

HIGHLIGHTS OF TREASURY OFFERING OF 45-DAY CASH MANAGEMENT BILL—Continued

Receipt of Tenders:	
Noncompetitive tenders	Prior to 11:00 a.m. Eastern Standard time on auction day.
Competitive tenders	Prior to 11:30 a.m. Eastern Standard time on auction day.
Payment Terms	By charge to a funds account at a Federal Reserve Bank on issue date, or payment of full par amount with tender.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 409, 410, and 424

[HCFA-1813-FC]

RIN 0938-AH13

Medicare Program; Coverage of Ambulance Services and Vehicle and Staff Requirements

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

ACTION: Final rule with comment period.

SUMMARY: This final rule with comment period revises and updates Medicare policy concerning ambulance services. It identifies destinations to which ambulance services are covered, establishes requirements for the vehicles and staff used to furnish ambulance services, and clarifies coverage of nonemergency ambulance services for Medicare beneficiaries. This rule also implements section 4531(c) of the Balanced Budget Act of 1997 concerning Medicare coverage for paramedic intercept services in rural communities.

DATES: *Effective Date:* These regulations are effective on February 24, 1999.

Comment Period: We will consider comments concerning Medicare coverage for paramedic intercept services in rural areas if we receive the comments at the appropriate address, as provided below, no later than 5 p.m. on March 26, 1999.

ADDRESSES: Mail written comments (an original and three copies) to the following address:

Health Care Financing Administration,
 Department of Health and Human Services, Attention: HCFA-1813-FC
 P.O. Box 7517, Baltimore, MD 21207-0517.

If you prefer, you may deliver your written comments (an original and three 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, Central Building, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Comments may also be submitted electronically to the following e-mail address: HCFA1813FC@hcfa.gov. For e-mail comment procedures, see the beginning of **SUPPLEMENTARY INFORMATION**. For further information on ordering copies of the **Federal Register** containing this document and on electronic access, see the beginning of **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: Robert Niemann, (410) 786-4569 for issues relating to payment for Paramedic Intercept Services. Margot Blige, (410) 786-4642 for all other issues.

SUPPLEMENTARY INFORMATION:

E-mail, Comments, Availability of Copies, and Electronic Access

E-mail comments must include the full name, postal address, and affiliation (if applicable) of the sender and must be submitted to the referenced address to be considered. All comments must be incorporated in the e-mail message because we may not be able to access attachments.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code HCFA-1813-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 443-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).

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512-1800 or by faxing to (202) 512-2250. The cost for each copy is \$8. As an alternative, you can view and photocopy the **Federal Register** document at most libraries designated as Federal Depository Libraries and at many other public and academic libraries throughout the country that receive the **Federal Register**.

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I. Background

A. 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.

B. Current 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.

II. Provisions of the Proposed Regulations

On June 17, 1997, we published a proposed rule in the **Federal Register** at 62 FR 32715 that would revise and update our ambulance regulations at § 410.40. Specifically, we proposed to provide coverage of ambulance services only if the supplier meets the proposed applicable vehicle, staff, and billing and reporting requirements and proposed medical necessity and origin and destination requirements. We also proposed to cover ambulance services in the United States at either the basic life support (BLS) or advanced life support (ALS) level of services. Under the proposed rule, we would base coverage on a beneficiary's medical condition as described by the International Classification of Diseases, 9th revision, Clinical Modification (ICD-9-CM) diagnosis codes; these codes would be used to bill for ambulance services. In addition, we proposed an exception to the ALS/BLS distinction for certain non-Metropolitan Statistical Areas.

We also proposed to provide for the coverage of nonemergency transportation, including but not limited to transportation for an end-stage renal disease (ESRD) beneficiary, if the ambulance supplier obtains a written physician's order certifying that the beneficiary be transported in an ambulance because other means of transportation are contraindicated.

Finally, we proposed to allow coverage of ambulance services for ESRD beneficiaries to the nearest treatment facility rather than to the nearest hospital-based facility.

III. The Balanced Budget Act of 1997

On August 5, 1997, after we had issued the ambulance services proposed rule, the Balanced Budget Act of 1997 (the BBA), Public Law 105-33, was enacted. Section 4531(b) of the BBA adds a new section 1834(l) to the Act, which provides for the establishment of a fee schedule for payment of ambulance services effective January 1, 2000. In addition, section 1834(l)(1) of the Act requires that the fee schedule be developed through a negotiated rulemaking process. Section 1834(l)(2)(B) of the Act provides that, in establishing the fee schedule, the Secretary must establish definitions for ambulance services that link payments to the types of services furnished.

As noted above, one of the provisions of the June 17, 1997 proposed rule would have defined ambulance services as either ALS or BLS services and linked the Medicare payment to the type of service (ALS or BLS) required by the beneficiary's condition. Under section 1834(l) of the Act, this type of service definition and resulting payment is required to be a part of the negotiated rulemaking. Therefore, we are deferring any final action on those provisions of the proposed rule. We will reopen the discussion of the definition of ambulance services and the appropriate payment as a part of the negotiated rulemaking process. We note, however, that our current policy, as stated in section 5116 of the Medicare Carriers Manual (MCM), which provides for the payment of two separate reasonable charge rates for ambulance services, one for BLS level of ambulance service and one for ALS level of service, remains applicable. In general, the ALS reasonable charge may be used as a basis for payment when an ALS level of ambulance service is provided. However, as stated in MCM section 5116.1, there may be instances when the supplier exhibits a pattern of uneconomical care such as repeated use of ALS ambulances in situations in which it should have known that the less expensive BLS ambulance was available and that its use would have been medically appropriate. While we allow higher payments for the ALS services, the carrier is responsible for evaluating the appropriate level of service for each claim.

In addition to providing for a fee schedule for ambulance services, section 4531(c) of the BBA authorizes the Secretary to include coverage of ALS services provided by a paramedic intercept service provider in a rural area if certain conditions are met. We are implementing this provision in this

final rule with comment period. We discuss, in detail, this provision and the changes to the regulations necessary to implement it, in section V of this preamble.

IV. Analysis of, and Responses to, Public Comments

In response to our proposed regulation published on June 17, 1997, we received 2,270 comments from ambulance service suppliers, emergency medical service personnel, ambulance associations, health care providers, Medicare contractors, and private citizens. As noted above, because we are not proceeding in this final rule with the proposed provisions related to basing coverage and payment of ambulance service on the level of medically necessary services, we are not responding to the comments we received concerning that proposal, including the use of ICD-9-CM diagnosis codes to determine medical necessity and the proposed exception to this policy for ALS services furnished in areas that are not part of a Metropolitan Statistical Area. We note that the vast majority of the comments concerned the definition of services as ALS or BLS. The remaining comments and our responses are set forth below.

A. Medicare Coverage of Ambulance Services—Basic Rule

In the proposed rule, we clarified in § 410.40(a) the circumstances under which an ambulance service is paid under Medicare Part B as opposed to Medicare Part A. We received one comment on this proposal.

Comment: A supplier commented that the proposed regulations are unclear on two points. First, they do not indicate the point at which Part A begins to cover transportation services and whether those services provided before admission to the hospital are covered under that Part or only those provided during the patient's hospital stay. Second, the proposed regulations seem to indicate that if a patient's stay in the hospital is covered by Part A, the ambulance service provided before admission and at discharge would be part of the Part A payment and could not be billed under Part B. If this is true, the commenter believed that this is a change in policy that would destroy many Part B ambulance services and be detrimental to hospitals.

Response: The proposed revisions to the regulations were made merely to clarify and restate current policy on the scope of benefits under Parts A and B of Medicare, not to make any change in policy. To explain the policy in this area, we must distinguish between

ambulance services, which are covered under Part B, and transportation services, which are covered under Part A. The movement of a beneficiary from his or her home, an accident scene, or any other point of origin to the nearest hospital, critical care access hospital (CAH) (formally known as a rural primary care hospital (RPCH)), or skilled nursing facility (SNF) that is capable of furnishing the required level and type of care for the beneficiary's illness or injury is covered, assuming medical necessity and other coverage criteria are met, only under Part B as an ambulance service. No Part A coverage is available because, at the time the beneficiary is transported, he or she is not an inpatient of any provider paid under Part A of the program. The transfer of a beneficiary from one provider to another (for example, from an acute care hospital to a long-term care hospital or to an SNF) is also not covered as a Part A provider service because, at the time the person is in transit, he or she is not a patient of either provider. This service may be covered under Part B.

