (nonemergency) code. Based on advice from various members of the Committee, for purposes of calculating the CF, we proposed converting the old emergency ALS codes according to the following formulas:

• For claims on which both the origin and destination was a hospital: 33 percent will convert to specialty care transport (SCT), 5 percent to advanced life support, level two (ALS2), and the remainder to ALS1-Emergency.

• For all other claims: 8.3 percent will convert to ALS2, and the remainder to ALS1-Emergency.

*Comment:* Commenters stated that the projected volume of 8.3 percent of current ALS emergency claims that will be billed under the fee schedule at the ALS2 rate is too high. The commenters stated that the projection provided by the Committee was only 2.3 percent.

*Response:* This comment was in error. We have verified with the Committee that the 8.3 percent projection was correct.

### 4. Low Billers

A concern was raised about low billers of ambulance services. Low billers are suppliers who currently bill less than the maximum charge allowed by Medicare. There are several reasons low billers exist. For example, an entity may have a low charge because the cost of its operation is subsidized by local taxes (for example, a municipal ambulance company); the entity may use volunteers; its charge may be regulated by local ordinances, limited by an inflation-indexed charge that is part of the Medicare program's current reasonable charge policy, or restricted for other reasons.

In the proposed rule, we stated that we have neither a means to estimate the extent to which low billing will continue after the fee schedule is implemented and the inflation-indexed charge limit no longer applies, nor a means to estimate the extent to which volunteer and municipal ambulances will choose not to file Medicare claims at the fee schedule amounts to which they could be entitled. Therefore, given the uncertainty of suppliers' future behavior, we proposed not to attempt to adjust the CF based on assumptions that low billing will or will not continue. We also stated that we will monitor payment and billing data and recalculate the CF as appropriate.

Because the total ambulance service payment amount is based on the actual allowed charges from the base year (1998), the CF will reflect historical charges for some suppliers that may have been lower than the reasonable charges of other suppliers. At the same time, if low billers of ambulance services continue to charge less than the ambulance fee schedule amount, we will continue to pay the lower amount as the law requires. Therefore, some members of the ambulance industry have urged us to increase the fee schedule CF, anticipating that, otherwise, savings would result from billers who continue to charge less than they could, in this case, less than the fee schedule amount. We have estimated that in the base year 1998, if all low billers had billed the maximum charges allowed by Medicare, total allowed charges for ambulance services would have been approximately \$150 million more than they were. Approximately half of this amount is attributable to charges that are 70 percent of the maximum allowed charges or greater. Assuming that billers whose current charge is 70 percent or more of the maximum will charge the full fee schedule amount and that one-half of the entities whose current charge is less than 70 percent of the maximum allowed charge may continue to bill at less than the fee schedule amount, approximately \$39 million in the base year 1998 might continue to be attributed to low billing. Adjusted for inflation, this amount (annualized) is approximately \$42 million in 2002.

*Comment:* We received many comments questioning our approach to low billers. In particular, commenters believe that we were calculating the CF in such a way that we would inappropriately achieve between \$75 million and \$150 million in savings by assuming all low billers would begin to bill at the full amount allowed under the fee schedule. Commenters stated that we were obligated to ensure that the implementation of the fee schedule was budget neutral.

*Response:* We believe some commenters misunderstood our reasoning when we referred to the fact that an approximately \$150 million difference existed in 1998 between ambulance suppliers' actual charges and the maximum charges allowed by Medicare and that approximately half of this amount (about \$77 million) is attributable to charges that are 70 percent of the maximum allowed charge or greater. For those suppliers already charging 70 percent or greater of the maximum charges allowed, our reasoning was that they are likely to increase their charges when the inflation-indexed charge limit no longer applies.

While we continue to believe that future billing behavior is unpredictable, we have decided to make an adjustment in the CF in response to this comment. We will increase the CF to account for approximately \$39 million in the base year 1998 (one-half of the amount attributable to the difference by which charges are less than 70 percent of the maximum allowed by Medicare (\$77 million)). In light of the lack of available data to project how many low billers will increase their charges, we have decided to assume that one-half of the remaining low billers (representing the billers whose charge is less than 70 percent of the maximum) may continue to bill at less than the fee schedule because we agree that some low billers may not increase their charges up to the fee schedule amount. We will review this issue as part of the annual review to determine whether a further adjustment is warranted. If the level of low charge billing is significantly different from the assumed level, we will adjust the CF and apply such an adjusted CF prospectively. We also note that, in other circumstances, we have made assumptions that resulted in a higher CF. For example, as discussed above, in the process of setting the CF, there were over one million claims that should have reported mileage but did not. We assigned a value of one mile to each of these claims. This has resulted in a higher CF than if we had assigned a higher mileage estimate to these claims.

#### B. FI Processed Claims

Because all FI processed claims contained mileage, we did not make any adjustment for mileage. However, we did have to determine the codes that represented items and services included under the ambulance fee schedule. In the case of claims filed by hospitalbased ambulance providers, services furnished in the emergency room and other outpatient departments of the hospital are reported on the same claim that is used to report the ambulance service. Therefore, it is impossible to know from the claims data where any of the nonambulance services were furnished. Because most of these nonambulance services were of the kind that would likely have been furnished in the hospital's emergency room, we did not include the data on them in data for the proposed ambulance fee schedule. Rather, we determined that

the billing codes that will be covered by the ambulance fee schedule are all billing codes representing ambulance services submitted by hospitals (for example, in the range of HCPCS codes A0030 through A0999 (excluding HCPCS code A0888, which is not covered by Medicare)).

Codes that represented the use of an ALS vehicle, but when no ALS level of service was furnished, were converted to the corresponding BLS billing code. However, in this case, no adjustment was made for payment because the correct data were already available since payment for these claims would have been made on a cost basis corrected to the proper amount at cost settlement.

*Comment:* A few commenters stated that the regulations do not address the issue of bad debt for ambulance services. Medicare has traditionally paid for hospitals' bad debts for uncollected beneficiary deductibles and copayments. The commenters believe that Medicare should be responsible for payment of reasonable costs associated with bad debt for ambulance services as well.

*Response:* There is no provision under the fee schedule for payment of bad debts. The law requires that the program pay 80 percent of the lower of the fee schedule amount or the billed charge and that the beneficiary is liable for the Part B coinsurance and any unmet Part B deductible amounts. Furthermore, sharing in bad debts for providers and not for independent suppliers would result in greater program payments to providers than suppliers for furnishing the same service. We believe that doing so would be antithetical to payment under a fee schedule.

## C. Air Ambulance

To establish a consistent system of RVUs that could be applied to ground and air ambulance services, we must know the cost per service in each setting. Unfortunately, these data do not exist. One member of the Committee presented data and stated that the data, when combined with an analysis by an economist, demonstrated that the total costs in 1998 for air ambulance services were between a minimum of approximately \$134.8 million and a maximum of \$168 million. The higher amount exceeded the billed charges for air ambulance services. Because definitive cost data do not exist, the Committee decided to compromise by setting a range of total air ambulance costs between \$134.8 million and \$158 million within which we would set an amount reflecting incurred costs.

We considered several approaches in an attempt to accurately estimate the appropriate amount for air ambulance services within the range prescribed by the Committee.

We considered using cost data from a ground ambulance services survey acquired by an independent source that was hired by a member of the Committee. We tried to compare the results of this survey to cost data from our estimate. Because the study was only a self-reporting survey and did not report audited costs, and because the results varied widely and were substantially different from our estimate, we could not establish an estimate based on the survey that fell within the range prescribed by the Committee.

We converted old billing codes to the proposed billing codes in the same way as discussed above for the carrierprocessed claims. Using the billed charge adjusted by the provider's costto-charge ratio, we are able to estimate the provider's Medicare-allowable cost for all ambulance services. However, we are unable to estimate with any certainty the split of air ambulance services costs and ground ambulance services costs from the same provider because Medicare cost-apportioning rules do not require data to be furnished in such detail. Originally, we assumed that the same cost-to-charge ratio within a provider applies to both air and ground ambulance services charges. However, because this assumption may not be correct, and because it results in an amount below the range specified by the Committee, we did not pursue this methodology.

Next, we considered using the billed charges for ambulance services. Over 80 percent of ground ambulance services are furnished by independent (not provider-based) ambulance suppliers. However, the average adjusted charge (that is, the charge adjusted by the provider's cost-to-charge ratio) for ALS and BLS ground ambulance services, excluding mileage, furnished by provider-based ambulance services is more than 65 percent greater than the average charge for independent ambulance services suppliers (\$342 vs. \$206 per trip). Assuming the appropriate payment for ground ambulance services is the average allowed charge for the independent suppliers, the amount of money misallocated to provider-based ground ambulance services substantially exceeds the amount that would represent a total payment for air ambulance services at the maximum recommended by the Committee (\$158 million). This large discrepancy

between the payment rates for providerbased and independent supplier ground ambulance services, and the fact that suppliers are able to furnish services at the lower rate, led us to conclude that the program cost apportionment process caused too much of providers' ambulance costs to be allocated to provider-based ground ambulance services and not enough of these costs were allocated to provider-based air ambulance services. We believe that the appropriate payment for ground ambulance services is closer to the independent supplier charge. Consequently, we have chosen the maximum air ambulance total amount designated by the Committee, that is, \$158 million.

Comment: A few commenters mentioned that the cap on per trip payment inflation imposed on providers by section 4531 of the BBA of 1997, which states that the Secretary shall not recognize the costs per trip in excess of costs recognized as reasonable for ambulance services provided on a per trip basis during the previous fiscal year increased for inflation, is currently applied as a combined cost per trip cap for both ground and air ambulance trips. This, they state, is inappropriate because the mix of air and ground trips may change from year to year. The commenter stated that there should be separate caps for ground and air ambulance trips.

*Response:* We have interpreted this provision of the law as requiring a single combined cost per trip inflation payment cap for providers, because the law refers to total "costs per trip." We do not believe that the law contemplates the construction suggested by commenters. We also note that this issue arises only during the transition period. Once the fee schedule is fully implemented, there will be no providerspecific cost per trip limit.

*Comment:* A few commenters wanted further clarification on the methodology used to set the air ambulance fee schedule rates. Some commenters stated that the air ambulance payment rates should not be increased to the point of the air ambulance recovering its cost when payments for the ground ambulance will be reduced further to an amount below its cost. Another commenter stated that it is not reasonable to set the air amount based on charges for ground services.

*Response:* We do not have cost data to specifically distinguish the cost for air or ground services. The Committee recommended a range of \$134.8–\$158 million, and we determined the appropriate amount within that range. Because we believe that we have providers' total costs for all ambulance services, we chose to use a proxy for the approximate charge (average charge for independent suppliers) for ground and subtract that amount from the total provider ambulance cost to estimate an appropriate amount for the air cost portion.

Considering the large discrepancy between the payment rates for providerbased and independent supplier ground ambulance services, we believe that the appropriate payment for these ground ambulance services is closer to the independent supplier charge for the following reasons: (1) Over 80 percent of ground ambulance services are furnished by independent (not providerbased) suppliers, and (2) 95 percent of suppliers' claims are paid on an assigned basis (that is, suppliers accept the Medicare allowed charge as payment in full). Consequently, we have chosen the maximum air ambulance total amount recommended by the Committee, which is \$158 million. Choosing an amount lower than \$158 million would lead us to pay ground ambulance rates at closer to the hospital-based rate than the independent supplier rate, which we believe to be unwarranted.

*Comment:* Some commenters cited abrupt and erratic increases in gas prices as a reason for the cost of air ambulance exceeding the proposed fee schedule rates. The impact will especially be felt for those providers whose aircraft consume from 60 to 103 gallons per hour.

*Response:* We believe that if increases in the cost of fuel occur, they will be accounted for by the inflation update factor applied to the ambulance fee schedule. We have set the rates for air at the maximum recommended by the Committee.

#### D. Calculation of the CF

We determined the total number of ambulance trips and loaded miles and the total amount of charges allowed by Medicare for ambulance services in the base year of 1998. In estimating the total volume of services at the new levels described under the fee schedule, we coded those cases in which an ALS vehicle was used in a nonemergency transport, but no ALS services were furnished, as BLS nonemergency services. Where an ALS vehicle was used in an emergency transport, we coded the transport as ALS1 if no ALS services were furnished because we assumed that an ALS assessment would always be performed; under the fee schedule, the criteria for ALS1 includes such an assessment.

To calculate the CF for ground ambulance services, we used the following procedures:

• We multiplied the volume of services for each level of ground ambulance service by the respective RVUs recommended by the Committee (including application of the practice expense of the GPCI and of the rural mileage rate as described above).

• We summed those products to arrive at the total number of RVUs.

• We subtracted the total allowed amount for air ambulance services (\$158 million as discussed above) from the total charges allowed by Medicare for ambulance services, which results in the total amount of charges allowed by Medicare for ground ambulance services.

• We subtracted the total amount of allowed charges for ground mileage from this total charge amount.

• We divided the remaining charge amount by the total number of RVUs for ground services and applied the cumulative ambulance inflation factor for the period 1998 through 2002, which results in a CF for ground ambulance trips of \$170.54.

