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Robert Bartholomew III,

Acting Deputy Assistant Secretary (Force Management, Manpower and Resources).

Kenneth J. Oscar,

Deputy Assistant Secretary of the Army (Procurement).

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 405 and 410

[HCFA-1813-F]

RIN 0938-AJ87

Medicare Program; Coverage of, and Payment for, Paramedic Intercept Ambulance Services

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: This final rule responds to public comments received on a final rule with comment period published on January 25, 1999 that implemented section 4531(c) of the Balanced Budget Act of 1997 concerning Medicare coverage of, and payment for, paramedic intercept ambulance services in rural communities. It also implements section 412 of the Medicare, Medicaid, and State Children's Health Insurance Programs Balanced Budget Refinement Act of 1999 by adding a new definition of a rural area.

EFFECTIVE DATE: These regulations are effective on April 14, 2000.

FOR FURTHER INFORMATION CONTACT: Robert Niemann, (410) 786-4569.

SUPPLEMENTARY INFORMATION:

I. Background

In general, Medicare payment for ambulance services provided in accordance with section 1861(s)(7) of the Social Security Act (the Act) may be made only to the ambulance supplier furnishing the ambulance transport. Paramedic intercept services are advanced life support (ALS) services delivered by paramedics who furnish services separately from the agency that furnishes the ambulance transport.

Except in the very limited circumstances described below, Medicare program payment for these services may be made only to the ambulance company furnishing the ambulance transport. Paramedic intercept services are most often furnished for an emergency ambulance transport in which a local volunteer ambulance that can furnish only basic life support (BLS) services is dispatched to transport a beneficiary. If the beneficiary needs ALS services (such as EKG monitoring, chest decompression, or IV therapy), another agency (typically a hospital or proprietary emergency medical service) dispatches a paramedic to meet the BLS ambulance at the scene or enroute to the hospital. The ALS paramedics then furnish the ALS services to the beneficiary. This tiered approach to life-saving may be cost effective in some areas because most volunteer ambulances do not charge for their services, and one paramedic service can cover many communities.

A. Balanced Budget Act of 1997

Section 4531(c) of the Balanced Budget Act of 1997 (BBA) provided that the Secretary could include limited coverage of these intercept services furnished in a rural area: that is, payment may be made directly to the agency furnishing the paramedic service in a rural area. The services, however, are covered only if they are furnished under contract with one or more volunteer ambulance services and they are medically necessary based on the condition of the beneficiary receiving the ambulance service. In addition, by law, the volunteer ambulance service involved must meet all of the following requirements:

- Furnish only BLS services at the time of the intercept.
- Be prohibited by State law from billing for any service.

Finally, the entity furnishing the ALS paramedic intercept service must meet the following requirements:

- Be certified as qualified to furnish the ambulance services under the Medicare program (including compliance with State laws and regulations).
- Bill all recipients who receive ALS paramedic intercept services from the entity, regardless of whether or not those recipients are Medicare beneficiaries.

B. The Final Rule with Comment Period

On January 25, 1999, we published a final rule with comment period in the **Federal Register** (64 FR 3637), which, in part, revised 42 CFR 410.40 to implement section 4531(c) of the BBA.

In implementing the law, we defined "rural area" in the same way it is defined for purposes of the Medicare hospital inpatient prospective payment system under section 1886(d)(2)(D) of the Act and in regulations at § 412.62(f). That is, a rural area is any area outside of a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area as defined by the Office of Management and Budget.

Although it provided the Secretary with the authority to cover paramedic intercept services under certain conditions, section 4531(c) of the BBA did not specify what the payment should be for those services. After considering several options, we decided to pay for paramedic intercept services based on the difference between the ALS payment rate and the BLS payment rate for each carrier's geographic pricing locality. We believed that this option balanced considerations for access to care and consistency with current ambulance payment policy. We would be providing the intercept company with a reasonable payment while not providing the same amount of payment that we generally would provide to an ambulance company that furnishes both the transport and the paramedic service. We reasoned that if we paid the difference between the ALS and BLS rates to the intercept company, we would be acknowledging the BLS rate that would have been paid to the volunteer company had it been permitted by the State to bill the program for the transport.