However, once a beneficiary has been admitted to a hospital, CAH, or SNF, it may be necessary to transport the beneficiary to another hospital or other site for specialized care. In this instance, the specialized services are furnished under arrangements made by the hospital, CAH, or SNF. Following that treatment, the beneficiary is returned to the hospital, CAH, or SNF to complete the inpatient stay. This movement of the beneficiary is considered "patient transportation" and is covered as an inpatient hospital or CAH service under Part A of the program and as an SNF service when the SNF is furnishing it as a covered SNF service, and Part A payment is made for that service. Because the service is covered and payable as a beneficiary transportation service under Part A, the service cannot be classified and paid for as an ambulance service under Part B. This is not a change from current policy, but has been the policy since the inception of the Medicare program. In order to more clearly indicate that ambulance services are covered under Part A when the beneficiary is an inpatient of a hospital or CAH, we have revised the regulations at § 409.10 to include this service as a covered inpatient hospital or CAH service. We have also revised § 409.20 to include it as a SNF covered service.

We note that, as provided in §§ 412.2(c)(5)(iii)(B) and 413.40(c)(2)(iii)(B), ambulance services are specifically excluded from the preadmission payment window

provisions applicable to hospital inpatient services. That is, ambulance services furnished during the 3 days before the day of a beneficiary's admission to a hospital (or 1 day for hospitals excluded from the prospective payment system) may be paid under Part B and are not considered inpatient hospital services.

B. Medical Necessity

Under current regulations, Medicare covers transportation provided by an ambulance if the beneficiary must be transported by an ambulance because other means of transportation are contraindicated. In the June 1997 proposed rule (62 FR 32719), we proposed that if a beneficiary is "bed-confined," other means of transportation would be presumed to be contraindicated. We also proposed that "bed-confined" would be defined as the inability to—

- Get up from bed without assistance;
- Ambulate; and
- Sit in a chair, including a wheelchair.

We noted that we used this term synonymously with the terms "bedridden" or "stretcher-bound." However, it is not synonymous with "bed rest" or "nonambulatory."

In addition, nonemergency transportation would be covered only if, before furnishing the service, the ambulance supplier obtained a physician's written order certifying that the beneficiary must be transported in an ambulance because other means of transportation are contraindicated (§ 410.40(c)(2)). The physician's order must be dated no more than 60 days before the date the service is furnished. We received several comments on these proposed policies.

Comment: A Medicare carrier and a national renal association supported the definition of bed-confined as proposed. They believed that the definition ensures that ambulance services will be provided only to those individuals with the greatest need and the most severe physical limitations.

Response: We agree with the commenters. Our purpose in developing this definition was to identify as eligible for covered ambulance services only those individuals who are not able to be up and out of bed under any condition and cannot tolerate other methods of transportation.

Comment: Three commenters stated that the definition of "bed-confined" as proposed is too restrictive and that the policy eliminates transportation for many individuals who would "in reality have no other way of obtaining medical care."

Response: It is important to note that the Medicare law contains no provisions for "transportation," but rather provides for coverage of ambulance services. Section 1861(s)(7) of the Act allows Medicare coverage of ambulance services only when the use of other methods of transportation is contraindicated by the beneficiary's condition. The regulations reflect the intent expressed in the House Ways and Means Committee and Senate Finance Committee reports on H.R. 6675, the 1965 Social Security Amendments (H. Rep. No. 213 at page 36 and S. Rep. No. 404 at page 43) that ambulance transportation be covered only if " * * * normal transportation would endanger the health of the patient * * *". Therefore, a patient whose condition permits transport in any type of vehicle other than an ambulance would not qualify for ambulance services under Medicare Part B.

Comment: Seven ambulance suppliers stated that all factors relating to the beneficiary's condition should be considered in evaluating if a beneficiary has met the medical necessity criteria for ambulance service. That is, bed-confinement should not be the sole criterion used in determining medical necessity because it is only one factor. The commenters suggested that suppliers should provide documentation on why the beneficiary is bed-confined.

Response: It is always the responsibility of the ambulance supplier to furnish complete and accurate documentation to demonstrate that the ambulance service being furnished meets the medical necessity criteria. The fact that a definition of bed-confined has been adopted does not suggest that bed-confinement is the sole determinant of medical necessity nor does it relieve the supplier of his or her responsibility to submit adequate information supporting the reason for a bed-confinement determination.

Comment: Three ambulance suppliers disagreed that the proposed bed-confined definition should be synonymous with "stretcher-bound." They suggested that "stretcher-bound" refers to the beneficiary being secured to the stretcher and not specifically to the condition of the beneficiary. They asked that we clarify that stretcher-bound is not a synonym for "bed-confined."

Response: We agree with the commenters and will not use the term "stretcher-bound" in describing the medical condition of the beneficiary. We proposed a definition of "bed-confined" as a part of our proposal to use ICD-9-CM medical condition codes. The ICD-9-CM list set forth in the

proposed rule included the diagnosis code V49.8, Other Specified Problems Influencing Health Status. We added a definition of bed-confined which could be used in conjunction with this code. As noted above, we are not including the proposed medical necessity provision based on ICD-9-CM codes in this final rule. However, as a result of comments, as well as past questions, we have specified certain criteria that must be met in order for ambulance services to be covered. In accordance with § 410.40(d), nonemergency ambulance transportation would be covered if the beneficiary is unable to get up from bed without assistance.

Comment: One ambulance supplier commented that the proposed definition will cause undue hardship for the beneficiary, family, physician, and ambulance supplier because some beneficiaries are able to sit in a wheelchair for brief periods of time, but cannot tolerate a wheelchair for the period of time required for transport. Under the proposed definition, ambulance transportation furnished to beneficiaries such as these would not be covered.

Response: If there are circumstances associated with the beneficiary's condition that warrant the need for ambulance transportation, the documentation submitted on behalf of that beneficiary should reflect the condition and support the need for the services. That documentation will then be considered by the carrier in processing the claim.

Comment: Several ambulance suppliers and a national ambulance association commented that the proposed definition of "bed-confined" is too narrow and that most beneficiaries who can "technically sit in a chair or wheelchair momentarily" or be "restrained" to a chair or wheelchair would not meet the definition and would therefore be denied ambulance services. They also expressed the belief that the definition should be based on the condition of the beneficiary at the time of transport rather than any period before or after the transport. One of the commenters suggested that it is not safe to transport someone in a wheelchair who must be restrained in order to travel. To ensure that the definition allows those beneficiaries who are bed-confined to receive ambulance benefits, commenters suggested the following revisions for the definition of "bed-confined":

- Add the phrase "without assistance" to the second and third criteria of the proposed definition.
- Add the phrase "* * * the inability to ride in a moving vehicle without

being restrained to that chair" to the last criterion.

- Revise the third criterion to read "* * * the inability to sit for an extended period of time in a chair or wheelchair, without restraint."

• The phrase "without assistance" should be removed from the first criterion and the "and" be replaced with "or" so that if any one of the criteria is met, the beneficiary would be determined to be "bed-confined."

Response: In developing the proposed definition, it was our intent to describe clearly individuals who are completely confined to bed and unable to tolerate any activity out of bed. We recognize that it is standard and accepted medical practice in both hospitals and nursing homes to take steps to ensure that beneficiaries are up and out of bed as often as their condition permits. Such beneficiaries are not bed-confined. It is incumbent upon health care professionals responsible for the care of individual beneficiaries to determine what is safe for those beneficiaries. If it is determined that it is unsafe for a particular beneficiary to be unmonitored during transport, then the documentation submitted for that particular transport should support the need for ambulance transportation. That documentation will be considered by the carrier in processing the claim.

We considered whether it would be appropriate to include a time-frame with respect to the "bed-confined" definition. That is, adding a phrase such as "for more than 10 minutes" to the various criteria. Because of the difficulty associated with obtaining accurate information related to how long an individual may have been out of bed as well as the difficulty associated with efforts to substantiate such information, we determined that it would be inappropriate to employ the use of absolute terms if we did not intend to identify a means by which a time factor could be measured.

We do not believe it is necessary to make the proposed revisions on the basis that the proposed definition encompasses the variations requested by the commenters. We will however, revise the definition to clarify that all three components must be met in order for the patient to meet the requirements of the definition of "bed-confined".

