

Plan (SIP) revision request submitted by the State of Illinois for reactor processes and distillation operation processes in the Synthetic Organic Chemical Manufacturing Industry (SOCMI) as part of the State's control measures for Volatile Organic Material (VOM) emissions for the Chicago and Metro-East (East St. Louis) areas. VOM, as defined by the State of Illinois, is identical to "volatile organic compounds" (VOC), as defined by EPA. VOC is one of the air pollutants which combine on hot summer days to form ground-level ozone, commonly known as smog. Ozone pollution is of particular concern because of its harmful effects upon lung tissue and breathing passages. This plan was submitted to meet the Clean Air Act (Act) requirement for States to adopt Reasonably Available Control Technology (RACT) rules for sources that are covered by Control Techniques Guideline (CTG) documents. In the final rules section of this **Federal Register**, the EPA is approving this action as a direct final rule without prior proposal because EPA views this as a noncontroversial action and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to that direct final rule, no further activity is contemplated in relation to this proposed rule. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on the proposed rule. EPA will not institute a second comment period on this action. Any parties interested in commenting on this document should do so at this time.

**DATES:** Comments on this proposed rule must be received on or before July 17, 1997.

**ADDRESSES:** Written comments should be mailed to: J. Elmer Bortzer, Chief, Regulation Development Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

Copies of the State submittal and EPA's analysis of it are available for inspection at: Regulation Development Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604.

**FOR FURTHER INFORMATION CONTACT:** David Pohlman, Regulation Development Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, Region 5, 77 West

Jackson Boulevard, Chicago, Illinois 60604, (312) 886-3299.

**SUPPLEMENTARY INFORMATION:** For additional information see the direct final rule published in the rules section of this **Federal Register**.

Dated: May 9, 1997.

**Valdas V. Adamkus,**  
*Regional Administrator.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Care Financing Administration

#### 42 CFR Parts 410 and 424

[BPD-813-P]

RIN 0938-AH13

#### Medicare Program; Ambulance Services

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

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would update and revise HCFA's policy on coverage of ambulance services. It would base Medicare coverage and payment for ambulance services on the level of medical services needed to treat the beneficiary's condition. It also clarifies Medicare policy on coverage of non-emergency ambulance services for Medicare beneficiaries.

**DATES:** Comments will be considered if we receive them at the appropriate address, as provided below, no later than 5 p.m. on August 18, 1997.

**ADDRESSES:** Mail written comments (1 original and 3 copies) to the following address: Health Care Financing Administration, Department of Health and Human Services, Attention: BPD-813-P, P.O. Box 26676, Baltimore, MD 21207-0476.

If you prefer, you may deliver your written comments (1 original and 3 copies) to one of the following addresses:

Room 309-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201, or Room C5-09-26, 7500 Security Boulevard, Baltimore, MD 21244-1850.

Because of staffing and resource limitations, we cannot accept comments by facsimile (FAX) transmission. In commenting, please refer to file code BPD-813-P. Comments received timely will be available for public inspection as they are received, generally beginning

approximately 3 weeks after publication of a document, in Room 309-G of the Department's offices at 200 Independence Avenue, SW., Washington, DC, on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (phone: (202) 690-7890).  
**FOR FURTHER INFORMATION CONTACT:** Margot Blige, (410) 786-4642.

#### SUPPLEMENTARY INFORMATION:

##### 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, at 43 (1965)). The reports indicate that transportation may also be made 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 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.

Section 410.40(a) defines an "ambulance" as a vehicle that is specially designed for transporting the sick or injured, containing a stretcher, linens, first aid supplies, oxygen equipment, and other lifesaving equipment required by State or local laws, and staffed with personnel trained to provide first aid treatment.

Section 410.40(b) permits Part B coverage of ambulance services when the use of other means of transportation

would be contraindicated and Part A coverage is not available. For hospital or rural primary care hospital (RPOCH) inpatients, it states that the transportation must be furnished by, or under arrangements made by, the hospital or RPOCH, or that the transportation be furnished by an ambulance supplier with which the hospital does not have an arrangement and the hospital has a waiver under which Medicare Part B payment may be made to the ambulance supplier.