C. Balanced Budget Refinement Act of 1999

Section 412 of the Medicare, Medicaid, and State Children's Health Insurance Programs Balanced Budget Refinement Act of 1999 (BBRA) (Pub. L. 106-113), enacted on November 29, 1999, amends section 4531(c) of the BBA. Section 412 states "* * * 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))." (The Goldsmith Modification is a methodology to identify small towns and rural areas within large metropolitan counties that are isolated from central areas by distance or other features. This Modification has been useful for expanding the eligibility for Federal programs that assist rural populations to include isolated rural populations of large metropolitan counties).

II. Discussion of Public Comments

In response to the final rule with comment period published on January 25, 1999, we received approximately 175 comments from ambulance suppliers and their employees, Medicare beneficiaries, and two members of the Congress. The majority of the comments were identical or nearly identical. The comments and responses are set forth below:

A. Definition of Rural Area

Comment: Commenters stated that using a rural definition based on MSAs and non-MSAs was not appropriate in the context of ambulance services. The commenters pointed out that, in large urban counties, many areas are very rural in nature. Because of the distance between these "rural" areas in an MSA and the nearest appropriate hospital, paramedic intercept services delivered in these rural areas are just as worthy of being recognized as those delivered in a rural county.

The commenters suggested alternatives that included: (1) the area where services are furnished meets either the non-MSA criterion or is located in a rural area as defined by the Census Bureau; (2) setting some other population density criterion; or (3) considering driving distance.

Some commenters stated that the paramedic intercept provision should not be limited to rural areas because this service is needed everywhere, not just in rural areas.

Response: Section 4531(c) of the BBA, as amended by section 412 of the BBRA, specifically limits coverage of this service to rural areas; therefore, we cannot extend the paramedic intercept provision to all areas. In accordance with the provisions of section 412 of the BBRA, we are revising the definition of "rural area" in § 410.40(c)(1). For this purpose, an area will 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)).

Comment: Some commenters inquired whether the rural criteria would be applied to the location from which the beneficiary is transported (that is, pick-up point) or the location of the garage for the intercept services vehicle. One commenter suggested that coverage be limited to a service furnished in whole or in part in a rural area regardless of the location of the garage housing the vehicle used by the paramedic.

Response: We are applying the rural area criteria to the location from which the beneficiary is transported, that is, the location of the beneficiary at the time the ambulance or the paramedic intercept encounters the beneficiary, whichever occurs first.

Comment: Some commenters stated that the paramedic intercept provision in the BBA is not fair because it requires that the volunteer BLS ambulance be prohibited by State law from billing anyone for its services and that the only State with such a law is New York. Therefore, no suppliers in States other than New York can qualify for this benefit. The commenters stated that we should implement this provision everywhere in the country equitably or not implement it at all.

Response: The statute clearly defines the conditions under which Medicare may cover paramedic intercept services. Section 4531(c) of the BBA states that the volunteer ambulance service involved in the intercept service must be prohibited by State law from billing for any services. Therefore, we have no discretion to broaden its application. The Congress gave the Secretary authority to implement the paramedic intercept provision only under the conditions set forth in the law. Thus, we believe our implementation of the provision is appropriate.

B. Payment for Paramedic Intercept Services

Comment: We received numerous comments on the payment rate that we established for paramedic intercept services. Some commenters believed that we should pay the cost or reasonable charge of the service. Others suggested we pay the full ALS rate. In addition, commenters suggested we pay for paramedic intercept mileage. Finally, one commenter believed that we should pay on a State-wide basis rather than on an individual carrier locality basis.