We made five (5) changes from the calculation of the CF described in the proposed rule (which was \$157.52). First, at the time of the proposed rule, we failed to crosswalk the emergency cases in which an ALS vehicle was used, but no ALS service was furnished, to the category of ALS1-Emergency services under the fee schedule; instead, we counted them as BLS-Emergency services. Second, there was a miscalculation of the number of rural ambulance miles that are less than or equal to 17 in the 1998 base data. Third, in this final rule, we added approximately \$42 million (the annualized amount for 2002) as an estimate of the amount of low billing that will occur under the fee schedule and, thus, the amount that will be available for other ground ambulance services. This is discussed further in section V.B. Fourth, we changed the inflation adjustment for 2001 to conform to the inflation adjustments contained in section 423 of BIPA. Fifth, we added back to the total amount used to calculate the CF the savings that would have accrued to the program had we implemented the policy proposed in June 1997 that would pay at the BLS rate for services furnished at the BLS level even though an ALS vehicle was used.

We followed a similar procedure to determine the fee schedule amount for air ambulance services. Because there are only two kinds of air ambulance fixed wing and rotary wing—we did not calculate RVUs and a CF, but calculated the actual fee schedule amounts directly. We divided the total number of billed air ambulance services into the total amount of payment available for these services (\$158 million). The amounts in the base year (1998) are \$2,286.52 and \$2,658.42 for fixed wing and rotary trips, respectively. These numbers would then also be adjusted by the cumulative inflation factor provided in section 1834(l) of the Act. (The inflation factor is discussed in more detail below.)

We will monitor payment data and evaluate whether our assumptions used to establish the original CF (for example, the ratio of the volume of BLS services to ALS services) are accurate. If the actual proportions among the different levels of service are different from the projected amounts, we will adjust the CF accordingly and apply this adjusted CF prospectively.

*Comment:* One commenter recommended a third air rate for air ambulance services furnished in remote, frontier areas such as Alaska. The commenter stated that the cost of furnishing these services is considerably higher than standard rural areas because of the sparse population and large distances that must be traveled.

*Response:* We are not making this change to the fee schedule. Consistent with the Committee Statement, there will be two air rates: fixed wing and rotary wing (helicopter). As explained under the section for rural modifiers, there will be a 50 percent add-on applied to the base rate and to all of the loaded mileage for air ambulance services in rural areas. Therefore, longer trips will be paid proportionately more than shorter trips.

*Comment:* Many commenters from various regions believe that the fee schedule rates are too low and that suppliers and providers will substantially lose profits. Some commenters suggested that, for various reasons, they should be exempt from the fee schedule and continue to be paid under the current system. For example, a commenter described the EMS system in New Jersey as unique and stated that placing New Jersey ambulance suppliers under the fee schedule would actually result in a higher cost to Medicare because it would ultimately force volunteer ambulance companies to close.

*Response:* Section 1834(l) of the Act requires that the Secretary establish a fee schedule for ambulance services through negotiated rulemaking. Although the statute does call for consideration of appropriate regional and operational differences in the design of the fee schedule, it does not authorize exemptions or waivers for individual providers or suppliers or groups of those providers or suppliers. However, with the enactment of BIPA, the Congress created one limited exemption from the fee schedule— CAHs that do not have another ambulance supplier within a 35-mile drive.

The Congress required that the fee schedule be implemented in such a way that Medicare payments for ambulance services would not exceed what they would have been absent the new fee schedule. The fee schedule will increase payments for providers and suppliers with unusually low rates, and decrease payments for those who have historically received payments above the national average, while still accounting for geographic differences in costs and other factors. In anticipation of such shifts, the Congress provided for a phase-in period to allow ambulance providers time to adjust to the new payment rates.

## **IV. Implementation Methodology**

Currently, payment of ambulance services follows one of two methodologies, depending on the type of ambulance biller. Claims from ambulance service suppliers are paid based on a reasonable charge methodology, whereas claims from providers are paid based on the provider's interim rate (which is a percentage based on the provider's historical cost-to-charge ratio multiplied by the submitted charge) and then costsettled at the end of the provider's fiscal year.

In the September 12, 2000 proposed rule, we stated that the ambulance fee schedule would be phased in over a 4year period. The transition was to begin on January 1, 2001 and the fee schedule was to be phased in on a CY basis. However, as explained above, we will implement the fee schedule beginning April 1, 2002. Therefore, for dates of service (DOS) beginning April 1, 2002, suppliers/providers would be paid based on 80 percent of the respective current payment allowance (as described in Program Memorandum AB-00-87) applicable to this time period plus 20 percent of the ambulance fee schedule amount. (See § 414.615 for additional information.) Based on comments received, we will phase-in implementation of the ambulance fee schedule under a 5-year transition, as follows:

	Former pay- ment percent- age	Fee schedule percentage
Year One (4/2002–12/2002)	80	20
Year Two (CY 2003)	60	40
Year Three (CY 2004)	40	60
Year Four (CY 2005)	20	80
Year Five (CY 2006)	0	100

*Comment:* Many commenters expressed concern over whether providers, suppliers, carriers, and CMS are fully prepared for the ambulance fee schedule implementation and whether all of the necessary steps to ensure successful implementation have been taken. Specifically, commenters believe there was insufficient time between the close of the comment period on November 13, 2000, and January 1, 2001, to:

• Educate intermediaries, carriers and all ambulance suppliers and beneficiaries in order to provide a smooth transition to the new system.

• Change our computer programs (and for suppliers to change theirs) and test these changes before placing them online.

The fee schedule creates new codes, new requirements (for example, zip code for point of pick-up), new levels of service, and a transition blending methodology. The commenters stated that neither suppliers nor beneficiaries will understand how they are to be paid. Several commenters requested that we delay the implementation from January 1, 2001, to a later date.

*Response:* Although the proposed rule was largely based on an agreement reached as part of a formal, negotiated rulemaking process with representatives of the ambulance industry and other interested parties, we received a large volume of comments. We did not have sufficient time to carefully consider all comments and publish a final rule in time to implement the fee schedule by January 1, 2001. Therefore, payment under the fee schedule structure (that is, a blend of fee schedule amounts and current payments) did not begin on that date. This has allowed suppliers additional time to adjust to the proposed payment methodology.

The proposed rule was published in the Federal Register on September 12, 2000 (65 FR 55078). Suppliers have also had access to the formal instructions we issued to contractors with respect to the systems changes necessary to implement the fee schedule. In addition, we held a training conference with intermediaries and carriers on November 16 and 17, 2000, on all issues related to the fee schedule. Contractors conducted training efforts directly with ambulance suppliers during December 2000. We will continue our training efforts as we implement the new billing codes.

*Comment:* One commenter suggested that we cancel implementation of the ambulance fee schedule.

*Response:* We are required by the Congress under section 1834(l) of the Act to implement a fee schedule for ambulance services. *Comment:* Two commenters stated that information in the Medicare and You publication was insufficient regarding the ambulance fee schedule.

*Response:* The *Medicare and You* publication is a handbook that provides a general synopsis of all services in Medicare: the level of detail concerning payment policy and implementation of the ambulance fee schedule in that publication are aimed at the general reader and not necessarily ambulance suppliers. Payment policies for ambulance services are published in detail in the **Federal Register** and subsequently in the CFR.

Comment: A few commenters disagreed with the phase-in schedule for the implementation of the ambulance fee schedule, stating that the implementation period was too short and not "in an efficient and fair manner" as required by the statute. The commenters stated that the phase-in is on a 3-year basis rather than a 4-year basis, as stated in the proposed rule. A few commenters wanted immediate, 100 percent implementation of the ambulance fee schedule, while others suggested other timeframes for a phasein. Some commenters suggested a slower transition for providers as opposed to suppliers. Also, a few commenters recommended that SCT service payments be fully and

immediately implemented separately from the rest of the fee schedule.

*Response:* We agree that suppliers and providers need additional time to adjust to the fee schedule. Therefore, we will change the phase-in schedule from the proposed 4 years to a 5-year transition, as shown above. Thus, the overall phase-in is reflected in a 5-year span, with year 5 being at 100 percent of the fee schedule.

*Comment:* A few commenters requested that phase-in of the fee schedule should be by fiscal year for hospitals rather than by calendar year.

*Response:* We have decided not to phase in the fee schedule for providers based on each provider's fiscal year. As described above in section III.C., in general, Medicare's payment per trip to providers is considerably higher than the payment per trip to suppliers. Allowing a phase-in schedule on the provider's fiscal year would provide an advantage for some providers over independent suppliers because the fee schedule would be implemented unevenly across ambulance entities. *Comment:* One commenter asked whether the limitation on review (in section 1834(l)(5) of the Act) refers only to the rates established under the ambulance fee schedule.

*Response:* The limitation on review, by its own terms, prohibits both administrative and judicial review of the amounts established under the fee schedule, including all the "considerations" contained in section 1834(l)(2) of the Act, for example, the definitions for ambulance services and appropriate regional and operational differences. Thus, review of all these issues is precluded.

Revisions and Additions to HCPCS Codes

Claims will be processed using the billing codes created for the ambulance fee schedule and contained in the proposed rule. From these codes, the amount for the portion of the payment based on the current system (80 percent in CY 2002) will be derived using the HCPCS crosswalks as shown below.

We have already changed "old" HCPCS ambulance codes in order to implement the ambulance fee schedule, effective January 1, 2001. The HCPCS codes formerly used to report ambulance services could not be used effective January 1, 2001, except for those HCPCS codes under which a method 3 or method 4 biller may bill for supplies separately (since such billing may continue during the transition period) and those codes previously used to bill for mileage. These codes will be used until the fee schedule is fully implemented.

The following chart shows how the former codes crosswalk to the final new codes under the ambulance fee schedule. Additionally, the chart shows "old" HCPCS codes that will not have a corresponding code under the final ambulance fee schedule. The items and services represented by these codes will be bundled into the base rate services.

Codes Not Valid Under the New Fee Schedule (Codes Terminate Effective 01/01/06): A0382, A0384, A0392, A0396, A0398, A0420, A0422, A0424, A0999.

HCPCS Code Changes:

Current HCPCS Code	New HCPCS Code	Descriptions of final new codes
A0380, A0390	A0425	Ground mileage (per statute mile).
A0306, A0326, A0346, A0366	A0426	Ambulance service, advanced life support, non-emergency transport, level 1 (ALS1).
A0310, A0330, A0350, A0370	A0427	Ambulance service, advanced life support, emergency transport, level 1 (ALS1-Emer- gency).
A0300, A0304*, A0320, A0324*, A0340, A0344*, A0360, A0364*.	A0428	Ambulance service, basic life support, non-emergency transport (BLS).
A0050, A0302, A0308**, A0322, A0328**, A0342, A0348**, A0362, A0368**.	A0429	Ambulance service, basic life support, emergency transport (BLS-Emergency).
A0030	A0430	Ambulance service, conventional air services, transport, one way (fixed wing (FW)).
A0040	A0431	Ambulance service, conventional air services, transport, one way (rotary wing (RW)).
Q0186	A0432	Paramedic ALS intercept (PI), rural area, transport furnished by a volunteer ambu- lance company which is prohibited by State law from billing third party payers.
	A0433	Advanced life support, Level 2 (ALS2). The administration of at least three different medications and/or the provision of one or more of the following ALS procedures: Manual defibrillation/cardioversion, endotracheal intubation, central venous line, cardiac pacing, chest decompression, surgical airway, intraosseous line.
	A0435	Air mileage; fixed wing (per statute mile).
	A0436	Air mileage; rotary wing (per statute mile).
	A0434	Specialty Care Transport (SCT). In a critically injured or ill beneficiary, a level of inter- facility service provided beyond the scope of the Paramedic. This service is nec- essary when a beneficiary's condition requires ongoing care that must be provided by one or more health professionals in an appropriate specialty area (for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training).
	Q3019	Ambulance service, Advanced Life Support (ALS) vehicle used, emergency transport, no ALS level service furnished.
	Q3020	Ambulance service, Advanced Life Support (ALS) vehicle used, non-emergency transport, no ALS level service furnished.

\* A new code will be established to indicate during the transition period that where an ALS vehicle was used in a non-emergency situation to furnish only BLS services, the service will be ALS-nonemergency for the old portion of the blended payment and BLS for the Fee Schedule portion of the blended payment.

\*\*A new code will be established to indicate during the transition period that where an ALS vehicle was used in an emergency response and furnished only BLS services, the service will be ALS-Emergency for the old portion of the blended payment and BLS-Emergency for the Fee Schedule portion of the blended payment.

Payment to new suppliers that have not billed Medicare in the past will be subject to the transition period rules. New suppliers will be assigned an allowed charge under the current reasonable charge rules (for new

suppliers, the allowed charge is set at the 50th percentile of all charges for the service) and will receive the same blended transition payments as other ambulance suppliers. In all cases, the transitional payment will be subject (as will the fully implemented fee schedule payment) to the Part B coinsurance and deductible requirements.