Section 410.40(c) limits origins and destinations. Medicare payment is made for transportation to a hospital, RPOCH, or skilled nursing facility (SNF), from any point of origin; to the home of a beneficiary from a hospital, RPOCH, or SNF; or round trip from a hospital, RPOCH, or SNF to a supplier outside of those facilities to obtain medically necessary diagnostic or therapeutic treatment not available where the beneficiary is an inpatient.

Section 410.40(d) limits Part B coverage of ambulance services furnished outside of the United States. Medicare payment is made for transportation to a foreign hospital only in conjunction with a beneficiary's admission for medically necessary inpatient services.

Section 410.40(e) limits Medicare payment for ambulance services. Medicare payment is made for the following services:

- Transportation to a facility that is in the same locality as the beneficiary's home or to the nearest facility if the one closest to the beneficiary's home is unable to provide the necessary service to the beneficiary.
- Transportation to the beneficiary's home from the facility where the beneficiary was treated.
- Round trip transportation to the nearest outside supplier capable of furnishing necessary diagnostic and therapeutic services not available at the facility where the beneficiary is an inpatient.

### *C. Current Medicare Policy and Manual Instructions for Ambulance Services*

We issue instructions to our contractors for processing Medicare claims in the Medicare Carriers Manual (MCM) and the Medicare Intermediary Manual (MIM). The current instructions for Medicare coverage and payment of ambulance services appear in sections 2120 and 5116 of the MCM and sections 3660 and 3618 in the MIM. For the most part, the manual instructions repeat the provisions of the regulations in part 410 pertaining to ambulance services.

The manual instructions expand on the regulations by—

- Requiring carriers to take appropriate action, including conducting on-site inspections, to verify that an existing ambulance supplier meets all applicable requirements when there are no State or local laws defining an ambulance, when suppliers fail to comply with the documentation requirements, or whenever there is a question about a supplier's compliance.
- Recognizing some technological advances in ambulance equipment and training of personnel that enable suppliers to make available medical treatment beyond the basic lifesaving techniques.

• Addressing the issue of determining the base rate allowance for the advanced life support (ALS) level of ambulance services, as contrasted with basic life support (BLS) level. The manual states that the ALS reasonable charge may be used as a basis for payment when an ALS level of ambulance services is used. However, there may be instances when the supplier exhibits a pattern of uneconomical care such as repeated use of ALS level 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 payment for the ALS level of ambulance services, the carrier is responsible for evaluating the appropriate level of services for each claim.

- Covering transportation of ESRD beneficiaries to renal dialysis facilities under certain circumstances, assuming that transportation in vehicles other than ambulances would be contraindicated. Transportation to a hospital is covered. Also, under the following circumstances, a nonhospital-based or independent renal dialysis facility may meet the destination requirements for purposes of coverage of ambulance services for an ESRD beneficiary:

- The facility is located "on or adjacent to" the premises of the hospital.
- The facility furnishes services to patients of the hospital, for example on an outpatient or emergency basis, even though the facility is primarily in business to furnish dialysis services to its own patients.
- There is an ongoing professional relationship between the two facilities. For example, the hospital and the facility have an agreement that provides for physician staff of the facility to abide by the bylaws and regulations of the hospital's medical staff.

Ambulance services from a beneficiary's home to any dialysis facility are not covered unless these

conditions are met. However, the carriers have the authority to interpret the meaning of the phrase "on or adjacent to" the premises of a hospital for purposes of coverage of ambulance services for ESRD beneficiaries to facilities to receive renal dialysis therapy. Medicare carriers have not been consistent in their interpretation of manual instructions on ambulance services for ESRD beneficiaries to and from hospital-based and nonhospital-based dialysis facilities.