Comment: A national ambulance association stated that because we did not define "emergency" and "nonemergency" in the proposed rule, ambulance suppliers will not know when physician certification is needed. The association does, however, support the need for physician certification, in 60-day intervals, for repetitive

transports. They recommended the following definition for repetitive patients:

"Multiple scheduled treatments (for example, dialysis or radiation therapy treatments) for the same diagnosis that requires ambulance transportation over an extended period of time."

Response: The applicable definition that we use to define emergency services is the definition set forth in section 1861(v)(1)(K)(ii) of the act, which defines the term "bona fide emergency services." This definition provides that an emergency service is one that 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; serious impairment to bodily functions; or serious dysfunction of any bodily organ or part. Any ambulance transportation service that does not meet these criteria would be a nonemergency service. This would include all scheduled transports (regardless of origin and destination), as well as transports to SNFs or to the beneficiary's residence. Medically necessary transports to and from dialysis facilities are scheduled and, therefore, are nonemergency ambulance services.

Comment: Four ambulance suppliers commented that the physician certification requirement should not apply to beneficiaries who reside at home or in facilities where they are not directly under the care of a physician.

Response: We agree that suppliers may often be unable to obtain the appropriate physician certificate for these patients for a unscheduled transport. We will revise the final regulations to provide that the physician certification will be required for these beneficiaries for scheduled, repetitive transports and scheduled, nonrepetitive transports because we can assume that beneficiaries who are scheduled for medical appointments are under a physician's care. In addition, for beneficiaries who reside in a facility and are under a physician's care, there should be little difficulty in obtaining the certificate for unscheduled transports. For nonemergency, unscheduled transportation of beneficiaries residing at home or in facilities where they are not under the direct care of a physician, the physician certification requirement will not apply.

Comment: Several commenters, including an Emergency Medical Services (EMS) Director, stated that nonscheduled, nonemergency transports

should be judged on their medical necessity and therefore exempt from the bed-confined requirement and that, to avoid unnecessary delays, it would be appropriate to obtain the physician certification with 48 hours after the ambulance service was furnished. The commenters do support use of a physician certification for those patients needing repetitive transports to receive specialized services.

Response: After considering the arguments and observations made by commenters, we concluded that we should proceed with our proposal to require physician certification for all nonemergency transports, both scheduled and unscheduled, except for the revisions discussed in the previous response to comments concerning beneficiaries who are not living in a facility directly under a physician's care. Nonemergency ambulance service is a Medicare service furnished to a beneficiary for whom a physician is responsible; therefore, the physician is responsible for the medical necessity determination. The physician certification requirement will help to ensure that the claims submitted for ambulance services are reasonable and necessary, because other methods of transportation are contraindicated. We believe that this requirement will help to avoid Medicare payment for unnecessary ambulance services that are not medically necessary even though they may be desirable to beneficiaries. However, we agree with the commenters that, to avoid unnecessary delays, for unscheduled transports, the required documentation can be obtained within 48 hours after the ambulance transportation service has been furnished. That is, it is not necessary that the ambulance suppliers have the physician certification in hand prior to furnishing the service. While it is reasonable to expect that an ambulance supplier could obtain pretransport physician certification for routine, scheduled trips, it is less reasonable to impose such a requirement on unscheduled transports. Therefore, we have revised the final regulations to reflect this change.

Comment: Two ambulance suppliers commented that physicians are unaware of the coverage requirements for ambulance services and that their decisions to request ambulance services may be based on "family preference or the inability to safely transport the beneficiary by other means rather than on the medical necessity requirement imposed by Medicare."

Response: Section 1861(s)(7) of the Act allows for Medicare coverage of ambulance services only when the use

of other methods of transportation is contraindicated by the beneficiary's condition. If the ability to safely transport the beneficiary, given the beneficiary's condition, is at issue, then the supplier may obtain from the physician the necessary documentation supporting the reason for the transportation. If the decision to use ambulance services is based on the convenience of the beneficiary, the beneficiary's family, the beneficiary's physician, or some other element of personal preference, Medicare coverage is not available.

To facilitate awareness of the Medicare rules as they relate to the ambulance service benefit, ambulance suppliers may need to educate the physician (or the physician's staff members) when making arrangements for the ambulance transportation of a beneficiary. Suppliers may wish to furnish an explanation of applicable medical necessity requirements as well as requirements for physician certification and to explain that the certification statement should indicate that the ambulance services being requested by the attending physician are medically necessary.

C. Origins and Destinations

In the proposed rule, we added a provision that allowed coverage of round-trip ambulance transportation for an ESRD beneficiary living at home to the nearest treatment facility capable of furnishing the necessary dialysis service regardless of whether the dialysis facility is located at a hospital. We currently cover the ambulance services only if the beneficiary is transported to a hospital-based facility for dialysis.

Comment: Several commenters, including a consortium of EMS Directors, renal associations, and dialysis facilities, believed that the proposed change concerning transportation to the nearest dialysis facility is not in the best interest of the beneficiary and that it will have an impact on the continuity of beneficiary care. That is, beneficiaries who have been receiving dialysis at the nearest hospital-based treatment facility may now be forced to go to another, closer nonhospital treatment facility. The commenters recommended that we allow for transport to the nearest facility where there is an "existing, established beneficiary care relationship" and the facility has an "available bed."

Response: While we were developing the proposed regulation, concerns were raised by representatives of the renal community that the current policy was detrimental to beneficiaries with ESRD because it forced some of them to travel

great distances to a hospital for dialysis when the same services were available closer to their homes. In response to these concerns, we proposed to allow coverage of ambulance services to the nearest appropriate dialysis facility. This policy is consistent with our general ambulance policy, set forth in section 2120.3.F of the MCM, for emergency services which, in general, limits payment for otherwise covered ambulance transportation services to the nearest facility capable of furnishing care.

If the closest dialysis facility is not able to perform the type of treatment the beneficiary requires or is unable to accommodate the beneficiary for another reason, for example, lack of capacity, then Medicare will pay for the beneficiary to be transported to the more distant facility. It is, of course, the prerogative of the beneficiary to choose the facility where he or she wishes to be treated. If the beneficiary decides to be transported to a facility farther away, and it is determined that the nearer facility was capable of providing the required type and level of care, Medicare payment for the ambulance service is limited to the amount that would have been paid to transport the beneficiary to the nearest appropriate dialysis facility.

Comment: Three ambulance suppliers commented that we should consider paying for other forms of transportation for ESRD beneficiaries.

Response: As noted above, the only transportation service covered by Medicare is that set forth at section 1861(s)(7) of the Act. That section allows Medicare coverage for ambulance services only when the use of other methods of transportation are contraindicated by the beneficiary's condition. We believe Congress made a distinction between "transportation by ambulance" and "normal transportation." We believe Congress intended, by this distinction that Medicare coverage be limited to ambulance services for beneficiaries who could not reach care any other way. Thus, a beneficiary whose condition permits transfer in any vehicle other than ambulance would not qualify for Medicare Part B payment.

Comment: A State ambulance association and a hospital-based ambulance provider commented that the proposed change for ESRD beneficiaries will increase the number of transports and the incidence of fraud and abuse.

Response: The proposed change in the policy for ESRD beneficiaries does not expand the coverage of transportation for these beneficiaries; it merely changes the allowable destinations for dialysis

treatment. We concluded the transporting ESRD beneficiaries from their residence to the nearest appropriate dialysis facility to receive medically necessary dialysis services could result in a cost savings to the Medicare program through the substitution of shorter trips for unnecessarily long trips and, in some cases, ambulance trips to distant hospital-based facilities to obtain dialysis. This modification, coupled with the 60-day physician certification requirement for nonemergency, scheduled ambulance transports and the medical necessity determination, provides limitations that should prevent inappropriate coverage of ambulance services furnished to ESRD beneficiaries. Therefore, we anticipate that this revision to the Medicare ambulance services policy will not result in an increased number of transports or an increase in the incidence of fraud and abuse.

Comment: Three ambulance suppliers commented that, in order to decrease the burden on local emergency rooms and to provide most cost-effective service, HCFA should consider expanding the allowable destinations for ambulances transportation to include physician's offices, urgent care facilities, and freestanding radiological facilities. In support of this recommendation, one supplier indicated that the Omnibus Reconciliation Act of 1980 (Public Law 96-499) specifically covered ambulance transportation to freestanding radiological facilities.