Response: Based on the comments, we are revising the payment methodology for paramedic intercept services (§ 405.502). Rather than basing the payment on the ALS rate minus the BLS rate, we will use the ALS rate minus 40 percent of the BLS rate. In the case of ALS intercept services, a full ALS service is being furnished except that the BLS ambulance cannot charge for the portion of the service it furnishes. In particular, the paramedic drives a "flycar" to the scene where the BLS crew is waiting with the beneficiary. (A "flycar" is the special vehicle that a paramedic drives to the BLS ambulance and that contains necessary medical supplies with which a BLS ambulance

is not equipped.) The paramedic transfers supplies and equipment from the flycar to the BLS ambulance and treats the beneficiary while the BLS ambulance crew drives the ambulance to the hospital. Because the BLS ambulance service is volunteer and cannot charge, we need to estimate the percentage of the service that is nonreimbursable. We estimate that the amount of the service that is furnished by the BLS volunteer ambulance is the nonlabor portion of the BLS ambulance service, which is about 40 percent of the total BLS payment allowance. The difference between the ALS payment rate and the BLS payment rate that we are paying is our estimate of the reimbursable costs of the equipment and supplies furnished by the paramedic as well as the labor portion that we are attributing to the paramedic intercept services. In addition, for administrative simplicity and equity of payment, we are establishing the rate on a carrier-wide basis, by using the median allowance from all localities within the individual carrier's jurisdiction. We are not paying mileage for the paramedic intercept because the intercept vehicle is not used to transport the beneficiary and Medicare covers only the mileage incurred to transport the beneficiary.

Comment: A commenter stated that the statute requires mandatory assignment of benefits for ambulance services effective January 1, 2000. This mandatory assignment would not allow the ALS intercept provider to recoup its cost from the beneficiary if the payment allowance remained less than the cost of furnishing the service.

Response: The mandatory assignment provision in the statute coincides with implementation of the ambulance fee schedule, which is currently being developed by a negotiated rulemaking committee. Mandatory assignment will not be implemented until payment under the fee schedule is implemented.

We note that, while this final rule sets forth a payment rate for paramedic intercept services in accordance with the authority in section 4531(c) of the BBA, section 4531(b) of the BBA requires the establishment of a fee schedule for Medicare ambulance services by negotiated rulemaking. This negotiated rulemaking process is currently underway and may result in a different payment rate from that provided in this final rule. We will set forth any new payment rate in the proposed rule that includes other provisions for the ambulance fee schedule. The subsequent final rule would supercede the provisions of this paramedic intercept final rule.

Finally, this rule affects only those paramedic intercept services that may be billed, and paid, by Medicare directly to the intercept provider. This rule will not affect any private arrangements between any BLS ambulance suppliers and providers of ALS services.

III. Provisions of the Final Rule for Paramedic Intercept Ambulance Services

Currently, under § 410.40(c), Medicare covers paramedic intercept services if they are furnished in a rural area as defined in § 412.62(f). We are revising § 410.40(c) to state that to qualify for Medicare coverage, paramedic intercept services must be furnished in an area that is designated as a rural area by any law or regulation of the State or that 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 Friday, February 27, 1992 (57 FR 6725)).

Additionally, we are revising the methodology for determining the payment rate. We are establishing the payment allowance on a carrier-wide basis, by using the median allowance from all localities within the individual carrier's jurisdiction. We chose the median because it is the most accurate statistical measure of central tendency of an array of numbers. We are also changing the formula. Rather than using the ALS rate minus the BLS rate, we are using the ALS rate minus 40 percent of the BLS rate. We will base Medicare payment for paramedic intercept services on the lower of the actual charge or the ALS rate minus 40 percent of the BLS rate. We are adding these payment rules as new paragraph (i) in § 405.502.

IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

V. Regulatory Impact Statement

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless the Secretary certifies that a rule will not have a significant economic impact on a substantial number of small entities. For purposes of the RFA, all suppliers of ambulance services are considered to be small entities. Individuals, carriers, and

States are not considered to be "small entities."

In addition, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 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 50 beds.