Currently, we pay the provider's claims based on the provider's interim rate (the provider's submitted charge multiplied by the provider's past year's cost-to-charge ratio). That interim rate is:

• Cost-settled at the end of the provider's fiscal year, and

• Limited by the statutory inflation factor, contained in section 4531 of the BBA, applied to the provider's allowed cost per ambulance trip from the previous year.

The fee schedule transition will begin on April 1, 2002 and the fee schedule will be phased in on a calendar year basis. Therefore, for providers that file cost reports on a basis other than a calendar year (January 1–December 31) cost-reporting period, for cost-reporting periods beginning after April 1, 2002, two different rates will be blended. Effective for services furnished during 2002, the proposed blended amount for provider claims will equal the sum of 80 percent of the current payment system amount and 20 percent of the ambulance fee schedule amount. Although some providers may receive substantially lower payments than at present, the Committee recommended this particular phase-in, and we believe that our implementing payment under the fee schedule at only 20 percent in the first year will give ambulance providers a period of time to adjust to the new payment amounts. For dates of service in CY 2003, the blended amount will equal the sum of 60 percent of the current payment system amount and 40 percent of the ambulance fee schedule amount. For dates of service in CY 2004, the blended amount will equal the sum of 40 percent of the current payment system amount and 60 percent of the ambulance fee schedule amount. For dates of service in CY 2005, the blended amount will equal the sum of 20 percent of the current payment system amount and 80 percent of the ambulance fee schedule amount. For dates of service in CY 2006 and beyond, the payment amount will equal the ambulance fee schedule amount. In all cases, the fee schedule portion of the blended rate equals the blending percentage multiplied by the lower of the fee schedule amount or the actual billed charges. The program's payment in all

cases will be subject to the Part B coinsurance and deductible requirements.

To assure that providers receive the correct payment amount during the transition period, all submitted charges attributable to ambulance services furnished during a cost-reporting period will be aggregated and treated separately from the submitted charges attributable to all other services furnished in the hospital. Also, providers must maintain statistics necessary for the Provider Statistics and Reimbursement report to ensure that the ambulance fee schedule portion of the blended transition payment will not be cost-settled at cost settlement time.

New providers will not have a cost per trip from the prior year. Therefore, there will be no cost per trip inflation limit applied to new providers in their first year of furnishing ambulance services.

New suppliers will use the CY 2000 allowed charge assigned for new suppliers in accordance with standard program procedures as described above, adjusted for each year of the transition period by the ambulance inflation factor that we announce.

Section 1834(l) of the Act also requires that all payments made for ambulance services under the proposed fee schedule be made on an assignmentrelated basis. Pursuant to section 1842(b)(18)(A) and (B) of the Act, incorporated by reference in section 1834(l)(6) of the Act, ambulance suppliers will have to accept the Medicare allowed charge as payment in full and not bill or collect from the beneficiary any amount other than the unmet Part B deductible and Part B coinsurance amounts. Violations of this requirement may subject suppliers to sanctions. The law provides that mandatory assignment applies to all services "for which payment is made under" section 1834(l) of the Act; therefore, there will be no transitional period for mandatory assignment of claims. Nor is there any transition to the mechanisms and definitions required by the law. Thus, for instance, the level of services definitions (for example, that claims will be paid for the fee schedule portion of the blended payment at the BLS level if an ALS vehicle was used but no ALS level of service was furnished) will not be subject to transition.

*Comment:* One commenter stated that we should share the new HCPCS codes with other payers in the interest of consistency among all payers.

*Response:* HCPCS codes, when established, are routinely shared with all payers.

*Comment:* A few commenters asked about HCPCS code A0888 (noncovered ambulance mileage) and whether it is being included in the crosswalk of old codes to new ones or is being terminated when the fee schedule is implemented.

*Response:* HCPCS code A0888 is the code for noncovered ambulance mileage (for example, mileage traveled beyond the closest appropriate facility). This code has not been deleted and may continue to be used as it was previously.

*Comment:* Some commenters suggested that we maintain current HCPCS codes for ambulance services for use by other payers.

*Response:* The new codes have been established in accordance with standard procedures that include approval by a national coding committee with representatives from private payers. As a result, HCPCS codes in effect prior to January 1, 2001, for ambulance services have been terminated and replaced by new codes.

*Comment:* Some commenters asked how payment would be made for new services that did not exist prior to the establishment of the new HCPCS codes (implemented January 1, 2001).

Response: We may determine that a new level of service is necessary to accommodate new expensive technologies. However, the Congress provided only for an inflation factor each year to update the aggregate amount paid under the fee schedule. There is no other provision for increasing the aggregate amount paid for ambulance services in successive years. Therefore, if a new code representing a new level of service is created, the CF would have to be recalculated to preserve this statutory payment limit.

*Comment:* A few commenters believe that, during the phase-in, suppliers should be allowed to bill for waiting time and an extra attendant.

*Response:* The phase-in builds upon suppliers' current payments as well as on the fee schedule. Therefore, to the extent that suppliers are currently allowed by their carrier to bill under the reasonable charge system for waiting time and an extra attendant, they may continue to bill in that way during the phase-in only.

Fee Schedule Amounts and Examples of Payment

The table below represents the fee schedule amounts for 2002 under this rule. Note that actual payment rates for 2002 will be a blend of the fee schedule amount and the payment allowances applicable for 2002.

Service level	RVUs	CF	Unadjusted base rate (UBR)+	Amount adjusted by GPCI (70% of UBR)	Amount not ad- justed (30% of UBR)	Loaded mileage	Rural ground mileage (miles 1– 17)	Rural ground mileage (miles 18– 50)*
BLS	1.00	170.54	\$170.54	\$121.65	\$52.14	\$5.47	\$8.21	\$6.84
BLS-Emergency	1.60	170.54	272.86	191.00	81.86	5.47	8.21	6.84
ALS1	1.20	170.54	204.65	143.26	61.40	5.47	8.21	6.84
ALS1-Emergency	1.90	170.54	324.03	226.82	97.21	5.47	8.21	6.84
ALS2	2.75	170.54	468.99	328.29	140.70	5.47	8.21	6.84
SCT	3.25	170.54	554.26	387.98	166.28	5.47	8.21	6.84
PI	1.75	170.54	298.45	208.91	89.54	(1)	No Mileage R	ate

Service level	Unadjusted base rate (UBR)	Amount ad- justed by GPCI (50% of UBR)	Amount not adjusted (50% of UBR)	Rural air base rate**	Loaded mileage	Rural air mileage***
FW	\$2,314.51	\$1,157.26	\$1,157.26	\$3,471.77	\$6.57	\$9.86
RW	2,690.96	1,345.48	1,345.48	4,036.44	17.51	26.27

\* A 50 percent add-on to the mileage rate (that is, a rate of \$8.21 per mile) for each of the first 17 miles identified as rural. A 25 percent add-on to the mileage rate (that is, a rate of \$6.84 per mile) for miles 18 through 50 identified as rural. The regular mileage allowance applies for every mile over 50 miles.

A 50 percent add-on to the air base rate is applied to air trips identified as rural.

\*\*\* A 50 percent add-on to the air mileage rate is applied to every mile identified as rural.

The payment rate for rural air ambulance (rural air mileage rate and rural air base rate) is 50 percent more than the corresponding payment rate for urban services (that is, the sum of the base rate adjusted by the geographic adjustment factor and the mileage). + This column illustrates the payment rates without adjustment by the GPCI. The conversion factor (CF) has been inflated for CY 2002.

#### Legend for Table 1

- ALS1—Advanced Life Support, Level 1 ALS2—Advanced Life Support, Level 2 **BLS**—Basic Life Support CF—Conversion Factor FW—Fixed Wing GPCI—Practice Expense Portion of the Geographic Practice Cost Index from the Physician Fee Schedule PI—Paramedic ALS Intercept
- **RVUs**—Relative Value Units
- RW-Rotary Wing
- SCT—Specialty Care Transport UBR—Unadjusted Base Rate

*Formulas*—The amounts in the above chart are used in the following formulas to determine the fee schedule payments-

#### Ground

Ground-Urban: Payment Rate = [(RVU\*(0.30+(0.70\*GPCI) ))\*CF]+[MGR\*#MILES].

- Ground-Rural: Payment Rate =
- [(RVU\*(0.30+(0.70\*GPCI)
- ))\*CF]+[(((1+RG1)\*MGR)\*#MILES≤17)+
- (((1+RG2)\*MGR)\*#MILES18-

50)+(MGR\*#MILES>50)] (Sign before

number 17 was erroneously published in the proposed rule.)

Air

Air-Urban: Payment Rate = [((UBR\*0.50)+((UBR\*0.50)\*GPCI) )]+[MAR\*#MILES].

Air-Rural: Payment Rate = [(1.00+RA)\*((UBR\*0.50)\*GPCI) )]+[(1.00+RA)\*(MAR\*#MILES)].

#### **Legend for Formulas**

- Symbol and Meaning
- $\leq$  = less than or equal to
- > = greater than
- \* = multiply
- CF = conversion factor (ground = \$159.56; air = 1.0
- GPCI = practice expense portion of the geographic practice cost index from the physician fee schedule
- MAR = mileage air rate (fixed wing rate = 6.49, helicopter rate = 17.30)
- MGR = mileage ground rate (5.40)
- #MILES = number of miles the beneficiary was transported
- #MILES<17 = number of miles the beneficiary was transported less than or equal to 17

#MILES18-50 = number of miles beneficiary was transported between 18 and 50

- #MILES>50 = number of miles the beneficiary was transported greater than 50 RA = rural air adjustment factor (0.50 on
  - entire claim)
- Rate = maximum allowed rate from ambulance fee schedule
- RG1 = rural ground adjustment factor
- amount: first 17 miles (0.50 on first 17 miles)
- RG2 = rural ground adjustment factor amount: miles 18 through 50 (0.25 on miles 18 through 50)
- RVUs = relative value units (from chart)
- UBR = the payment rates without adjustment by the GPCI (unadjusted base rate)

Notes: The GPCI is determined by the address (zip code) of the point of pickup.

#### **Examples Demonstrating Use of Fee Schedule Amounts**

The examples in the table and in the discussion below demonstrate the use of the ambulance fee schedule amounts during the first year (2002). Examples 1 through 4 relate to independent supplier claims, and Example 5 relates to hospital-based supplier claims.

TABLE 2.—EXAMPLES DEMONSTRATING	USE OF FEE SCHEDULE AMOUNTS
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Example	Reasonable charge IIC	$\begin{array}{c} \text{Reasonable} \\ \text{charge IIC} \times \\ 80\% \end{array}$	2002 fee schedule	$\begin{array}{c} \text{2002 fee} \\ \text{schedule} \times \\ \text{20\%} \end{array}$	Total allowed charge
1	\$315.62	\$252.50	\$343.66	\$68.73	\$321.23
2	292.44	233.95	425.62	85.12	319.07
3	1,982.26	1,585.81	2,987.23	597.45	2,183.26
4	1,564.80	1,251.84	6,250.83	1,250.17	2,502.01

Example	Reasonable charge IIC	Reasonable charge IIC × 80%	2002 fee schedule	2002 fee schedule × 20%	Total allowed charge
			(Erroneously giv \$4,599.69	ren in proposed ru as: \$919.94	ule in Example 4 \$2,171.78)

TABLE 2.—EXAMPLES DEMONSTRATING USE OF FEE SCHEDULE AMOUNTS—Continued

### Example 1: Ground Ambulance, Urban (Independent Supplier)

A Medicare beneficiary residing in Baltimore, Maryland, was transported via ground ambulance from his or her home to the nearest appropriate hospital 2 miles away. An emergency response was required, and ALS services, including an ALS assessment, were furnished. Therefore, the level of service is ALS1-Emergency.

Assuming that the beneficiary was placed on board the ambulance in Baltimore, it will be an urban trip. Therefore, no rural payment rate will apply. In Baltimore, the GPCI = 1.038. The fee schedule amount will be calculated as follows—

- Payment Rate = [(RVU\*(0.30 + (0.70\*GPCI))) \*CF] + [MGR\*#MILES]
- Payment Rate = [(1.90\*(0.30 + (0.70\*1.038)))\*170.54] + [5.47\*2.00]
- Payment Rate = [(1.90\*(0.30 + 0.727))\*170.54] + [10.94]
- Payment Rate = [(1.90\*1.027)\*170.54] + [10.94]
- Payment Rate = [1.951\*170.54] + [10.94]
- Payment Rate = [332.724] + [10.94]
- Payment Rate = 343.664
- Payment Rate = \$343.66 (subject to Part B deductible and coinsurance requirements)

Because 2002 will be the first year of a 5-year transition period, the ambulance fee schedule payment rate will be multiplied by 20 percent and added to 80 percent of the payment calculated by the current payment system. The payment rate for Year 2 (CY 2003) will be calculated by multiplying the ambulance fee schedule payment rate by 40 percent and adding the result to 60 percent of the current payment system amount. The payment rate for Year 3 (CY 2004) will be calculated by multiplying the ambulance fee schedule payment rate by 60 percent and adding the result to 40 percent of the current payment system amount. The payment rate for Year 4 (CY 2005) will be calculated by multiplying the ambulance fee schedule payment rate by 80 percent and adding the result to 20 percent of the current payment system amount. The payment for Year 5 (CY

2006) will be based solely on the ambulance fee schedule.