### *D. Studies and Reports on Ambulance Services*

In a 3-year period, four government reports were issued addressing Medicare payments for ambulance services.

Under the Omnibus Budget Reconciliation Act of 1989 (OBRA '89) (Pub. L. 101-239), the Congress mandated a study of payment practices for ambulance services under Medicare. This study, "A Study of Payments for Ambulance Services Under Medicare", was conducted by Project Hope and was issued in 1994. The study focused on the rapid growth of Medicare Part B payments for ambulance services. In 1987 (the year selected for this report's analysis), Medicare's allowed charges for ambulance services amounted to almost \$602 million. By 1991, allowed charges increased to \$1.23 billion, double the amount of 1987. The report showed that Medicare's allowed charges for ambulance services have risen at an average annual rate of 20 percent since 1974.

The rapid increase of Medicare Part B payments for ambulance services was also highlighted in an October 1992 audit report conducted by the Department's Office of Inspector General (OIG) entitled, "Review of Medical Necessity for Ambulance Services, (A-01-91-00513)". In its report, the OIG notes that, in the 3-year period between 1986 and 1989, there was a significant increase in the use of and payment for the ALS level of ambulance services when compared to the BLS level of ambulance services.

The report further indicates that some carriers pay Medicare claims at the ALS level when that level of services is required by State or local laws. The study noted that the significant increase in the use of the ALS level of services and in Medicare payments could be attributed to our coverage and payment policies under which payment is based on the type of ambulance in which a beneficiary is transported and not on the medical necessity for the level of services furnished by the ambulance.

The OIG recommended that we take the following actions: (1) Modify the MCM to require carriers to pay for non-emergency ambulance services at the BLS level of service if they are medically necessary, (2) establish controls for the carriers to ensure that Medicare payment for the ALS level of service is based solely on the medical need of the beneficiary, and (3) closely monitor carrier compliance.

After we published the ambulance regulations, major legislative changes provided broad coverage for dialysis services to end-stage renal disease (ESRD) beneficiaries. Between 1978 and 1990, there was a significant increase in the number of ESRD beneficiaries. Ambulance services furnished to this population also increased significantly. The OIG issued two reports concerning ambulance services furnished to ESRD beneficiaries.

The first ESRD report, "Ambulance Services For Medicare End-Stage Renal Disease Beneficiaries: Payment Practices, (OEI-03-90-02131)", issued in March 1994, found that about two percent of ESRD beneficiaries are associated with an extremely high frequency of using ambulance services; that is, these ESRD beneficiaries are using ambulance services three times a week for transportation to routine maintenance dialysis. The report notes that we do not differentiate between predictable routine, scheduled transportation, and emergency acute care transportation. It concludes that we do not take advantage of lower costs associated with high-volume scheduled transportation. The report also notes that some carriers do not use the HCFA Common Procedural Coding System (HCPCS) codes uniformly. The report recommends that we require uniform use of the HCPCS codes and establish a code for scheduled, non-emergency transportation.

(We recently implemented coding changes through an update to the MCM that addresses the latter recommendation. These coding changes differentiate between transportation to a hospital-based dialysis facility (or hospital-related) and a nonhospital dialysis facility.)

The second ESRD report, "Ambulance Services for Medicare End-Stage Renal Disease Beneficiaries: Medical Necessity, (OEI-03-90-02130)", issued in August 1994, retrospectively examines the medical necessity of ambulance claims for ESRD beneficiaries. This report concludes that 70 percent of the dialysis-related ambulance services did not meet Medicare coverage guidelines. However, claims were not being denied as

medically unnecessary. The report offers several alternative strategies for making improvements to the program. Some of the recommendations suggest significant policy changes that we believe represent potential improvements to administering the ambulance services benefits.