Response: Although we proposed to allow ESRD beneficiaries residing at home to receive medically necessary ambulance transportation to the nearest appropriate dialysis facility, even if that facility is not hospital-based, we are not proposing to extend ambulance coverage for transport to other facilities or for other populations of beneficiaries. In making our decision to expand the destination sites for ESRD beneficiaries, we considered the fact that many beneficiaries who are confined to home may have a broader range of needs on a routine basis, such as visits to the physician, for which they might wish to have ambulance transportation could be available. However, an expansion of this type would be difficult to monitor to ensure that the ambulance services benefit was being used only for medically necessary transportation where all other means of transportation were unacceptable. Without built-in limitations (for example, routinely requiring the use of physician certifications) and extensive rules for determining when the need for medical

services justifies coverage of ambulance transportation, the ambulance services benefit could easily become a benefit for general transportation services, which would be inconsistent with Congressional intent and program history.

It is also important to note that, generally, Medicare does not provide coverage for ambulance transportation to a physician's office, for example, transportation to a physician's office for a follow-up visit with an attending physician. There are two exceptions to this rule. First, under Medicare Part A, we cover ambulance transportation of hospital or SNF inpatients to the nearest appropriate treatment facility including a physician's office to obtain medically necessary diagnostic or therapeutic services not available at the institution where the beneficiary is an inpatient. This exception may be applied only if the services cannot reasonably be brought to the beneficiary or the cost of transporting the beneficiary is less than the cost of bringing the services to the beneficiary. Second, if while transporting a beneficiary to a hospital, the ambulance stops at a physician's office because of the beneficiary's dire need for professional attention, and, immediately thereafter, the ambulance continues to the hospital, Medicare coverage may be available.

The House Report of the Committee on the Budget that accompanied Public Law 96-499 did recommend that we consider including coverage of round-trip ambulance transportation for beneficiaries in SNFs or confined to their homes to obtain medically necessary radiological services furnished in a nonhospital setting. However, the suggestion to provide coverage for round-trip ambulance transportation services to freestanding radiological facilities was not included in the final provisions of the law.

D. Requirements for Ambulance Suppliers

1. Vehicles

We proposed that any vehicle used as an ambulance must be designed and equipped to respond to medical emergencies and, in nonemergency situations, be capable of transporting beneficiaries with acute medical conditions. The vehicle must also comply with all applicable State and local laws governing the licensing and certification of an emergency medical transportation vehicle. In addition, we proposed that, at a minimum, the ambulance must contain a stretcher, linens, emergency medical supplies, oxygen equipment, and other lifesaving

emergency medical equipment and be equipped with emergency warning lights, sirens, and two-way telecommunications.

Comment: Several ambulance suppliers commented that requiring "two-way telecommunications" is unnecessary, cost prohibitive, and not practical for rural areas. One commenter suggested that the requirement be revised to state, "* * * be equipped with telecommunications equipment as required by State or local law, to include, at a minimum, one two-way voice radio or wireless telephone."

Response: We agree that the commenter's alternative will satisfy our needs for safety and efficiency. We have decided, therefore, that we will adopt the commenter's suggestion.

Comment: Three ambulance suppliers commented that the reference to "lifesaving equipment" is vague. One commenter suggested that we specifically enumerate the ALS equipment required.

Response: It is our intent to defer to State or local requirements where vehicle equipment and personnel certification requirements are concerned. In addition, a review of the proposal reflects an inadvertent omission of the phrase "* * * as required by State or local law"; therefore, § 410.41(a) will be revised accordingly.

2. Vehicle Staff

We proposed staffing requirements at both the BLS and ALS level of service. As proposed, a BLS vehicle would have to be staffed by at least two persons, each trained to provide first aid and certified as an emergency medical technician-basic (EMT-B) by the State or local authority where the services are furnished and legally authorized to operate all lifesaving equipment on board the vehicle.

An ALS vehicle would need to include at least two persons: one person trained to provide basic first aid at the EMT-B level and one person trained and certified as a paramedic or emergency medical technician-advance (EMT-A) who is also trained and certified to perform one or more ALS services. The EMT-A or paramedic would have had to be certified by the State in which the services are furnished and legally authorized to operate all lifesaving equipment on board the vehicle.

Comment: Several ambulance suppliers commented that the proposed staffing requirements are contrary to existing State standards and the proposed requirement that a BLS ambulance be staffed with two EMTs

would have a detrimental effect on volunteer companies. The commenters recommended that we revise the staffing requirements to defer to State or local requirements for ambulance staffing. Many comments pointed out that the State EMS offices set the minimum staffing level requirements.

Response: We agree with the commenters that it is sufficient for Medicare purposes if the BLS vehicle staffing meets the State and local laws. Based on a review of the comments, we acknowledge that a requirement for a minimum of two EMTs, as proposed, has the potential of placing considerable burden on volunteer ambulance services and may possibly lead to the elimination of such services, particularly in rural areas. We will revise the regulations accordingly.

Comment: Three suppliers requested that we define the following terms: EMT-A, EMT-B, and paramedic.

Response: Based on comments received in response to the proposed regulation, we acknowledge that the terms EMT-A and EMT-B are no longer used by the EMS industry; thus, we are deleting reference to EMT-A and EMT-B. We will, however, maintain our proposed requirement that if an ALS staff member is authorized, under State or local laws, to operate as an ALS crew member, then the EMT must be certified to perform one or more ALS services. The term "paramedic" is defined by State and local laws.

3. Billing and Reporting Requirements

In the proposed rule, we stated that we would require ambulance suppliers to use the HCFA Common Procedure Coding System (HCPCS) codes to describe the origin and destination of ambulance trips. We also proposed that, at the carrier's request, a supplier would complete and submit an ambulance supplier form established by HCFA and provide the carrier with documentation of the supplier's compliance with State and local emergency vehicle and staff licensure and certification requirements. In addition, suppliers would be required to provide any information requested by the carrier for purposes of documenting the ambulance supplier's compliance with the regulations and to support claims processing.

Comment: A majority of the commenters objected to the proposed billing and reporting requirements on the ground that they are unfunded mandates that are burdensome and in excess of the informational updates required at the State or local level. They also believe that the carriers should not be allowed unlimited access to records,

many of which are protected under other Federal laws and regulations.

Response: Current Medicare instructions (section 2120.1 of the MCM) require ambulance suppliers to submit a statement and other documentary evidence that their vehicles and personnel meet all of the requirements set by State or local authorities. The guideline specifies that, in addition to the submission of documentary evidence, the statement should describe the equipment and beneficiary care items with which the vehicles are equipped, the extent of first-aid training acquired by personnel staffing those vehicles and the supplier's agreement to notify the carrier of any changes in operation that would affect the coverage of the supplier's ambulance services. Our intent in proposing that suppliers complete a HCFA-developed Ambulance Supplier Form was to promote consistency in the collection of this already-required information as well as make it easier for suppliers by providing them with a preprinted form to complete.

Current guidelines also specify that when the required information is not submitted or whenever there is a question about the supplier's compliance with the requirements, the carrier should take appropriate action. The appropriate action may include conducting an on-site visit as well as requesting additional information. We disagree with commenters that the proposed requirement allow unlimited access to protected records. This requirement formalizes, in a consistent format, an informational requirement that has been in effect for several years.

Based on comments, we will revise the final regulations to clarify that, upon carriers' request, suppliers will be required to submit additional information and documentation as it relates to vehicle and personnel operations. That is, suppliers will not be required to automatically submit information and documentation for each new vehicle that is purchased or crew member that is hired.

Comment: Several suppliers stated that verification of compliance information should be obtained from State databases and not directly from the ambulance supplier.

Response: To coordinate the transfer of information between various State computer systems and the systems used by our Medicare contractors could present administrative problems for the State as well as the carrier. We would also need to take into consideration system capabilities, compatibility, and the potential cost to the State, carrier,

HCFA, and the supplier. We are not requiring the submission of documentation that is inconsistent with information suppliers are already required to report to the State or local authority. This provision requires suppliers to complete the standardized Ambulance Supplier Form and to photocopy documentation already in their possession.