The applicable codes are A0427 and A0425. Assuming application of the inflation indexed charge (IIC) in 2002, the reasonable charge allowance for this service in Maryland is 315.62 (303.00 for the base trip plus  $6.31 \times 2$  miles).

Assuming that the Part B deductible has been met, the program will pay 80 percent, and the beneficiary's liability will be 20 percent, representing the Part B coinsurance amount, and the total allowed charge for this service during CY 2002 will be:

Medicare payment (80%)	Beneficiary li- ability (20%)
\$256.98	\$64.25

Example 2: Ground Ambulance, Rural (Independent Supplier)

A Medicare beneficiary residing in Cottle County, Texas was transported via ground ambulance from his or her home to the nearest appropriate facility located in Quanah, Texas. Cottle County, where the beneficiary was placed on board the ambulance, is a non-MSA and, therefore, is, for purposes of this fee schedule, rural. A rural mileage rate will apply. The total distance from the beneficiary's home to the facility is 36 miles. A BLS nonemergency assessment was performed. Under this rule, the level of service will be BLS (nonemergency).

For this part of Texas, the GPCI = 0.880. The proposed ambulance fee schedule amount will be calculated as follows—

- 36 mile trip = 17 miles at the 50% rural mileage increased rate plus 19 miles at the 25% rural mileage increased rate.
- Payment Rate =  $[(RVU^{*}(0.30 + (0.70^{*}GPCI)))^{*}CF] + [(((1+ RG1)^{*}MGR)^{*}#MILES \le 17) + (((1+RG2)^{*}MGR)^{*}# MILES 18-50) + (MGR^{*}#MILES > 50)]$
- Payment Rate = [(1.00\*(0.30 + (0.70\*0.880)))\*170.54] + [(((1.00 + 0.50)\*5.47)\*17.00) + (((1.00 + 0.25)\*5.47)\*19.00) + (5.47\*0.00)]
- Payment Rate = [(1.00\*(0.30+0.616))]\*170.54] + [((1.50\*5.47)\*17.00)+((1.25\*5.47)\*19.00) + (0.00)]

- Payment Rate = [(1.00\*0.916)\*170.54] + [(8.21\*17.00) + (6.84\*19.00) + (0.00)]
- Payment Rate = [0.916\*170.54] + [139.49 + 129.91 + 0.00]
- Payment Rate = [156.215] + [269.40]

Payment Rate = 425.615

Payment Rate = \$425.62 (subject to Part B deductible and coinsurance requirements)

The total allowed charge for this service during 2002 under our ambulance fee schedule is based on the following codes:

Old HCPCS Code(s) = A0300 and A0380 New HCPCS Code(s) = A0428 and

A0425

Assuming application of the inflation indexed charge (IIC) in 2002, the reasonable charge rate for this service in Texas will be \$292.44 (\$152.76 for HCPCS A0300, \$3.88  $\times$  36 miles for A0380).

Assuming that the Part B deductible was met, the program will pay 80 percent, and the beneficiary's liability will be 20 percent, representing the Part B coinsurance amount and the total allowed charge for this service during 2002 will be:

Medicare payment (80%)	Beneficiary li- ability (20%)
\$255.26	\$63.81

## Example 3: Air Ambulance, Urban (Independent Supplier)

A Medicare beneficiary was involved in an automobile accident along a busy interstate near Detroit, Michigan. A helicopter transported the beneficiary to the nearest appropriate facility located within the city limits of Detroit. The total distance from the accident to the facility was 14 miles. The level of service was rotary wing.

Assuming that the patient was placed on board the air ambulance within the Detroit MSA, and because this is not a Goldsmith county, the trip will be urban. Therefore, no rural payment rate will apply. In the Detroit metropolitan area, the GPCI = 1.038. The ambulance fee schedule amount will be calculated as follows—

- Payment Rate =
- [((UBR\*0.50)+((UBR\*0.50)

\*GPCI))]+[MAR\*#MILES] Payment Rate =

- [((2690.96\*0.50)+((2690.96\*0.50) \*1.038))]+[17.51\*14.00]
- Payment Rate =
  - [(1345.48+(1345.48\*1.038) )]+[245.14]
- Payment Rate = [(1345.48+1396.608)]+[245.14]
- Payment Rate = [2742.088] + [245.14]
- Payment Rate = 2987.228
- Payment Rate = \$2,987.23 (subject to Part B deductible and coinsurance requirements)

The total allowed charge for this service during 2002 is based on the following codes:

Old HCPCS Code = A0040

New HCPCS Code = A0431 and A0436 Assuming application of the inflation

indexed charge (IIC) in 2002, the reasonable charge rate for this service in Michigan is \$1,982.26.

Assuming that the Part B deductible has been met, the program will pay 80 percent, and the beneficiary's liability will be 20 percent, representing the Part B coinsurance amount; and the total allowed charge for this service during 2002 will be:

Medicare payment (80%)	Beneficiary li- ability (20%)
\$1,746.61	\$436.65

## Example 4: Air Ambulance, Rural (Independent Supplier)

A Medicare beneficiary was transported via helicopter from a rural county in Arizona to the nearest appropriate facility. The total distance from point of pick-up to the facility was 86 miles. The level of service was rotary wing.

Because the point of pick-up was in a rural, non-MSA area, this transport will be a rural trip under this rule. Therefore, a rural payment rate will apply. In Arizona, the GPCI = 0.978. The ambulance fee schedule amount will be calculated as follows—

Payment Rate =

- [(1.00+RA)\*((UBR\*0.50)+ ((UBR\*0.50)\*GPCI))]+
- [(1.00+RA)\*(MAR\*#MILES)]
- Payment Rate =
  - [(1.00+0.50)\*((2690.96\*0.50)+ ((2690.96\*0.50)\*0.978))]+
- [(1.00+0.50)\*(17.51\*86.00)]
- Payment Rate = [(1.50)\*(1345.48+
- (1345.48\*0.978) )]+[1.50\*1505.86] Payment Rate =
- [(1.50)\*(1345.48+1315.879)]+[2258.79]
- Payment Rate =  $\frac{1}{2238.79}$
- [1.50\*2661.359]+[2258.79]

Payment Rate = [3992.039]+[2258.79] Payment Rate = 6250.829

Payment Rate = \$6,250.83 (subject to Part B deductible and coinsurance requirements)

The total allowed charge for this service during 2002 is based on the following codes:

- Old HCPCS Code = A0040
- New HCPCS Code = A0431 and A0436

Assuming application of the inflation indexed charge (IIC) for the example in question, in 2002 the reasonable charge rate for this service in Arizona will be \$1,564.80.

Assuming that the Part B deductible has been met, the program will pay 80 percent and 20 percent will be the beneficiary's liability and the total allowed charge for this service during 2002 will be:

Medicare payment (80%)	Beneficiary li- ability (20%)
\$2,001.61	\$500.40

(These figures were erroneously given in the proposed rule as:

Medicare payment (80%)	Beneficiary li- ability (20%)
\$1,737.42	\$434.36)

## Example 5: Ground Ambulance, Rural (Hospital-Based Supplier)

A Medicare beneficiary residing in a rural area in the state of Iowa was transported via ground ambulance from her home located in a rural area (non-MSA) to the nearest appropriate facility (Hospital A). Because the point of pickup is in a rural area, under our final rule, a rural payment rate will apply. The total distance from the beneficiary's home to Hospital A is 14 miles. A BLS nonemergency transport was furnished. The level of service will be BLS (nonemergency).

For Iowa, the GPCI = 0.876. The ambulance fee schedule amount will be calculated as follows—

14 mile trip = 14 miles at the rural mileage rate plus 0 miles at the regular urban rate.

The HCPCS codes to be used under the fee schedule are A0428 and A0425.

Payment Rate =  $[(RVU^{(0.30 + (0.70 * GPCI)))*CF] + [(((1 + RG1)*MGR)* #MILES \le 17)+(((1 + RG2)*MGR)*# MILES 18-50) + (MGR*#MILES > 50)]$ 

Payment Rate = [(1.00\*(0.30 + (0.70\*0.876)))\*170.54] + [(((1.00 + 0.50)\*5.47)\*14.00) + (((1.00+0.25)\*5.47)\*0.00) + (5.47\*0.00)]

- Payment Rate = [(1.00\*(0.30 + 0.613)))\*170.54] + [((1.50\*5.47)\*14.00) + ((1.25\*5.47)\*0.00) + (0.00)]
- Payment Rate = [(1.00\*0.913)\*170.54] + [(8.205\*14.00) + (6.838\*0
- (0.00)] Payment Rate = [0.913\*170.54] +
- [114.87 + 0.00 + 0.00]

Payment Rate = [155.703] + [114.87]

- Payment Rate = 270.573
- Payment Rate = \$270.57 (subject to Part B deductible and coinsurance requirements)

Since 2002 will be the first year of a 5-year transition period, the ambulance fee schedule payment rate will be multiplied by 20 percent. The portion of the total payment under the final fee schedule for 2002 is:

Payment Rate = Fee Schedule \*

Transition Percentage Payment Rate = 270.57\*0.2

Payment Rate = 54.114

Payment Rate = \$54.11

The remaining 80 percent of the

payment rate is determined by the current payment system. For FIs, the current payment calculation is as follows.

Assume that Hospital A's charge (HCB) for a BLS-nonemergency service is \$220.00, its charge for mileage (HCM) is \$4.00 per mile, and its past year's cost-to-charge ratio (CCR) is 0.9.

Assuming that the beneficiary's Medicare Part B deductible has been met, the beneficiary's coinsurance liability for 2002 will be \$55.10, calculated as follows:

- Total Charge = HCB + (HCM\*#MILES)
- Total Charge = 220.00 + (4\*14)
- Total Charge = 220.00 + 56
- Total Charge = \$276.00 (Current system) For 2002, the coinsurance is equal to
- 20 percent of:
- Total rate = (0.80\*Current System) + (0.20\*FS)
- Total rate =  $(0.80 \times 276.00) + (54.71)$
- Total rate = (220.80) + (54.71)
- Total rate = \$275.51
- Coinsurance = 0.20\*275.51 = \$55.10 For 2002, the transition payment rate
- is equal to:
- Transition payment rate = [0.80\*current rate] + [0.20\*FS]
- Transition Payment Rate =
  - [0.80\*((HCB)+(HCM\*#MILES)) \*CCR]+[0.20\*FS]
- Transition Payment Rate =
- $[0.80^{*}((220.00) + (4^{*}14))^{*}0.9] +$ 
  - [54.11]
- Transition Payment Rate =
- [0.80\*((220.00)+(56)) \*0.9] + [54.11] Transition Payment Rate =
  - $[0.80^{*}(276.00)^{*}0.9] + [54.11]$
- Transition Payment Rate = [198.72] + [54.11]
- Transition Payment Rate = \$252.83

Assuming the part B deductible is met:

Medicare program payment = (transition payment rate) – (coinsurance)

Medicare program payment = 252.83 -55.10

Medicare program payment = \$197.73

## V. Mechanisms To Control Expenditures for Ambulance Services

We do not anticipate that the number of ambulance services furnished will increase to offset the effects of lower payments per service, and the Committee did not suggest mechanisms to control expenditures. However, we will monitor payment data and evaluate whether our assumptions used to calculate the original CF (for example, the ratio of the volume of BLS services to ALS services or the number of low billers) are accurate. If the actual proportions of the various levels of service are different (higher or lower) than those projected, we will adjust the CF accordingly.

## VI. Adjustments To Account for Inflation and Other Factors

In setting the CF for CY 2002, we are adjusting the base year data from 1998 for inflation. Section 4531 of the Balanced Budget Act of 1997, as amended by section 423 of BIPA, prescribes the inflation factor to be used in determining the payment allowances for ambulance services paid under the current Medicare payment system. The inflation factor is equal to the projected consumer price index for all urban consumers (U.S. city average) (CPI–U) minus 1 percentage point from Marchto-March for claims paid under cost payment (providers) and from June-to-June for claims paid under the reasonable charge system (carrier processed claims). The base year for our data is 1998. The inflation factors as percents are:

	March-to-March (provider claims) (percentage)	June-to-June (carrier claims) (percentage)
1999/1998         2000/1999         2001/2000*         2002/2001	0.9 2.4 3.7 2.2	1.1 2.0 3.7 2.2
Compounded inflation factor * (DOS = 1/1/02–12/31/02)	9.50	9.29

\*For date of service (DOS) during the 6-month period 1/1/01–6/30/01, the inflation factor was 2.7 percent, and for the 6-month period 7/1/01– 12/31/01, the statutory inflation factor is 4.7 percent for an average of 3.7 percent for 2001.