As illustrated below, the impact of this regulation does not meet the criteria under Executive Order 12866 to require a regulatory impact analysis; however, the following information, together with information provided elsewhere in this preamble, constitutes a voluntary analysis and meets the requirements of the RFA.

Effective with services furnished on February 24, 1999, Medicare began paying for paramedic intercept services that meet the conditions for coverage. When these services have been furnished to a Medicare beneficiary, the ALS paramedic intercept company has had an incentive to bill the beneficiary for the difference between its full charge for the intercept service and 80 percent of the Medicare payment rate if it believed that the Medicare payment rate was inadequate to cover the cost of the service. Now that the payment rate will be increased, we anticipate that the paramedic intercept suppliers will accept Medicare's rate and bill the beneficiary for only the applicable deductible and coinsurance amounts. This will benefit both the company and the beneficiary.

As we stated in the January 25, 1999 final rule with comment period, we believe that the only State in which the conditions described in section 4531(c) of the BBA exist is New York. After consultations with the ambulance industry in New York and examination of the Medicare program data, we estimate the volume of services that will be covered under this provision in a year will be between 2,000 and 4,000. The current payment rates for these services range from about \$88 to about \$162 depending upon the location of the service. A payment allowance of approximately \$262 per service (the difference between the carrier-wide payment allowance for ALS and 40 percent of the carrier-wide allowance for BLS) in western New York State, and approximately \$223 for the rest of the State yields a negligible cost compared to the current rates paid for these services. For paramedic intercept

services that meet the conditions for Medicare coverage, we estimate the total cost for the first year of implementation of this rule to be between \$200,000 to \$400,000. Because the Medicare Part B coinsurance and deductible provisions apply, the program portion of this cost is estimated to be between \$160,000 and \$320,000. The remainder of the cost will be the responsibility of beneficiaries.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any final rule that may result in an expenditure in any one year by State, local or tribal government, in the aggregate, or by the private sector of \$100 million. This final rule will not have an effect on the governments mentioned, and private sector costs will be less than the \$100 million threshold.

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

We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism. We have determined that it does not significantly affect the rights, roles, and responsibilities of States.

List of Subjects

42 CFR Part 405

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

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Rural areas, X-rays.

For the reasons set forth in the preamble, 42 CFR chapter IV is amended as set forth below:

PART 405—FEDERAL HEALTH INSURANCE FOR THE AGED AND DISABLED

A. Part 405, subpart E is amended as follows:

1. The authority citation for part 405, subpart E continues to read as follows:

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

2. In § 405.502, we are adding a new paragraph (i) to read as follows:

§ 405.502 Criteria for determining reasonable charges.

* * * * *

(i) Paramedic intercept ambulance services. (1) HCFA establishes its

payment allowance on a carrier-wide basis by using the median allowance from all localities within an individual carrier's jurisdiction.

(2) HCFA's payment allowance is equal to the advanced life support rate minus 40 percent of the basic life support rate.

(3) HCFA bases payment on the lower of the actual charge or the amount described in paragraph (i)(1) and (i)(2) of this section.

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

B. Part 410 is amended to read as follows:

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).

2. In § 410.40, the introductory text to paragraph (c) is republished, and paragraph (c)(1) is revised to read as follows:

§ 410.40 Coverage of ambulance services.
* * * * *

(c) Paramedic ALS intercept services. Paramedic ALS intercept services must meet the following requirements:

(1) Be furnished in an area that is designated as a rural area by any law or regulation of the State or that is located in a rural census tract of a metropolitan statistical area (as determined under the most recent Goldsmith Modification). (The Goldsmith Modification is a methodology to identify small towns

and rural areas within large metropolitan counties that are isolated from central areas by distance or other features.)
* * * * *

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program)

Dated: January 31, 2000.

Nancy Ann-Min DeParle,
Administrator, Health Care Financing Administration.

Dated: March 9, 2000.

Donna E. Shalala
Secretary.

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