Comment: One ambulance supplier commented that the Ambulance Supplier Form appears to contradict the information provided in the HCFA-855, Medicare Provider/Supplier Enrollment form. The supplier questioned whether the State ambulance license will be acceptable in lieu of vehicle and staffing information required on the HCFA-855 application.

Response: The HCFA-855 is required to be completed by all providers and suppliers who wish to enroll in the Medicare program (except for those who are required to enroll through the survey and certification process). The information being requested on that form is used to determine eligibility and to make proper payments under the Medicare program. Attachment 2 of the HCFA-855 Enrollment Application form indicates that, "If you are licensed by your State as an Ambulance Supply Service, you are not required to submit the information on the supplier form Attachment 2." The information that Attachment 2 requires related to vehicle descriptions for each vehicle including specifying the type of vehicle, license number, and the list of first-aid, ALS equipment, if applicable, safety and other care items. Even in instances where a supplier does complete the Ambulance Supplier Form shown in the attachment, because the service is not licensed by the State, the company would still be required to submit to the carrier evidence of recertification. This is the same requirement imposed on suppliers who are State licensed. The enrollment form instructions specify that evidence of vehicle and personnel recertification must be submitted to the carrier on an ongoing basis and that copies of applicable certificates and licenses should be included. This instruction guideline is applicable to all ambulance service suppliers.

In conclusion, the proposed billing and reporting requirements, which require submission of the Ambulance Supplier Form, are not new requirements. This form is the method by which suppliers will submit evidence of vehicle and crew recertification. The form was developed to provide a consistent format for the collection of verification of compliance

information currently required by Medicare instructional guidelines.

V. Paramedic Intercept Provisions of the BBA

Paramedic intercept services are ALS services delivered by paramedics who 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 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 agency, typically a hospital or proprietary emergency medical service, dispatches a paramedic to meet the BLS ambulance at the scene or en route to the hospital. The ALS paramedics then provide their services to the beneficiary.

This tiered approach to life-saving may be cost effective in many areas because most volunteer ambulances do not charge for their service, and one paramedic service can cover many communities. Under current policy, Medicare payment may be made for these services only when the claim is submitted by the ambulance provider (that is, the actual transporting ambulance unit). Payment cannot be made directly to the intercept service supplier because there is no benefit category in the Medicare statute for the intercept service itself. With the limited exception provided in section 4531(c) of the BBA (discussed below), the only statutory basis for covering these services is under section 1861(s)(7) of the Act, as an integral part of the ambulance transportation benefit. In a jurisdiction that prohibits volunteer ambulances from billing Medicare and other health insurance, the intercept service cannot be paid for treating a Medicare beneficiary and is forced to bill the beneficiary for the intercept service.

Section 4531(c) of the BBA provided that the Secretary could include limited coverage of these intercept services provided in a rural area; that is, payment may be made directly to the agency providing the paramedic service. However, the services could be covered only if they are provided 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, the volunteer ambulance service involved must meet all of the following requirements:

- Be certified as qualified to provide ambulance services for purposes of this provision.

- Provide only BLS services at the time of the intercept.

- Be prohibited by State law from billing for any service. Finally, the entity providing the ALS paramedic intercept service must meet the following requirements:

- Be certified as qualified to provide the services under the Medicare program.

- Bill all Recipients who receive ALS paramedic intercept services from the entity, regardless of whether or not those recipients are Medicare Beneficiaries.

We are revising § 410.40 to include these provisions. We are defining 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). A rural area is any area outside of a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA) as defined by the Office of Management and Budget. (Please see Tables 4A and 4B in the final rule in the July 31, 1998 **Federal Register** entitled, Health Care Financing Administration, Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 1999 Rates; Final Rule.)

Although it provided the Secretary with the authority to cover ALS paramedic intercept services under certain conditions, section 4531(c) of the BBA did not specify what the payment should be for those services. We considered three different methods of payment for these services.

First, we considered paying the full ALS payment rate. We discussed the issue with several ambulance companies that furnish paramedic intercept services, that believe that the total cost of providing these services is virtually the same as that of providing the full ALS ambulance service. In addition, because these services are furnished in rural areas, there is a low utilization rate that raises their cost per service. That is, the paramedic intercept service has the same fixed costs as ambulance company (i.e., flycar vehicle, life saving equipment, labor and overhead) but these costs are spread over only 2 or 3 calls per day, whereas the typical ALS ambulance company has 30 to 40 calls per day.

A second option would be to pay for intercept services based on the difference between the ALS ambulance service rate and the BLS ambulance service rate. This would place a value on the intercept service consistent with the fact that the full ALS service is comprised of two components: the

intercept service and a transport service. The transport would be valued at the BLS rate and the intercept service would be valued as the difference between the ALS rate and the BLS rate.

Finally, we could pay the average salary of a paramedic multiplied by the average amount of time involved for an intercept service. While this option would cover the costs associated with the paramedic's services during an intercept, it would not recognize other costs such as standby time, the vehicle used by the paramedics, medical equipment carried on that vehicle, and other overhead expenses.

After examining these options, we believe the best option would be the second option; that is, pay the difference between the ALS payment rate and the BLS payment rate. If we were to pay the full ALS rate, we would be recognizing the intercept service as virtually equivalent to the full ALS ambulance service. However, the ALS ambulance service is actually equivalent to a paramedic intercept service plus a transport service. We do not believe that it is appropriate to price a component of the ALS service at the same rate as the total ALS service. However, to pay only the costs of the paramedics' services does not recognize the additional costs associated with furnishing the BLS service.

We believe the second option balances 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 would to an ambulance company that provides both the transport and the paramedic service. If we pay 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 to bill the program for the transport.

VI. Provisions of the Final Regulations

Other than the changes made to implement section 4531(c) of the BBA, those provisions of this final rule that differ from the proposed rule are as follows:

- We are revising §§ 409.10 and 409.20 to clarify that ambulance services are covered under Medicare Part A as hospital, CAH, and SNF inpatient services.

- We have revised the medical necessity requirements in § 410.40(d) to specify when a beneficiary can be determined to be bed-confined and,

thus, potentially eligible for ambulance services.

- We have revised the physician certification requirements for nonemergency, unscheduled ambulance services in § 410.40(d). In cases where a beneficiary requires a nonemergency, unscheduled ambulance transport, the written physician certificate can be obtained 48 hours after the ambulance transportation has been furnished. We are also revising the regulations to provide that in situations where nonemergency, unscheduled ambulance transportation is required for beneficiaries residing at home (private residence) or in facilities where they are not under the direct care of a physician, the physician certification will not be required.

- We have revised the provision in § 410.41(a) that identifies the minimum equipment required on a vehicle used as an ambulance, to require that a vehicle used as an ambulance must be equipped with telecommunication equipment as required by State or local law, to include, at a minimum, one two-way voice radio or wireless telephone.

- We have revised § 410.41(b), which established minimum vehicle staffing requirements for both the BLS and ALS level of service. For BLS vehicles, we require that, at a minimum, the staff must meet staffing requirements established by State or local authorities.

For ALS vehicles, we have revised this provision to delete reference to EMT-A and EMT-B designations.

VII. Collection of Information Requirements

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

- Whether the information collection is necessary and useful to carry 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.

Section 410.40 Coverage of Ambulance Services

The information collection requirements in § 410.40 require the ambulance supplier to obtain written certification from the beneficiary's

attending physician certifying that the medical necessity requirements of paragraph (d)(1) of this section are met, before furnishing non-emergency, scheduled ambulance services. The physician's order must be dated no earlier than 60 days before the date the service is furnished. And, for nonemergency, unscheduled ambulance services for a resident of a facility who is under the care of a physician, the ambulance supplier must obtain the written certification, within 48 hours after the transport, from the beneficiary's attending physician certifying that the medical necessity requirements of paragraph (d)(1) of this section are met.

The requirement for the physician's certification does not require a particular form or format and can be simply a written statement to describe the beneficiary's condition that supports the need for ambulance services. Some suppliers have developed their own physician certification forms. We estimate that a physician's certification could take, on average, 10 minutes of the physician's time per beneficiary and, in cases involving repetitive transports, one certificate could be used by the supplier for a 60-day period. The following chart shows the potential paperwork burden that may be imposed on physicians by this final rule.