In addition, the Committee acknowledged that the statutory provisions in section 1834(l)(3)(B) of the Act, regarding annual updates to the fee schedule, will be used to make adjustments to account for inflation. That section of the Act provides for an annual update to the ambulance fee schedule based on the percentage increase in the CPI–U for the 12-month period ending with June of the previous year. Section 4531 of the BBA provided that, for 2001 and 2002, the increase in the CPI–U would be reduced by 1.0 percentage point for each year. However, this section was amended by BIPA, which mandated that the inflation factor for the period July 1, 2001 through December 31, 2001 be 4.7 percent.

As we indicated in the proposed rule, we will monitor payment data and evaluate whether certain assumptions used to establish the original CF (for example, the ratio of the volume of BLS services to ALS services) are accurate. Where appropriate, we will adjust the CF accordingly.

In addition, we note that the inflation factor also applies to all mileage rates.

*Comment:* Some commenters stated that the inflation factor referred to in the proposed rule is not correct for the year 2001. They stated that it should be the change in the CPI–U over the one-year period ending with June 30, 2000, minus one percent. The commenters recommended that, since the statutory inflation factor for 2001 is the CPI–U increase for the 12-month period ending in June of the previous year, we should be using that factor for the 2001 update, rather than an estimate for the 12-month period ending in June of 2001.

*Response:* We agree. However, the Congress has since enacted a change in the ambulance inflation factor for part of 2001. Section 423 of BIPA provides that this factor be increased to 4.7 percent for the period July 1, 2001 through December 31, 2001.

*Comment:* Some commenters requested that we limit any adjustments to the CF to include only adjustments for the factors mentioned in the preamble. They state, for example, that the industry has no control over total volume of services and believe that we should not reduce the CF to offset increased charges resulting from any possible increase in total ambulance trips.

*Response:* We are not reducing the CF to offset increased program payments that result from an increase in the total volume of ambulance trips.

*Comment:* One commenter stated that operational costs in California (for example, personnel, insurance, fuel) are higher than other areas and the fee schedule should recognize these higher costs.

*Response:* Differences in operational costs due to location are reflected in the fee schedule through the GPCI. This index is derived from cost-of-living

factors in the operation of a physician's office, such as personnel, insurance, electricity. The Committee believed that this index was the most appropriate of the indices available to use for the ambulance fee schedule.

#### VII. Medical Conditions Lists

When the Congress mandated that the ambulance fee schedule be developed through the negotiated rulemaking process, we deferred final action on our earlier proposal to base Medicare payment on the level of ambulance service required to treat the beneficiary's condition. The proposed ambulance coverage rule, published on June 17, 1997 (62 FR 32715), also included diagnostic codes based on the International Classification of Diseases, 9th revision, Clinical Modification (ICD-9-CM) that would have described the nature of the beneficiary's medical condition. Use of the ICD-9-CM codes would have assisted ambulance suppliers in billing the medically necessary level of ambulance service.

While we did not propose a medical conditions list in the September 2000 proposed rule (65 FR 55078), and while a medical conditions list, or codes for such a list, were not an official part of the negotiated rulemaking process, some of the negotiated rulemaking participants and other medical professionals, including carrier medical directors, emergency room physicians, and the Emergency Nurses Association, came together as an ad hoc workgroup to discuss this issue. Their aim was to develop a list of medical conditions, not diagnoses, that generally require ambulance services and to identify the appropriate level of care for these conditions. The identified condition(s) would describe the beneficiary's medical condition, as presented to the ambulance crew upon arrival on the scene. The workgroup's final report was submitted to the Committee as a recommendation for further consideration.

We published the list of medical conditions as Addendum A in the September 12, 2000 proposed rule (66 FR 55096). Suppliers and providers may submit these conditions on their Medicare claims. If they choose to do so, the condition must be reported in the "remarks" field on the claim. We will instruct Medicare contractors that they may not deny or reject claims solely because a supplier or provider has reported on the claim one of the conditions from the list of conditions. Also, the presence of a condition, in and of itself, does not establish the ambulance service as reasonable and necessary. Regardless of the presence of the condition on the claim, ambulance suppliers and providers must maintain and, upon request by the Medicare contractor, submit documentation sufficient to show that the service was reasonable and necessary. In other words, the presence of an identified condition on the claim will not make the claim payable if the beneficiary could have been safely transported by other means.

We noted in the proposed rule that we have solicited information from interested parties on the need for such a list and the development of codes used in association with such a list that would best support the processing of claims for ambulance services. We also noted that, while we were not requiring the use of the conditions list at that time, we intended to work with members of the industry and other affected parties to develop a more complete set of conditions as well as a coding system that could be used under the fee schedule. Any such coding system, after August 16, 2002, would have to be created consistent with the electronic claim standards developed pursuant to the Health Insurance Portability and Accountability Act of 1996, Public Law 104-91 (HIPAA), described in the Federal Register on August 17, 2000 (65 FR 50311).

*Comment:* The majority of the comments on this subject stated that the list of condition descriptions should be adopted as written. Some commenters recommended that we not implement the fee schedule until we can implement the medical conditions list. The commenters stated that a coding system, upon which the new fee schedule is based, should include a means for suppliers and providers to indicate on the claim the symptoms presented by the beneficiary to the ambulance crew at the time of arrival on the scene that justify the level of service they furnish.

Commenters also expressed concern that the medical conditions list is necessary for providers and suppliers to be able to report the appropriate level of service. One commenter noted that implementing the fee schedule without the medical conditions list will cause great hardship and confusion for ambulance suppliers and carriers regarding billing and claims processing.

*Response:* The ambulance fee schedule is based upon HCPCS codes that reflect the level of services provided to the beneficiary. We have set forth in this final rule the seven levels of service upon which payment for ground ambulance services will be based. Although the medical conditions may be used as a guide to indicate the appropriate level of ground ambulance service, they are not necessary in order to proceed with the implementation of the fee schedule. The ambulance fee schedule, which is simply a pricing mechanism, does not depend upon the use of a coding system denoting the list of conditions.

Under the current billing rules for ambulance services, Medicare carriers may request that suppliers document that the trip was medically necessary and that the appropriate level of service was provided. Currently, suppliers provide this documentation by using— (a) an explanation on the claims forms, (b) ICD–9–CM diagnosis codes, and/or (c) medical records.

As we stated above and in the proposed rule, we agree that a medical conditions list would help the ambulance supplier to identify the level of service at which a claim may be paid and would also aid Medicare contractors in their efforts to ensure that claims for ambulance services are paid appropriately. We understand the importance of implementing a uniform set of condition codes that all providers and suppliers can use. While this regulation does not contain such a set of codes, we pledge to work with the ambulance providers and suppliers, including hospitals, to develop a uniform set of codes over the next year. If a provider or supplier wishes to use the existing set of ICD-9-CM diagnosis codes, we will instruct our carriers and

intermediaries to review that set of codes.

However, when the issue of a list of medical conditions was raised in the Committee, we advised the Committee that, while defining the levels of ambulance service was within the scope of the Committee, establishing the medical conditions that justify those levels of payment was not within that scope. Furthermore, we advised that recommendations about a coding system would have to be consistent with the regulations published pursuant to HIPAA. The HIPAA standards for electronic transactions final rule (65 FR 50312), which was published on August 17, 2000, established, among other things, Standards for the health care claims or equivalent encounter information transaction (45 CFR 162.1102). In general, the standards for that transaction require a specific format, the ASC X12N 837, and specify the use of certain medical data code sets when the transaction is transmitted electronically by an entity subject to the rule. Under HIPAA, the ASC X12N 837 and the specified code sets for the health care claims transactions do not currently support the use of condition descriptions lists. However, HIPAA provides for the maintenance and modification of adopted standards and for the adoption of new standards, as set forth in the regulations at § 162.910. Therefore, it is possible that, in the future, the health claims standards could be modified or expanded, or new standards created, in accordance with the procedures set forth in regulations, to accommodate condition descriptions lists.

*Comment:* Commenters did not agree on the appropriate coding system to be used for the conditions list. Some commenters believe that ICD-9 or ICD-10 codes should be associated with the condition descriptions, while others believe that we should not specify ICD-9 or ICD-10 codes as an appropriate system to determine medical conditions. Still others suggested that most conditions in the list could be mapped to existing ICD-9-CM codes, and the remaining conditions could be mapped to HCPCS codes. This approach would avoid the large expense to providers of implementing another coding system.

*Response:* As noted above, there are many factors to be considered before we make a final decision regarding the development of an ambulance-specific medical condition coding system. We also note that the example in the proposed rule mistakenly referenced ICD-10-CM codes and should have referenced ICD-9-CM codes. *Comment:* One commenter stated that we should require Medicaid to use the new medical condition codes.

*Response:* States are not obligated to adopt Medicare guidelines for ambulance services.

## IX. Provisions of the Final Rule

## A. BIPA

BIPA provides the following changes to the ambulance fee schedule that have been incorporated into this rule.

 Critical Access Hospital (CAH)— The proposed rule would apply the ambulance fee schedule to all entities furnishing ambulance services to Medicare beneficiaries. Section 205 of BIPA provides that CAHs, or entities owned and operated by them, are paid for ambulance services based on reasonable cost, if there is no other ambulance provider or supplier within a 35-mile drive. As a result, these entities are exempt from the ambulance fee schedule described in this final rule. These entities are also exempt from the current cost-per-trip inflation cap applicable to providers. This cap, established by section 4531(a)(1) of the BBA, limits increases in the cost per trip of ambulance services from each year to the next by the consumer price index for all urban consumers, reduced by 1 percentage point. Implementation of section 205 of BIPA requires us to establish a process for a CAH to qualify for this exemption. Such a process was addressed in a separate final rule, "Medicare Program; Changes to the Hospital Inpatient Prospective Payment

Systems and Rates and Costs of Graduate Medical Education; Fiscal Year 2002 Rates, etc.; Final Rules," published August 1, 2001 (66 FR 39828). The payment policy component is addressed in this rule.

• Rural Ambulance Mileage—The proposed rule would pay rural mileage greater than 17 at the same rate as mileage within urban areas. Section 221 of BIPA provided that the payment rate for rural ambulance mileage greater than 17 miles and up to 50 miles be increased by not less than one-half of the additional payment per mile established for the first 17 miles of a rural ambulance trip. We are waiving proposed rulemaking for this provision because we believe this amount is the minimum that is required by the plain language of the law and is not discretionary. We believe that proposed rulemaking, which would be necessary to set the amount at a level higher than the minimum, is impracticable in this instance for timely implementation of the law and will therefore implement it as a final with comment. Therefore, we

will accept public comments on this policy.

• Inflation Factor—The proposed rule would increase the per trip payments for services furnished in 2001 over the per trip payments for these services furnished in 2000 by an amount equal to the change in the CPI–U reduced by one percent. Section 423 of BIPA provided that the ambulance inflation factor for services furnished during the period July 1, 2001 through December 31, 2001 be equal to 4.7 percent. We have implemented this provision without proposed rulemaking because it was self-implementing and neither permitted nor required interpretation.

 Ground Ambulance Mileage—The proposed rule would pay for all ground ambulance mileage during a four-year transition period based on a blend of the current payment rate and the fee schedule rate. Section 423 of BIPA also provided that all mileage furnished by suppliers and paid by carriers would be paid at the full fee schedule amount without any phased-in blended payment, but only in those States in which, prior to the fee schedule, the carrier paid separately for all mileage outside the county from which the beneficiary was transported, but did not pay separately for any in-county ambulance mileage. This provision does not apply to providers. We are waiving proposed rulemaking for this provision because we believe this amount is the minimum that is required by the plain language of the law and is not discretionary. We believe that proposed rulemaking is impracticable in this instance for implementation of the law and will therefore implement it as a final with comment. Therefore, we will accept public comments on this policy.

## B. Inflation

First, we corrected the inflation factor for 2001 to be equal to the percentage increase in the CPI–U minus one percent for the 12-month period ending in June of the previous year. This factor is applied to services furnished in the period January 1, 2002 through December 31, 2002.

Second, we clarify that the ambulance inflation factor applies to all mileage rates.

## C. Physician Certification

We added a provision which states that the health care professional who may certify the necessity of an unscheduled non-emergency ambulance transport may be an employee of the attending physician. Previously, we had required this person to be an employee of the facility in which the beneficiary was receiving treatment. We also clarified that all of the Medicare regulatory requirements and State licensure requirements for these health care professionals apply.

We changed the requirement for certification for non-repetitive scheduled non-emergency ambulance transports. These transports no longer require certification in advance. They are now treated the same as unscheduled non-emergency ambulance transports for certification purposes. Certification in advance is now required only for repetitive scheduled nonemergency ambulance transports.

In addition, we added the words "provider or" to clarify that the same certification requirements apply to both providers and suppliers.

#### D. Bed-Confined

We clarified that bed-confinement is not necessarily sufficient justification for the medical necessity of a nonemergency ambulance transport. Other documentation may also be required. Other conditions in beneficiaries who are not bed-confined may also justify the medical necessity of a nonemergency transport by ambulance.

## *E.* Future Adjustments to the Conversion Factor

We clarified the factors for which we will adjust the CF. We will not, for example, adjust the CF in response to an increase in the total number of ambulance transports over the number of transports in the previous year. We will adjust the CF if actual experience under the fee schedule is significantly different from the assumptions used to calculate the CF (for example, the relative volumes of the different levels of service or the extent of charges below the fee schedule (that is, "low billers")).

## F. Adjustment for "Low Billing"

We have decided to assume that onehalf of these "low billers" (that is, those billers whose charge is less than 70 percent of the maximum allowed by Medicare) would continue to charge an amount that is lower than the fee schedule amount. Therefore, we have increased the CF to account for approximately \$42 million that we anticipated as the difference between the aggregate fee schedule amount and actual charges that will be significantly less than the fee schedule amount (that is, "low billing").

#### G. Ambulance Blueprint

We changed the criteria in the definitions of the services that constitute a BLS level and an ALS level of care from those in the national Blueprint to the criteria contained in State and local laws.

## H. ALS Assessment

We changed the definition of ALS assessment to conform to the definition in the Committee Statement and to clarify that an ALS assessment is recognized only in an emergency situation.

### I. Emergency Response Definition

In the proposed rule, we stated that an emergency response means responding immediately to an emergency medical condition. An immediate response is one in which the ambulance supplier begins as quickly as possible to take the steps necessary to respond to a call. We deleted the phrase "emergency medical condition" from the definition of "emergency response." We clarified that the additional payment for emergency response is for the additional overhead cost of maintaining the resources required to respond immediately to a call and not for the cost of furnishing a certain level of service to the beneficiary. We also clarified that "emergency response" refers only to a BLS or ALS1 level of service.

#### J. Delayed Implementation

We will implement the fee schedule on April 1, 2002. The proposed rule had stated implementation would be January 1, 2001.

## K. Drug Administration Which Supports an ALS2 Level of Services

We clarified the types of drugs that must be administered to the beneficiary in order for the ambulance transport during which the administration occurs to qualify for payment at the ALS2 level. We also clarified that three separate administrations of the same drug qualifies for the ALS2 level of care.

## L. Multiple Patients

We changed the amount paid for transports in which there is more than

one patient onboard the ambulance. In the proposed rule, we stated that a single transport fee would be allowed and distributed equally among the patients. In this final rule, we provide that payment will be made as follows. If two patients are transported simultaneously, for each Medicare beneficiary, we will allow 75 percent of the payment allowance for the base rate applicable to the level of care furnished to that beneficiary. If three or more patients are transported simultaneously, then the payment allowance for the Medicare beneficiary (or each of them) is equal to 60 percent of the service payment allowance applicable for the level of care furnished to the beneficiary. However, a single payment allowance for mileage would continue to be prorated by the number of patients onboard.

## M. Changes to the Conversion Factor

Several changes have been made to the calculation of the CF from the methodology described in the proposed rule. The inflation factor used for calendar year 2001 was set at 3.7 percent. This is the annualized inflation factor provided by BIPA which has the effect of an inflation factor of 2.7 percent for the period January 1, 2001 through June 30, 2001, and 4.7 percent for the period July 1, 2001 through December 31, 2001 (as described above). Second, the CF was increased to reflect the assumption that some "low billers" (as described above) will continue to submit charges less than the fee schedule amount. Third, we corrected the number of rural miles equal to or less than 17 miles that were billed in calendar year 1998. Fourth, we revised our assumption with respect to the number of services that we believe will be billed at the ALS1-Emergency level because a supplier that provides an "ALS assessment" may receive payment for an ALS1-Emergency level of service. Fifth, we added back to the total amount used to calculate the CF the savings that would have accrued to the program had we implemented the policy proposed in June 1997 that would pay at the BLS rate for services furnished at the BLS level even though an ALS vehicle was used.

## N. Deceased Beneficiary

We have clarified that, in the case of an air ambulance responding to a call for a beneficiary who was pronounced dead while the ambulance was enroute to the scene, payment will be made in the amount of the appropriate air base rate and not in the amount of a BLS ground rate. No payment will be made for mileage.

## O. Medical Conditions List

We have specified that suppliers and providers may choose to submit a condition from the list of conditions and, if they do submit a condition, they must report that condition in the "remarks" field on the claim. Contractors may not deny or reject claims solely because a supplier or provider has reported a condition on the claim. Also, the presence of a condition, in and of itself, does not establish whether the services were reasonable and necessary. Regardless of the presence of the condition on the claim, ambulance suppliers and providers must maintain and, upon request by the Medicare contractor, submit documentation sufficient to show that the service was reasonable and necessary.

## P. Transition Period

The transition period has been changed from the four-year transition in the proposed rule. The final rule provides a five-year transition with blended payments as follows:

	Former payment percentage	Fee schedule percentage
Year One (4/2002–12/2002) Year Two (CY 2003) Year Three (CY 2004) Year Four (CY 2005) Year Five (CY 2006)	80 60 40 20	20 40 60 80 100

## Q. Payment for BLS Services Furnished by ALS Vehicle During Transition Period

In the proposed rule, we stated that during the transition period the "old" portion of the blended payment for BLS services furnished using an ALS vehicle would be the payment allowance for a BLS trip. In the final rule, we are phasing in this policy and the "old" portion of the blended payment will be at the allowance for an ALS trip.

## X. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 30-day notice in the **Federal Register** and solicit public comment when a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the PRA requires that we solicit comment on the following issues:

• The need for the information collection and its usefulness in carrying out the proper functions of our agency.

• The accuracy of our estimate of the information collection burden.

• The quality, utility, and clarity of the information to be collected.

• Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements.

Coverage of Ambulance Services (§ 410.40(d)(2))

This section is revised so that it no longer requires that an ambulance provider or supplier, before furnishing nonemergency, scheduled, nonrepetitive services to a beneficiary obtain a written order from the beneficiary's attending physician certifying that the services are medically necessary prior to the date the service is furnished.

## Coverage of Ambulance Services (§ 410.40(d)(3)(iii))

This section states that if the ambulance provider or supplier is unable to obtain a signed physician certification statement from the beneficiary's attending physician, a signed certification statement must be obtained from either the physician assistant (PA), nurse practitioner (NP), clinical nurse specialist (CNS), registered nurse (RN), or discharge planner, who has personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished. This individual must be employed by the beneficiary's attending physician, or by the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported. Medicare regulations for PAs, NPs, and CNSs apply and all applicable State licensure laws apply.

The burden associated with this requirement is the time and effort necessary for the required hospital or physician's employee to provide the certification. We estimate that there will be approximately 5,000 certifications on an annual basis at an estimated 5 minutes per certification. Therefore, the annual national burden associated with this requirement is 417 hours.

Coverage of Ambulance Services (§ 410.40(d)(3)(iv) & (v))

The following paragraphs also have information collection requirements:

Paragraph (d)(3)(iv): If the ambulance provider or supplier is unable to obtain the required certification within 21 calendar days following the date of the service, the ambulance provider or supplier must document its attempts to obtain the requested certification and may then submit the claim. Acceptable documentation includes a signed return receipt from the U.S. Postal Service or other similar service that evidences that the ambulance provider or supplier attempted to obtain the required signature from the beneficiary's attending physician or other individual named in paragraph (d)(3)(iii) above.

Paragraph (d)(3)(v): In all cases, the provider or supplier must keep appropriate documentation on file and, upon request, present it to the contractor. The presence of the signed certification statement or signed return receipt does not alone demonstrate that the ambulance transport was medically necessary. All other program criteria must be met in order for payment to be made.

The burden associated with these requirements is the time and effort necessary for the ambulance provider or supplier to document its attempts to obtain the requested certification statement and the time and effort necessary for the hospital or physician's employee to document the certification statement itself. We estimate that 5,000 providers or suppliers will be required to submit a receipt instead of certification for an average of 12 instances each on an annual basis, at an estimated 5 minutes per instance for a total annual national burden of 5,000 hours. We also estimate that there will be 5,000 certifications to be documented by the hospital or physician's employee at 5 minutes per instance for a total annual national burden of 417 hours.

#### Point of Pick-Up (§ 414.610(e))

This section states that the zip code of the point of pick-up must be reported on each claim for ambulance services so that the correct GAF and RAF may be applied, as appropriate.

In the proposed rule, we stated that the burden associated with this requirement is the time and effort necessary for the ambulance provider or supplier to note the required zip code for each claim of service. We estimated that, of the 9,000 (potential) providers or suppliers, 5,000 providers or suppliers will be required to provide the documentation, for an estimated 550,000 (5% of total claims volume of 11 million) instances on an annual basis. Per provider or supplier (5,000), we estimate 1 minute per instance to meet this requirement, for a burden of 2 hours per provider or supplier on an annual basis. Therefore, the annual national burden associated with this requirement is 10,000 hours.

*Comment:* A few commenters stated that the burden of reporting the zip code on the claim applies to 100 percent of total volume of claims and more than 2 hours per supplier per year.

Response: We agree with the commenters. The burden of reporting the zip code applies to all claims for ambulance services and to all providers and suppliers. We estimate that there will be approximately 10 million claims for ambulance services, from approximately 10,000 ambulance providers and suppliers, each of which will require the zip code to be entered. We estimate that entering the zip code requires about 15 seconds, giving a total annual burden of approximately 40,000 hours or an average of 4 hours per provider or supplier per year. We expect that this burden will diminish as providers and suppliers become familiar with the zip codes in their service area.

If you comment on these information collection and recordkeeping requirements, please mail copies directly to the following:

- Centers for Medicare & Medicaid Services, Office of Information Services, Information Technology Investment Management Group, Attn.: Dawn Willinghan (Attn: CMS–1002– om N2–14–26, 7500 Security Boulevard, Baltimore, MD 21244– 1850; and
- Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10235, New Executive Office Building, Washington, DC 20503, Attn: Allison Herron Eydt, CMS Desk Officer.

#### XI. Regulatory Impact Analysis

#### A. Overall Impact

We have examined the impacts of this rule as required by Executive Order 12866 and the Regulatory Flexibility Act (RFA) (Public Law 96–354). 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 annually). This final regulation will have no fiscal impact on the Medicare program; therefore, we have determined that this is not a major rule. However, we are providing a regulatory impact analysis because some entities will experience a decrease in payments while others will experience an increase in payments. This impact is less than the \$70 million savings estimate for FY 2002 shown in the proposed rule because we are paying for BLS services furnished by ALS vehicles at the ALS rate for the reasonable charge portion of the blended rate during the transition period and because we have increased the amount of spending upon which the CF is based by the amount paid for ALS vehicles that furnished only a BLS level of service. In addition, our data indicate that payments (80 percent of which will be program expenditures and the remainder because of Medicare Part B coinsurance and deductible requirements) will be redistributed among entities that furnish ambulance services

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 \$5 million or less annually. For purposes of the RFA, most ambulance providers and most ambulance suppliers are considered to be small entities. Individuals and States are not included in the definition of a small entity.

In addition, section 1102(b) of the Act requires us to prepare an RIA 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 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. In the aggregate, in 2002, rural entities, which include both rural hospitals and rural ambulance suppliers, will receive an increase in total revenue while urban entities will experience a decrease in total revenue as summarized in the chart, below. It is also true that some rural entities will be paid less than their current rate. While we do not have specific data on the number of small rural hospitals that furnish ambulance services, we

recognize that the rural adjustment factor incorporated in this proposal may not completely offset the higher costs of low-volume suppliers. As stated earlier, we recognize that this rural adjustment is a temporary proxy to acknowledge the higher costs of certain low-volume isolated and essential suppliers. We will consider alternative methodologies that would more appropriately address payment to isolated, low-volume rural ambulance suppliers. In addition, critical access hospitals that do not have an ambulance supplier within a 35-mile drive will be paid for ambulance services based on cost.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in an expenditure in any one year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. The final rule will not have any unfunded mandates.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct compliance costs on State and local governments, preempts State law, or otherwise has Federalism implications. The final rule will not impose compliance costs on the governments mentioned.

Although we view the anticipated results of this final regulation as beneficial to the Medicare program and to Medicare beneficiaries, we recognize that not all of the potential effects of this final rule can be anticipated.

The foregoing analysis concludes that this regulation may have a financial impact on a number of small entities. This analysis, in combination with the rest of the preamble, is consistent with the standards for analysis set forth by the RFA.

Comment: Many commenters noted that this is a major rule and that we should conduct a regulatory impact analysis under Executive Order 12866. They argue that the impact is more than \$84.5 million because it should include: (1) The effects of our treatment in calculating the conversion factor of suppliers with low charges and those that do not bill for mileage; (2) redistribution effects; and (3) the effect of mandatory assignment of benefits. In addition, the rule does not discuss the impact on public safety of the ambulance suppliers who will experience a reduction in payments. The commenters noted that we should conduct a State-by-State impact assessment of the proposed rule to

determine if there are regulatory alternatives that would have a less drastic effect on ambulance providers, many of whom are small businesses.