ESTIMATED PAPERWORK BURDEN ON PHYSICIANS

CFR Section	Estimated annual number of ambulance trips per supplier (9,000 suppliers) requiring certification statements	Estimated average time in minutes to complete each statement (Minutes)	Estimated total annual burden for all physicians combined (9,000 × 3,000 certificates per supplier × 10 minutes) (Hours)
410.40(d)(2) & (3)(i)	3,000	10	4,500,000

In addition, suppliers will be required to retain all physician certifications on file and make the certifications available upon request by the Medicare carrier or intermediary. The burden associated with this requirement is the time required for the supplier to retain the physician certification. We estimate that this could take, on average, 2 minutes to file each physician certification. Given that we estimate 3,000 certifications per year, the total burden associated with these requirements is 6,000 minutes or 100 annual hours, per supplier. The total burden imposed by the requirements of this section are 4,500,000 hours for all physicians and (9,000 × 100 hours record keeping) 900,000 hours for suppliers. This paperwork burden requirement will

impact all physicians. We estimate that there are 500,000 physicians. Total burden hours imposed on physicians times \$15 (the estimated hourly cost for an administrative employee to complete the form, less the attending physician's signature) equals an additional cost of \$67.5 million for physicians and a cost of \$9 million for ambulance suppliers.

Section 410.41 Requirements for ambulance suppliers

This section requires an ambulance supplier to bill for ambulance services using HCFA-designated procedure codes to describe origin and destination and indicate on the claims form that the physician certification is on file and available for review upon request by the Medicare carrier or intermediary. The

burden associated with this requirement is captured during the completion of the HCFA 1500/1491 common claim file form, approved under OMB number 0938-0008. Therefore, we are assigning one token-hour of burden for this requirement.

This section also requires, upon a carrier's request, an ambulance supplier to complete and return the attached Ambulance Supplier Form and to submit documentation of emergency vehicle and staff licensure and certification requirements in keeping with State and local laws to the Medicare carrier.

This requires completion of the Ambulance Supplier Form, photocopying documentation already required by State or local laws and in

the possession of the supplier, and sending those copies, along with the completed form to the carrier. We will require ambulance suppliers to complete the Ambulance Supplier Form on an annual basis or in keeping with licensure or certification requirements established by State or local laws. It is our understanding that an

overwhelming number of States require ambulance supplier licensure or certification renewal on an annual basis.

Our decision not to state a specific time frame, for example requiring annual submission of the documentation, in which ambulance suppliers will be required to submit the form took into consideration the potential burden on those suppliers

operating in areas with renewal requirements other than on an annual basis. It is estimated that the time to complete this form is no more than 32 minutes.

The following chart shows the potential paperwork burden that may be imposed on ambulance suppliers by this final rule.

ESTIMATED ANNUAL SUPPLIER REPORTING BURDEN

CFR Sections	Estimated no. of ambulance suppliers	Estimated average burden per response (Minutes)	Estimated annual burden (Hours)
410.41(c)(2) ambulance supplier form and documentation	9,000	32	4,530

We have submitted a copy of this final rule to OMB for its review of the information collection requirements in §§ 410.40 and 410.41. The information collection requirements are not effective until they have been approved by OMB. A notice will be published in the **Federal Register** when approval is obtained.

If you comment on these information collection and record keeping requirements, or the attached form, please mail copies directly to the following:

Health Care Financing Administration,
Office of Information Services,
Security and Standards Group,
Division of HCFA Enterprise
Standards, Room C2-26-17, 7500
Security Boulevard, Baltimore, MD
21244-1850, Attn: John Burke,
HCFA-1813-FC, or
Office of Information and Regulatory
Affairs, Office of Management and
Budget, Room 10235, New Executive
Office Building, Washington, DC
20503, Attn: Allison Herron Eydt,
HCFA Desk Officer

VIII. 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.

First, this final rule was initiated partly because of the concern over the rapid increase in the cost to the Medicare program for furnishing ambulance services to beneficiaries. This rapid increase in expenditures can be attributed to a variety of causes that include the following:

- High costs for equipment, supplies, and trained personnel incurred by all ambulance suppliers are passed on to the public.
- Provision of nonemergency, scheduled ambulance services to ESRD beneficiaries for treatment or therapy to hospital-based facilities that may be farther away from the beneficiary's home than nonhospital-based facilities offering the same service. These transports cost the Medicare program more because of the higher mileage charges.

• Erroneous Medicare payment of claims for ambulance services from suppliers using nonemergency vehicles that transport beneficiaries whose medical condition is such that transportation in an ambulance is unnecessary.

Second, we believe the policies contained in this rule will result in the consequences outlined below:

- The requirement that ambulance services be furnished in a vehicle equipped and staffed to respond to a medical emergency or an acute care situation will improve the overall quality of services furnished to beneficiaries and eliminate payment for transportation services that are furnished in a vehicle not equipped or staffed to provide ambulance services. This particular aspect of the final rule may cause some suppliers to have to upgrade their vehicles, equipment or staff training and certification so that the vehicles meet the definition of an ambulance. There may be some, however, who may not be able to upgrade their vehicles or staff. We do not know how many suppliers this requirement would affect; however, because we believe the entities that may be affected by this final rule primarily provide transportation services, such as wheelchair van transportation, we do not believe the number to be substantial.

- The requirement for physicians to certify the need for scheduled and certain unscheduled, nonemergency ambulance services for beneficiaries to receive therapy or treatment will ensure that those beneficiaries receiving the ambulance services actually require that level of transport.

—This requirement will affect all physicians. We estimate that there are 500,000 physicians. Total burden hours imposed on physicians times \$15 (the estimated hourly cost for an administrative employee to complete the form, less the attending physician's signature) equals an additional cost of \$67.5 million for physicians and a cost of \$9 million for ambulance suppliers.

—The physician certification provision also affects the suppliers:

- The physician certification provision requires, in situations

involving scheduled, nonemergency transportation, suppliers to obtain, from the beneficiary's attending physician, a written physician's order certifying the need for ambulance transportation. The certification is renewable every 60 days. Many suppliers currently provide carriers with similar documentation to certify medical necessity when transporting beneficiaries with ESRD. In cases where a beneficiary requires a nonemergency, unscheduled ambulance transport, the supplier must obtain, from the beneficiary's attending physician, the physician's written certificate 48 hours after the ambulance transportation has been furnished.

- The billing and reporting provision set forth in § 410.41(c)(2) requires ambulance suppliers to verify compliance with State or local licensure and certification requirements. This provision does not require the submission of information that is inconsistent with information suppliers provide to State or local authorities. Suppliers are already required to complete the standardized HCFA-Ambulance Supplier Form and submit the appropriate documentary evidence. This provision will require the photocopying of documentary evidence in the possession of the supplier.

—The provision permitting ESRD beneficiaries to be transported to the nonhospital-based facilities nearest their home will be more convenient, since they will no longer have to be transported to hospital-based facilities that may be farther away. In addition, for those beneficiaries this is a more cost-effective policy since regularly transporting beneficiaries farther from their homes is more costly.

- For the first time, Medicare payment may be made for paramedic intercept services that meet the conditions for coverage. Currently, when these services have been provided to a Medicare beneficiary, the ALS paramedic intercept company has been free to bill the beneficiary for the full charge of the intercept service because it was not a covered service. Now that the service is covered, Medicare payment will be made to the intercept company, and the beneficiary will be responsible for only the applicable deductible and coinsurance. This will benefit both the company and the beneficiary.

The only State that we are aware of 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. A payment allowance of \$150.00 per service (the difference between the average allowance for ALS and the average allowance for BLS in New York) yields a negligible cost. Because the Medicare Part B coinsurance and deductible provisions apply, the program payment will be between \$240,000 and \$480,000. 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 with comment period that may result in an annual expenditure by State, local or tribal government, in the aggregate, or by the private sector of \$100 million. The final rule with comment period will not have an effect on the governments mentioned, and private sector costs will be less than the \$100 million threshold. The physician certification provision requires, in situations involving scheduled, nonemergency transportation, suppliers to obtain, from the beneficiary's attending physician, a written physician's order certifying the need for ambulance transportation. The certification is renewable every 60 days. Many suppliers currently provide carriers with similar documentation to certify medical necessity when transporting beneficiaries with ESRD. In cases where a beneficiary requires a nonemergency, unscheduled ambulance transport, the supplier must obtain, from the beneficiary's attending physician, the physician's written certificate 48 hours after the ambulance transportation has been furnished.

The billing and reporting provision set forth in § 410.41(c)(2) requires ambulance suppliers to verify compliance with State or local licensure and certification requirements. This provision does not require the submission of information that is inconsistent with information suppliers provide to State or local authorities. Suppliers are already required to complete the standardized HCFA-Ambulance Supplier Form and submit the appropriate documentary evidence. This provision will require the photocopying of documentary evidence in the possession of the supplier.

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

IX. Other Required Information

A. Waiver of Notice of Proposed Rulemaking

This final rule contains a provision relating to ambulance services that was not included in the proposed rule published on June 17, 1997. That provision, the limited Medicare coverage of paramedic intercept services in rural areas, was authorized by section 4531(c) of the BBA. We ordinarily publish a notice of proposed rulemaking in the **Federal Register** to provide a period for public comment before the provisions of the final rule take effect. However, we may waive that procedure if we find good cause that prior notice and comment are impracticable, unnecessary, or contrary to the public interest.

As explained in detail in section V of this preamble, section 4531(c) of the BBA authorizes us to provide coverage of paramedic intercept services under very limited conditions, which are specifically stated in the law. Because of the specificity of the law, we have little discretion in the manner in which we implement this extension of the ambulance benefit.

This provision was not included in the proposed rule because publication of the proposed rule predated enactment of the BBA. Nonetheless, we have received many letters requesting that we implement the provision as soon as possible. As discussed above, this change will allow suppliers of paramedic intercept services that meet the statutory requirements to receive payment for those services. Because those suppliers are now prohibited from billing Medicare for their services, Medicare beneficiaries are responsible for paying the full charge for the services. We believe that it is appropriate to implement this change as soon as possible to reduce the burden on Medicare beneficiaries who must pay for these services out-of-pocket. Thus, we find that, in this case, prior notice and comment would be impracticable and unnecessary, therefore, we find good cause to waive proposed rulemaking for the revisions set forth at § 410.40(c) and to issue these regulations as final. However, we are providing a 60-day period for public comment, as indicated at the beginning of this rule, on these changes.

B. Response to Comments

Because of the large number of items of correspondence we normally receive on **Federal Register** documents published for comment, we are not able to acknowledge or respond to them individually. Comments on the

paramedic intercept provision will be considered if we receive them by the date specified in the DATES section of this preamble. We will not consider comments concerning the provisions of this final rule that were published in the June 17, 1997 proposed rule, whether those provisions are presented in this final rule as unchanged or have been revised based on public comment.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

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

42 CFR Part 424

Emergency medical services, Health facilities, Health professions, Medicare. 42 CFR Chapter IV is amended as set forth below:

Part 409—HOSPITAL INSURANCE BENEFITS

A. Part 409 is amended as set forth below:

1. The authority citation for part 409 continues to read as follows:

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

§ 409.10 [Amended]

2. In § 409.10, the following amendments are made:

a. In paragraphs (a)(1) through (a)(5), the semicolon at the end of each paragraph is removed, and a period is added in its place.

b. In paragraph (a)(6), the words "services; and" are removed, and "services." is added in their place.

c. A new paragraph (a)(8) is added to read as follows:

§ 409.10 Included services.

(a) * * *

(8) Transportation services, including transport by ambulance.

* * * * *

§ 409.20 [Amended]

3. In § 409.20, the following amendments are made:

a. In paragraph (a), the period at the end of the introductory text is removed, and a colon is added in its place.

b. In paragraph (a)(1) through (a)(5), the semicolon at the end of each paragraph is removed, and a period is added in its place.

c. In paragraph (a)(6), ";" and " is removed, and a period is added in its place.

d. A new paragraph (a)(8) is added to read as follows:

§ 409.20 Coverage of services.

(a) * * *

(8) Transportation services, including transport by ambulance.

* * * * *

PART 410—SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

B. 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).

2. Section 410.40 is revised to read as follows:

§ 410.40 Coverage of ambulance services.

(a) *Basic rules.* Medicare Part B covers ambulance services if the following conditions are met:

(1) The supplier meets the applicable vehicle, staff, and billing and reporting requirements of § 410.41 and the service meets the medical necessity and origin and destination requirements of paragraphs (d) and (e) of this section.

(2) Medicare Part A payment is not made directly or indirectly for the services.

(b) *Levels of services.* Medicare covers ambulance services within the United States at the following levels of services:

(1) Basic life support (BLS) services.

(2) Advanced life support (ALS) services.

(3) Paramedic ALS intercept services described in paragraph (c) of this section.

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

(1) Be furnished in a rural area (as defined in § 412.62(f) of this chapter).

(2) Be furnished under contract with one or more volunteer ambulance services that meet the following conditions:

(i) Are certified to furnish ambulance services as required under § 410.41.

(ii) Furnish services only at the BLS level.

(iii) Be prohibited by State law from billing for any service.

(3) Be furnished by a paramedic ALS intercept supplier that meets the following conditions:

(i) Is certified to furnish ALS services as required in § 410.41(b)(2).

(ii) Bills all the recipients who receive ALS intercept services from the entity, regardless of whether or not those recipients are Medicare beneficiaries.

(d) *Medical necessity requirements—*
(1) *General rule.* Medicare covers ambulance services only if they are furnished to a beneficiary whose medical condition is such that other means of transportation would be contraindicated. For nonemergency ambulance transportation, the following criteria must be met to ensure that ambulance transportation is medically necessary:

(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 ambulance services.*

Medicare covers nonemergency, scheduled ambulance services if the ambulance 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, unscheduled ambulance services.*

Medicare covers nonemergency, unscheduled ambulance services under the following circumstances:

(i) For a resident of a facility who is under the care of a physician if the ambulance 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.

(ii) For a beneficiary residing at home or in a facility who is not under the direct care of a physician. A physician certification is not required.

(e) *Origin and destination requirements.* Medicare covers the following ambulance transportation:

(1) From any point of origin to the nearest hospital, CAH, or SNF that is capable of furnishing the required level and type of care for the beneficiary's illness or injury. The hospital or CAH must have available the type of physician or physician specialist needed to treat the beneficiary's condition.

(2) From a hospital, CAH, or SNF to the beneficiary's home.

(3) From a SNF to the nearest supplier of medically necessary services not available at the SNF where the beneficiary is a resident, including the return trip.

(4) For a beneficiary who is receiving renal dialysis for treatment of ESRD, from the beneficiary's home to the

nearest facility that furnishes renal dialysis, including the return trip.

(f) *Specific limits on coverage of ambulance services outside the United States.* If services are furnished outside the United States, Medicare Part B covers ambulance transportation to a foreign hospital only in conjunction with the beneficiary's admission for medically necessary inpatient services as specified in subpart H of part 424 of this chapter.

3. A new § 410.41 is added to read as follows:

§ 410.41 Requirements for ambulance suppliers.

(a) *Vehicle.* A vehicle used as an ambulance must meet the following requirements:

(1) Be specially designed to respond to medical emergencies or provide acute medical care to transport the sick and injured and comply with all State and local laws governing an emergency transportation vehicle.

(2) Be equipped with emergency warning lights and sirens, as required by State or local laws

(3) Be equipped with telecommunications equipment as required by State or local law to include, at a minimum, one two-way voice radio or wireless telephone.

(4) Be equipped with a stretcher, linens, emergency medical supplies, oxygen equipment, and other lifesaving emergency medical equipment as required by State or local laws.

(b) *Vehicle staff—(1) BLS vehicles.* A vehicle furnishing ambulance services must be staffed by at least two people, one of whom must meet the following requirements:

(i) Be certified as an emergency medical technician by the State or local authority where the services are furnished.

(ii) Be legally authorized to operate all lifesaving and life-sustaining equipment on board the vehicle.

(2) *ALS vehicles.* In addition to meeting the vehicle staff requirements of paragraph (b)(1) of this section, one of the two staff members must be certified as a paramedic or an emergency medical technician, by the State or local authority where the services are being furnished, to perform one or more ALS services.

(c) *Billing and reporting requirements.* An ambulance supplier must comply with the following requirements:

(1) Bill for ambulance services using HCFA-designated procedure codes to describe origin and destination and indicate on claims form that the physician certification is on file.

(2) Upon a carrier's request, complete and return the ambulance supplier form

designated by HCFA and provide the Medicare carrier with documentation of compliance with emergency vehicle and staff licensure and certification requirements in accordance with State and local laws.