*Response:* As stated above, we have determined that this is not a major rule and that this final rule has no fiscal impact on the program. With respect to the mandatory assignment requirement, historically, ninety-five percent of ambulance services have been submitted to Medicare under assignment, and, while the fee schedule redistributes payments, we do not anticipate that the assignment requirement will be a major issue nationally. There may be areas of the country where balanced billing occurs more often than in other parts; however, the effect on total payments is unclear because payment in any of the areas may increase under the fee schedule. Also, as stated above, mandatory assignment of benefits is a requirement of the law and not subject to the discretion of the Secretary through this regulatory action. Also, we have included an amount in this final rule for suppliers of ambulance services who may choose not to bill the program at the full fee schedule amount.

## B. Anticipated Effects

Implementation of the ambulance fee schedule will have several general effects. Section 1834(l)(3)(A) of the Act requires that the aggregate amount paid under the ambulance fee schedule not exceed the aggregate amount that would have been paid absent the fee schedule. One of the characteristics of the present payment system is that widely varying amounts are paid for the same type of service depending upon the location of the service. In effect, the ambulance fee schedule will lower payments in areas of high current levels of payment and raise payments in areas of low current levels of payment. Thus, a given area could have a large reduction in payment only because such an area had historically been paid at a rate higher than average for the type of service. Even with a reduction, such an area may continue to have payment rates under the fee schedule that are higher than the national average.

## 1. Effect on Ambulance Providers and Suppliers

One effect of the fee schedule will be that revenue will be redistributed from providers to ambulance suppliers because providers have been paid, on average, more for the same service furnished by a supplier. 2. Effects on Urban, Rural, and Air Ambulance Services

Payment could be redistributed from urban ambulance services to rural ambulance services for two reasons:

(1) Services furnished in urban areas have been paid more, on average, than the same services furnished in rural areas.

(2) The ambulance fee schedule will pay more for the same services furnished in a rural area than in an urban area because of the rural adjustment factor (RAF). Payment will also be redistributed from urban air ambulance services to rural air ambulance services because of the RAF for air services.

(3) Finally, there will be a redistribution of payment from ground ambulance services to air ambulance services. This effect is explained in greater detail in the discussion of the CF.

Currently, providers (for example, hospital-based ambulance services) are paid on average 66 percent more than independent suppliers for the same type of ambulance service. This is because providers are currently paid based on reasonable cost and suppliers are paid based on reasonable charges capped by the inflation indexed charge (IIC). The IIC has limited the growth of suppliers' payments over the years, whereas, until enactment of the BBA in 1997, there had not been a limit on the growth of providers' reimbursable cost for ambulance services. As a result, providers of ambulance services will experience a reduction in total revenue while independent ambulance suppliers will experience an increase in total revenue.

There are offsetting factors that affect payment in urban versus rural areas. While payment rates in rural areas will generally be lowered by the GPCI (because the GPCI is generally lower in rural areas than it is in urban areas), rural payment rates will increase because of the rural mileage add-on. The net result is that payments will be redistributed from providers and suppliers in urban areas to providers and suppliers in rural areas.

Furthermore, payments will be redistributed from providers and suppliers of ground ambulance services to providers and suppliers of air ambulance services.

The following chart summarizes these findings for 2002:

From	То	Revenue (million)
Providers	Suppliers	\$14
Urban	Rural	17

From	То	Revenue (million)
Ground	Air	5

These amounts represent total revenue, that is, the 80 percent Medicare portion plus the 20 percent beneficiary coinsurance liability. The redistributive effects of this final rule represent a negligible fraction of the total revenue (both Medicare at \$2.7 billion plus all other non-Medicare sources of revenue) for ambulance providers and suppliers. Therefore, we conclude and the Secretary certifies that this final rule does not have a significant impact on a substantial number of small entities.

3. Effect on the Medicare Program

We estimate that this final rule will have no fiscal impact on the Medicare program.

#### C. Alternatives Considered

While there were many alternatives considered during the course of the negotiated rulemaking process, the statute requires that total program expenditures not exceed what the payments would have been without the fee schedule. None of the alternatives considered changed total program expenditures. The alternatives varied in the manner in which the total amount of program expenditures might be distributed among the entities that furnish ambulance services to Medicare beneficiaries. For example, the Committee considered other geographical adjustment factors, other relative values for the levels of ambulance service, other definitions for the levels of ambulance service and other definitions for "rural entities," but it did not adopt them for various reasons. (A full description of these alternatives may be found at the Web site: www.hcfa.gov/medicare/ ambmain.htm.)

## D. Effect on Beneficiaries

The ambulance fee schedule will have a leveling effect on coinsurance liability. About 10 percent of the 37 million beneficiaries enrolled in Medicare Part B receive a Medicare benefit for ambulance services. While beneficiaries in those areas of historically higher than average payment rates will benefit from lower coinsurance liability, beneficiaries in areas of historically lower than average payment rates will experience an upward trend of coinsurance liability. While, on average, for all Medicare beneficiaries receiving a Medicare benefit for ambulance services there is no change in coinsurance liability, the average

beneficiary coinsurance liability will increase by one percent for beneficiaries located in rural areas with the same decrease in coinsurance liability for beneficiaries in urban areas.

Beneficiaries will also benefit in those cases in which suppliers previously did not accept assignment and billed the beneficiary the difference between the Medicare program allowed amount and their actual charge, because under the fee schedule all suppliers must accept assignment.

#### E. Conclusion

We anticipate that the ambulance fee schedule amounts for entities that have historically received lower than average payment rates will be relatively higher and the fee schedule amounts for entities that have historically received higher than average payment rates will be relatively lower. Generally, this will mean higher rates in the future for rural transports, lower rates in the future for urban transports, and higher rates in the future for air ambulance services. We believe that the statutory requirement to establish mechanisms to control increases in expenditures for ambulance services under Part B of the Medicare program is met by continuance of the application of the inflation factors prescribed in the statute.

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

## List of Subjects Affected in 42 CFR Part 410

Ambulances, Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, Xrays.

### 42 CFR Part 414

Administrative practice and procedure, Health facilities, Health professions, Kidney diseases, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services amends 42 CFR chapter IV as follows:

## PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

A. Part 410 is amended as set forth below:

1. The authority citation for part 410 continues to read as follows:

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

## Subpart B—Medical and Other Health Services

2. Section 410.40 is amended by:

A. Revising paragraph (b).

B. Revising paragraph (d)(1).

C. Revising paragraph (d)(2).

D. Revising the paragraph (d)(3)

heading and introductory text.

E. Revising paragraph (d)(3)(i).

F. Adding new paragraphs (d)(3)(iii), (d)(3)(iv), and (d)(3)(v).

The revisions and additions read as follows:

## §410.40 Coverage of ambulance services.

(b) *Levels of service.* Medicare covers the following levels of ambulance service, which are defined in § 414.605 of this chapter:

- (1) Basic life support (BLS) (emergency and nonemergency).
- (2) Advanced life support, level 1

(ALS1) (emergency and nonemergency). (3) Advanced life support, level 2

- (ALS2).
- (4) Paramedic ALS intercept (PI).
- (5) Specialty care transport (SCT).
- (6) Fixed wing transport (FW).

(7) Rotary wing transport (RW).

(d) Medical necessity requirements— (1) General rule. Medicare covers ambulance services, including fixed wing and rotary wing ambulance services, only if they are furnished to a beneficiary whose medical condition is such that other means of transportation are contraindicated. The beneficiary's condition must require both the ambulance transportation itself and the level of service provided in order for the billed service to be considered medically necessary. Nonemergency transportation by ambulance is appropriate if either: the beneficiary is bed-confined, and it is documented that the beneficiary's condition is such that other methods of transportation are contraindicated; or, if his or her medical condition, regardless of bed confinement, is such that transportation by ambulance is medically required. Thus, bed confinement is not the sole criterion in determining the medical necessity of ambulance transportation. It is one factor that is considered in medical necessity determinations. For a beneficiary to be considered bedconfined, the following criteria must be met

(i) The beneficiary is unable to get up from bed without assistance.

- (ii) The beneficiary is unable to ambulate.
- (iii) The beneficiary is unable to sit in a chair or wheelchair.

(2) Special rule for nonemergency, scheduled, repetitive ambulance

services. Medicare covers medically necessary nonemergency, scheduled, repetitive ambulance services if the ambulance provider or supplier, before furnishing the service to the beneficiary, obtains a written order from the beneficiary's attending physician certifying that the medical necessity requirements of paragraph (d)(1) of this section are met. The physician's order must be dated no earlier than 60 days before the date the service is furnished.

(3) Special rule for nonemergency ambulance services that are either unscheduled or that are scheduled on a nonrepetitive basis. Medicare covers medically necessary nonemergency ambulance services that are either unscheduled or that are scheduled on a nonrepetitive basis under one of the following circumstances:

(i) For a resident of a facility who is under the care of a physician if the ambulance provider or supplier obtains a written order from the beneficiary's attending physician, within 48 hours after the transport, certifying that the medical necessity requirements of paragraph (d)(1) of this section are met.

(iii) If the ambulance provider or supplier is unable to obtain a signed physician certification statement from the beneficiary's attending physician, a signed certification statement must be obtained from either the physician assistant (PA), nurse practitioner (NP), clinical nurse specialist (CNS), registered nurse (RN), or discharge planner, who has personal knowledge of the beneficiary's condition at the time the ambulance transport is ordered or the service is furnished. This individual must be employed by the beneficiary's attending physician or by the hospital or facility where the beneficiary is being treated and from which the beneficiary is transported. Medicare regulations for PAs, NPs, and CNSs apply and all applicable State licensure laws apply; or.

(iv) If the ambulance provider or supplier is unable to obtain the required certification within 21 calendar days following the date of the service, the ambulance supplier must document its attempts to obtain the requested certification and may then submit the claim. Acceptable documentation includes a signed return receipt from the U.S. Postal Service or other similar service that evidences that the ambulance supplier attempted to obtain the required signature from the beneficiary's attending physician or other individual named in paragraph (d)(3)(iii) of this section.]

(v) In all cases, the provider or supplier must keep appropriate

documentation on file and, upon request, present it to the contractor. The presence of the signed certification statement or signed return receipt does not alone demonstrate that the ambulance transport was medically necessary. All other program criteria must be met in order for payment to be made.

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## PART 414—PAYMENT FOR PART B MEDICAL AND OTHER HEALTH SERVICES

B. Part 414 is amended as set forth below:

1. The authority citation for part 414 continues to read as follows:

Authority: Secs. 1102, 1871, and 1881(b)(1) of the Social Security Act (42 U.S.C. 1302, 1395hh, 1395rr(b)(1)).

2. Section 414.1 is revised to read as follows:

#### §414.1 Basis and scope.

This part implements the following provisions of the Act:

1802—Rules for private contracts by Medicare beneficiaries.

1833—Rules for payment for most Part B services.

1834(a) and (h)—Amounts and frequency of payments for durable medical equipment and for prosthetic devices and orthotics and prosthetics.

- 1834(l)—Establishment of a fee schedule for ambulance services.
- 1834(m)—Rules for Medicare reimbursement for telehealth services. 1848—Fee schedule for physician
- services.

1881(b)—Rules for payment for services to ESRD beneficiaries.

1887—Payment of charges for physician services to patients in providers.

3. A new subpart H, consisting of §§ 414.601 through 414.625, is added to read as follows:

## Subpart H—Fee Schedule for Ambulance Services

Sec.

- 414.601 Purpose.
- 414.605 Definitions.
- 414.610 Basis of payment.
- 414.615 Transition to the ambulance fee schedule.
- 414.620 Publication of the ambulance fee schedule.
- 414.625 Limitation on review.

## Subpart H—Fee Schedule for Ambulance Services

## §414.601 Purpose.

This subpart implements section 1834(l) of the Act by establishing a fee schedule for the payment of ambulance services. Section 1834(l) of the Act requires that, except for services furnished by certain critical access hospitals (see § 413.70(b)(5) of this chapter), payment for all ambulance services, otherwise previously payable on a reasonable charge basis or retrospective reasonable cost basis, be made under a fee schedule.

### §414.605 Definitions.

As used in this subpart, the following definitions apply to both land and water (hereafter collectively referred to as "ground") ambulance services and to air ambulance services unless otherwise specified:

Advanced life support (ALS) assessment is an assessment performed by an ALS crew as part of an emergency response that was necessary because the patient's reported condition at the time of dispatch was such that only an ALS crew was qualified to perform the assessment. An ALS assessment does not necessarily result in a determination that the patient requires an ALS level of service.

Advanced life support (ALS) intervention means a procedure that is, in accordance with State and local laws, beyond the scope of authority of an emergency medical technician-basic (EMT-Basic).

Advanced life support, level 1 (ALS1) means transportation by ground ambulance vehicle, medically necessary supplies and services and either an ALS assessment by ALS personnel or the provision of at least one ALS intervention.

Advanced life support, level 2 (ALS2) means either transportation by ground ambulance vehicle, medically necessary supplies and services, and the administration of at least three medications by intravenous push/bolus or by continuous infusion excluding crystalloid, hypotonic, isotonic, and hypertonic solutions (Dextrose, Normal Saline, Ringer's Lactate); or transportation, medically necessary supplies and services, and the provision of at least one of the following ALS procedures:

(1) Manual defibrillation/ cardioversion.