(3) Upon a carrier's request, provide additional information and documentation as required.

PART 424—CONDITIONS FOR MEDICARE PAYMENT

1. The authority citation for part 424 continues to read as follows:

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

§ 424.124 [Amended]

In § 424.124, paragraph (c)(2) is amended by removing the reference to “§ 410.140” and adding in its place the reference to “§ 410.41”.

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

Dated: December 10, 1998.

Nancy-Ann Min DeParle,

Administrator, Health Care Financing Administration.

Dated: January 13, 1999.

Donna E. Shalala,

Secretary.

Note: Addendum 1 and Addendum 2 will not appear in the Code of Federal Regulations.

Addendum 1

NOTE TO: (INSERT NAME OF MEDICARE SUPPLIER)

FROM: (INSERT NAME OF MEDICARE CARRIER)

SUBJECT: Completion of Attached Ambulance Supplier Form

The attached form must be completed by you whenever your State and Local laws require that you update the licensure of your vehicles and/or staff. We are also requiring that this form be completed at the carrier's discretion so that the latest documentation will be on file with the carrier to make appropriate claims payment determinations.

The form is self explanatory and, therefore, there are no program instructions for its completion. We do not expect that it will take longer than 30 minutes to answer the questions and will require only another minute or two to copy and attach the photocopies supporting the response to some of the questions.

If you have any questions about completing this form please contact us at (fill in the telephone number and or address of the carrier).

Addendum 2—Ambulance Supplier Form

1. Corporate/Business Name of Ambulance Company: _____

Trade Name of Ambulance Company: _____

(Exactly as it appears on the vehicle(s))

2. Medicare Provider Number: _____

Federal Tax Identification Number: _____

3. License Number(s): _____

(A copy of the current license/certificate *must* be submitted with this form. The effective date and expiration must be stated on the license/certificate. Program payment will be based these dates.)

4. Physical Address of Ambulance Company Headquarters: _____

Mailing Address (If different): _____

(Post Office Boxes and Drop Boxes are *not* acceptable as a physical business address.)

Physical address locations of any substations, other than Headquarters, where vehicles are garaged (if applicable):

a. _____

b. _____

(Attach additional sheets if necessary)

What geographic area(s) do you serve? _____

5. Business Telephone Number(s): (____) _____

Fax Machine Number(s): (____) _____

(List telephone numbers for all locations. The business telephone number(s) must be a number where patients or customers can reach you or register complaints.)

Name of Daily Contact Person: _____

(Please print name, title, and provide a telephone number, if different from the business telephone number.)

6. Owner's Name(s) and Social Security Number(s): _____

(Identify all individuals and their Social Security Numbers or entities who have ownership or controlling interest in this company. Attach additional sheets if necessary.)

7. Indicate the number of vehicles providing each type of service. Provide a copy of the license/certification documentation from the State or local regulatory agency for each vehicle:

- ____ Advanced Life Support
- ____ Advanced Life Support (Paramedic Intercept Squad Unit)
- ____ Advanced Life Support (Mobile Intensive Care Unit)
- ____ Basic Life Support
- ____ Air Ambulance

Identify all vehicles in your fleet by providing the following information:

(Attach additional sheets if necessary)

Year Make Model VIN#

8. List the name of each crew member and their individual training (e.g., CPR, first aid, ACLS, etc.) A copy of their certificate(s) of training *must* be attached. (Attach additional sheets if necessary.)

Name: _____

Training: _____

Name: _____

Training: _____

9. Name of Medical Director: _____

Medical License Number of Medical Director: _____

Telephone Number: (____) _____

10. Has your company or any owner ever been excluded from participation in the Medicare or Medicaid program?

Yes _____ No _____

If yes, under what corporate/business name(s), trade name(s) and owner(s), did the exclusion occur?

List prior Medicare Identification Number(s): _____

Provide name(s) and location(s) of prior Carrier(s): _____

(If service was provided under the Medicaid program, list the prior Medicaid Identification Number and the State where the service was provided.)

11. You agree to notify this office of any change in operation, ownership, or revocation of licensure. It is also understood that representatives from the Health Care Financing Administration (HCFA) and HCFA Medicare contractors may make on-site inspections at any time.

By signing, I agree to the above statement and verify that I have reviewed all of the information contained herein, or submitted separately in support of this verification of compliance form, and verify that the information is accurate and complete.

Name and Title (please print): _____

Address: _____

Signature: _____

Date: _____

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB number for this information collection is 0938-xxxx. The time required to complete this information collection is estimated to average xx hours (or minutes) per response, including the time to review instructions, search existing data resources, gather the data needed, and complete and review the information collection. If you have any comments concerning the accuracy of the time estimate(s) or suggestions for improving this form, please write to: HCFA, 7500 Security Boulevard, Baltimore, Maryland 21244-1850, Mail Stop N2-14-26 and to the Office of the Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

[FR Doc. 99-1547 Filed 1-20-99; 4:15 pm]

BILLING CODE 4120-03-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[MM Docket No. 90-318, RM-7311, 7516]

Radio Broadcasting Services; Chillicothe, Forest, Lima, New Washington, Peebles and Reynoldsburg, Ohio

AGENCY: Federal Communications Commission.

ACTION: Final Rule; Petition for Reconsideration.

SUMMARY: At the request of Pearl Broadcasting, Inc., this document dismisses the Petition for Reconsideration filed by Pearl Broadcasting, Inc. of the *Report and Order*, 61 FR 44288 (Aug. 28, 1996) which denied Pearl's request to change the community of license of Station WKKJ(FM), Channel 227B from Chillicothe to Reynoldsburg, Ohio and denied proposed allotments at Peebles, Forest and Lima, Ohio. The Commission determined that the request for dismissal complied with the requirements of § 1.420(j) of the Commission's Rules. With this action, this proceeding is terminated.

EFFECTIVE DATE: January 25, 1999.

FOR FURTHER INFORMATION CONTACT: Arthur D. Scrutchins, Mass Media Bureau, (202) 418-2180.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission's Memorandum Opinion and Order, MM Docket No. 90-318, adopted January 6, 1999 and released January 15, 1999. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Reference Center (Room 239), 1919 M St, N.W., Washington, D.C. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Services, Inc., (202) 857-3800, 1231 20th Street, N.W., Washington, D.C. 20036.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Charles W. Logan,

Chief, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 99-1640 Filed 1-22-99; 8:45 am]

BILLING CODE 6712-01-U

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 622

[Docket No. 961204340-7087-02; I.D. 011999D]

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic; Closure

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

ACTION: Closure.

SUMMARY: NMFS closes the commercial run-around gillnet fishery for king mackerel in the exclusive economic zone (EEZ) in the Florida west coast subzone. This closure is necessary to protect the overfished Gulf king mackerel resource.

DATES: Effective 12:00 noon, local time, January 20, 1999, through June 30, 1999.

FOR FURTHER INFORMATION CONTACT: Mark Godcharles, 727-570-5305.

SUPPLEMENTARY INFORMATION: The fishery for coastal migratory pelagic fish (king mackerel, Spanish mackerel, cero, cobia, little tunny, dolphin, and, in the Gulf of Mexico only, bluefish) is managed under the Fishery Management Plan for the Coastal Migratory Pelagic Resources of the Gulf of Mexico and South Atlantic (FMP). The FMP was prepared by the Gulf of Mexico and South Atlantic Fishery Management Councils (Councils) and is implemented under the authority of the Magnuson-Stevens Fishery Conservation and Management Act by regulations at 50 CFR part 622.

Based on the Councils' recommended total allowable catch and the allocation ratios in the FMP, on February 19, 1998 (63 FR 8353), NMFS implemented a commercial quota for the Gulf of Mexico migratory group of king mackerel in the Florida west coast subzone of 1.17 million lb (0.53 million kg). That quota was further divided into two equal quotas of 585,000 lb (265,352 kg) for vessels in each of two groups by gear types—vessels fishing with run-around gillnets and those using hook-and-line gear (50 CFR 622.42(c)(1)(i)(A)(2)).

Under 50 CFR 622.43(a)(3), NMFS is required to close any segment of the king mackerel commercial fishery when its quota has been reached or is projected to be reached by filing a notification at the Office of the Federal Register. NMFS has determined that the