- (2) Endotracheal intubation.
- (3) Central venous line.
- (4) Cardiac pacing.
- (5) Chest decompression.
- (6) Surgical airway.
- (7) Intraosseous line.

Advanced life support (ALS) personnel means an individual trained to the level of the emergency medical technician-intermediate (EMT– Intermediate) or paramedic. The EMT– Intermediate is defined as an individual who is qualified, in accordance with State and local laws, as an EMT–Basic and who is also qualified in accordance with State and local laws to perform essential advanced techniques and to administer a limited number of medications. The EMT–Paramedic is defined as possessing the qualifications of the EMT–Intermediate and also, in accordance with State and local laws, as having enhanced skills that include being able to administer additional interventions and medications.

Basic life support (BLS) means transportation by ground ambulance vehicle and medically necessary supplies and services, plus the provision of BLS ambulance services. The ambulance must be staffed by an individual who is qualified in accordance with State and local laws as an emergency medical technician-basic (EMT–Basic). These laws may vary from State to State. For example, only in some States is an EMT-Basic permitted to operate limited equipment on board the vehicle, assist more qualified personnel in performing assessments and interventions, and establish a peripheral intravenous (IV) line.

*Conversion factor (CF)* is the dollar amount established by CMS that is multiplied by relative value units to produce ground ambulance service base rates.

*Emergency response* means responding immediately at the BLS or ALS1 level of service to a 911 call or the equivalent in areas without a 911 call system. An immediate response is one in which the ambulance supplier begins as quickly as possible to take the steps necessary to respond to the call.

Fixed wing air ambulance (FW) means transportation by a fixed wing aircraft that is certified as a fixed wing air ambulance and such services and supplies as may be medically necessary.

Geographic adjustment factor (GAF) means the practice expense (PE) portion of the geographic practice cost index (GPCI) from the physician fee schedule as applied to a percentage of the base rate. For ground ambulance services, the PE portion of the GPCI is applied to 70 percent of the base rate for each level of service. For air ambulance services, the PE portion of the GPCI is applied to 50 percent of the applicable base rate.

*Goldsmith modification* means the recognition of rural areas within certain Standard Metropolitan Statistical Areas wherein a census tract is deemed to be rural when located within a large metropolitan county of at least 1,225 square miles, but is so isolated from the metropolitan core of that county by distance or physical features as to be more rural than urban in character. *Loaded mileage* means the number of miles the Medicare beneficiary is transported in the ambulance vehicle.

Paramedic ALS intercept (PI) means EMT–Paramedic services furnished by an entity that does not furnish the ground ambulance transport, provided the services meet the requirements specified in § 410.40(c) of this chapter.

*Point of pick-up* means the location of the beneficiary at the time he or she is placed on board the ambulance.

*Relative value units (RVUs)* means a value assigned to a ground ambulance service.

Rotary wing air ambulance (RW) means transportation by a helicopter that is certified as an ambulance and such services and supplies as may be medically necessary.

Rural adjustment factor (RAF) means an adjustment applied to the base payment rate when the point of pick-up is located in a rural area.

Rural area means an area located outside a Metropolitan Statistical Area (MSA), or a New England County Metropolitan Area (NECMA), or an area within an MSA that is identified as rural by the Goldsmith modification.

Specialty care transport (SCT) means interfacility transportation of a critically injured or ill beneficiary by a ground ambulance vehicle, including medically necessary supplies and services, at a level of service beyond the scope of the EMT–Paramedic. SCT is necessary when a beneficiary's condition requires ongoing care that must be furnished by one or more health professionals in an appropriate specialty area, for example, nursing, emergency medicine, respiratory care, cardiovascular care, or a paramedic with additional training.

#### §414.610 Basis of payment.

(a) Method of payment. Medicare payment for ambulance services is based on the lesser of the actual charge or the applicable fee schedule amount. The fee schedule payment for ambulance services equals a base rate for the level of service plus payment for mileage and applicable adjustment factors. Except for services furnished by certain critical access hospitals or entities owned and operated by them, as described in §413.70(b) of this chapter, all ambulance services are paid under the fee schedule specified in this subpart (regardless of the vehicle furnishing the service).

(b) Mandatory assignment. Effective with implementation of the ambulance fee schedule described in § 414.601 (that is, for services furnished on or after April 1, 2002), all payments made for ambulance services are made only on an assignment-related basis. Ambulance suppliers must accept the Medicare allowed charge as payment in full and may not bill or collect from the beneficiary any amount other than the unmet Part B deductible and Part B coinsurance amounts. Violations of this requirement may subject the provider or supplier to sanctions, as provided by law (part 402 of this chapter).

(c) *Formula for computation of payment amounts.* The fee schedule payment amount for ambulance services is computed according to the following provisions:

(1) Ground ambulance service levels. The CF is multiplied by the applicable RVUs for each level of service to produce a service-level base rate. The service-level base rate is then adjusted by the GAF. Compare this amount to the actual charge. The lesser of the charge or the GAF adjusted base rate amount is added to the payment rate per mile, multiplied by the number of miles that the beneficiary was transported. When applicable, the appropriate RAF is applied to the ground mileage rate to determine the appropriate payment rates. The RVU scale for the ambulance fee schedule is as follows:

Service level	Relative value units (RVUs)
BLS BLS-Emergency ALS1 ALS1-Emergency ALS2 SCT	1.00 1.60 1.20 2.75 3.25 1.75
PI	1.75

(2) Air ambulance service levels. The base payment rate for the applicable type of air ambulance service is adjusted by the GAF and, when applicable, by the appropriate RAF to determine the amount of payment. Air ambulance services have no CF or RVUs. This amount is compared to the actual charge. The lesser of the charge or the adjusted GAF rate amount is added to the payment rate per mile, multiplied by the number of miles that the beneficiary was transported. When applicable, the appropriate RAF is also applied to the air mileage rate.

(3) Loaded mileage. Payment is made for each loaded mile. Air mileage is based on loaded miles flown as expressed in statute miles. There are three mileage payment rates: a rate for FW services, a rate for RW services, and a rate for all levels of ground transportation.

(4) *Geographic adjustment factor* (*GAF*). For ground ambulance services, the PE portion of the GPCI from the physician fee schedule is applied to 70 percent of the base rate for ground ambulance services. For air ambulance services, the PE portion of the physician fee schedule GPCI is applied to 50 percent of the base rate for air ambulance services.

(5) *Rural adjustment factor (RAF).* For ground ambulance services where the point of pickup is in a rural area, the mileage rate is increased by 50 percent for each of the first 17 miles and by 25 percent for miles 18 through 50. The standard mileage rate applies to every mile over 50 miles. For air ambulance services where the point of pickup is in a rural area, the total payment is increased by 50 percent; that is, the rural adjustment factor applies to the sum of the base rate and the mileage rate.

(6) *Multiple patients*. The allowable amount per beneficiary for a single ambulance transport when more than one patient is transported simultaneously is based on the total number of patients (both Medicare and non-Medicare) on board. If two patients are transported simultaneously, then the payment allowance for the beneficiary (or for each of them if both patients are beneficiaries) is equal to 75 percent of the service payment allowance applicable for the level of care furnished to the beneficiary, plus 50 percent of the applicable mileage payment allowance. If three or more patients are transported simultaneously, the payment allowance for the beneficiary (or each of them) is equal to 60 percent of the service payment allowance applicable for the level of care furnished to the beneficiary, plus the applicable mileage payment allowance divided by the number of patients on board.

(d) *Payment*. Payment, in accordance with this subpart, represents payment in full (subject to applicable Medicare Part B deductible and coinsurance requirements as described in subpart G of part 409 of this chapter or in subpart I of part 410 of this chapter) for all services, supplies, and other costs for an ambulance service furnished to a Medicare beneficiary. No direct payment will be made under this subpart if billing for the ambulance service is required to be consolidated with billing for another benefit for which payment may be made under this chapter.

(e) *Point of pick-up.* The zip code of the point of pick-up must be reported on each claim for ambulance services so that the correct GAF and RAF may be applied, as appropriate.

(f) *Updates.* The CF, the air ambulance base rates, and the mileage rates are updated annually by an inflation factor established by law. The inflation factor is based on the consumer price index for all urban consumers (CPI–U) (U.S. city average) for the 12-month period ending with June of the previous year.

(g) Adjustments. The Secretary will annually review rates and will adjust the CF and air ambulance rates if actual experience under the fee schedule is significantly different from the assumptions used to determine the initial CF and air ambulance rates. The CF and air ambulance rates will not be adjusted solely because of changes in the total number of ambulance transports.

## § 414.615 Transition to the ambulance fee schedule.

The fee schedule for ambulance services will be phased in over 5 years beginning April 1, 2002. Subject to the first sentence in § 414.610(a), payment for services furnished during the transition period is made based on a combination of the fee schedule payment for ambulance services and the amount the program would have paid absent the fee schedule for ambulance services, as follows:

(a) 2002 Payment. For services furnished in 2002, the payment for the service component, the mileage component and, if applicable, the supply component is based on 80 percent of the reasonable charge for independent suppliers or on 80 percent of reasonable cost for providers, plus 20 percent of the ambulance fee schedule amount for the service and mileage components. The reasonable charge or reasonable cost portion of payment in CY 2002 is equal to the supplier's reasonable charge allowance or provider's reasonable cost allowance for CY 2001, multiplied by the statutory inflation factor for ambulance services.

(b) 2003 Payment. For services furnished in CY 2003, payment is based on 60 percent of the reasonable charge or reasonable cost, as applicable, plus 40 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2003 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2002, multiplied by the statutory inflation factor for ambulance services.

(c) 2004 Payment. For services furnished in CY 2004, payment is based on 40 percent of the reasonable charge or reasonable cost, as applicable, plus 60 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2004 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2003, multiplied by the statutory inflation factor for ambulance services. (d) 2005 Payment. For services furnished in CY 2005, payment is based on 20 percent of the reasonable charge or reasonable cost, as applicable, plus 80 percent of the ambulance fee schedule amount. The reasonable charge and reasonable cost portion in CY 2005 is equal to the supplier's reasonable charge or provider's reasonable cost for CY 2004, multiplied by the statutory inflation factor for ambulance services.

(e) 2006 and Beyond Payment. For services furnished in CY 2006 and thereafter, the payment is based solely on the ambulance fee schedule amount.

(f) *Updates*. The portion of the transition payment that is based on the existing payment methodology (that is, the non-fee-schedule portion) is updated annually for inflation by a factor equal to the percentage increase in the CPI-U (U.S. city average) for the 12-month period ending with June of the previous year. The CY 2002 inflation update factor used to update the 2001 payment amounts is applied to the annualized (average) payment amounts for CY 2001. For the period January 1, 2001 through June 30, 2001, the inflation update factor is 2.7 percent. For the period July 1, 2001 through December 31, 2001, the inflation update factor is 4.7 percent. The average for the year is 3.7 percent. Thus, the annualized (average) CY 2001 payment amounts used to derive the CY 2002 payment amounts are equivalent to the CY 2001 payment amounts that would have been determined had the inflation update

factor for the entire CY 2001 been 3.7 percent. Both portions of the transition payment (that is, the portion that is based on reasonable charge or reasonable cost and the portion that is based on the ambulance fee schedule) are updated annually for inflation by the inflation factor described in § 414.610(f).

(g) *Exception*. There will be no blended payment allowance as described in paragraphs (a), (b), (c), and (d) of this section for ground mileage in those States where the Medicare carrier paid separately for all out-of-county ground ambulance mileage, but did not, before the implementation of the Medicare ambulance fee schedule, make a separate payment for any ground ambulance mileage within the county in which the beneficiary was transported. Payment for ground ambulance mileage in that State will be made based on the full ambulance fee schedule amount for ground mileage. This exception applies only to carrier-processed claims and only in those States in which the carrier paid separately for out-of-county ambulance mileage, but did not make separate payment for any in-county mileage throughout the entire State.

## §414.620 Publication of the ambulance fee schedule.

Changes in payment rates resulting from incorporation of the annual inflation factor described in § 414.610(f) will be announced by notice in the **Federal Register** without opportunity for prior comment. CMS will follow applicable rulemaking procedures in publishing revisions to the fee schedule for ambulance services that result from any factors other than the inflation factor.

## §414.625 Limitation on review.

There will be no administrative or judicial review under section 1869 of the Act or otherwise of the amounts established under the fee schedule for ambulance services, including the following:

(a) Establishing mechanisms to control increases in expenditures for ambulance services.

(b) Establishing definitions for ambulance services that link payments to the type of services provided.

(c) Considering appropriate regional and operational differences.

(d) Considering adjustments to payment rates to account for inflation and other relevant factors.

(e) Phasing in the application of the payment rates under the fee schedule in an efficient and fair manner.

(Catalog of Federal Domestic Assistance Program No. 93.774, Medicare— Supplementary Medical Insurance Program)

Dated: December 7, 2001.

#### Thomas A. Scully,

Administrator, Centers for Medicare & Medicaid Services.

Dated: December 19, 2001.

Tommy G. Thompson,

Secretary.

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