## **II. Reasons for Considering Changing Medicare Policy and Regulations**

### *A. Public Concerns about Ambulance Services*

For many years, we have had discussions with representatives from the ambulance industry covering a variety of issues including: The definition of an ambulance, the appropriate billing for the ALS level of services, and clarification of our coverage and payment guidelines regarding ALS and BLS levels of services. A frequent question is whether the coverage of an ambulance service is affected by the individual beneficiary's need for specific services or by the type of vehicle and staff that are used to transport the beneficiary.

In December 1994, the Subcommittee on Labor, HHS, Education, and Related Agencies under the Senate Appropriations Committee held a hearing, "Ambulance Costs under Medicare", to review Medicare coverage and payment of ambulance services. Many of the issues identified in the government reports described earlier were raised by this subcommittee. At the hearing, we assured the members of the subcommittee that we would act aggressively to revise our regulations to address the problems identified with the increasing expenditures for ambulance services and the suppliers furnishing the services.

In January 1995, we held a 2-day conference on ambulance services with representatives from the ambulance industry. We met with several entities, including the American Ambulance Association, the National Association of State Emergency Medical Services Directors, the International Association of Firefighters, the American College of Emergency Physicians, and the American Hospital Association. The meeting allowed us to consult with experts in ambulance services and discuss issues of particular concern to us and ambulance suppliers before we developed regulations and instructions that change our ambulance services policy. The meeting provided us with an opportunity to establish positive working relationships and access to valuable information resources.

The industry representatives provided us with a considerable amount of

information about the industry and made recommendations on various Medicare policy issues related to ambulance services. Two frequent problems they brought to our attention follow:

- Some local ordinances mandate that all 911 emergency calls be answered by an ALS-level ambulance rather than a BLS-level ambulance. This causes a problem when a carrier determines that payment should be made at the BLS level.

- There is a need for national policy requiring physician certification for scheduled ambulance transportation.

In addition to issues raised by the industry, the OIG identified as problematic the notable increases in the use of ALS-level ambulances to transport Medicare ESRD beneficiaries to scheduled, routine dialysis treatments. The OIG believes scheduled services can usually be furnished by a BLS-level ambulance.

The industry representatives (and others) urged us to comprehensively revise the regulations covering ambulance services to address these problems.

### *B. Vehicles Used To Furnish Services*

Section 410.40(a) does not explicitly state that ambulance services must be furnished in a vehicle designed and equipped to respond to medical emergencies. In most States, an ambulance is defined by State or local laws as a vehicle that is intended for emergency transportation of patients. In some States or localities, there are no laws defining an ambulance; in others, the laws do not require that the vehicles used as ambulances be designed or equipped as emergency vehicles.

In addition, there are suppliers operating in some States who believe their vehicles, despite not meeting State or local requirements, meet the Federal definition of an ambulance contained in §410.40(a). These suppliers bill Medicare for transportation in vehicles that are not equipped to respond to emergencies even though they are required by State or local law to be so equipped. As a result, we have made Medicare payments to some suppliers of transportation services for furnishing transportation in a vehicle that is not an ambulance or does not meet State or local requirements for emergency vehicles. Typically these suppliers furnish services to persons who have scheduled medical or other appointments and use vehicles such as ambulettes, ambu-vans, medi-transports, invalid coaches, and other similar vehicles. Transportation in these vehicles is furnished to persons who

may need assistance in being transported to caregivers, for example, because of difficulty ambulating, but who do not require emergency transportation for purposes of obtaining acute care. More specifically, the condition of the beneficiary is such that transportation by means other than in a vehicle designed and equipped to respond to a medical emergency would not be contraindicated. Transportation in these vehicles is *not* covered by Medicare Part B. In other instances, ambulance suppliers fail to submit adequate documentation to carriers showing that they comply with State or local laws.

### C. Staff Furnishing Services

Section 410.40(a) states that a vehicle used as an ambulance must be staffed with personnel trained to provide first aid treatment. In the absence of applicable State or local requirements, the staff must meet standards established by the Federal Department of Transportation.

A vehicle used for emergency transportation generally contains highly sophisticated medical and communications equipment. Hence, the major differences between BLS and ALS levels of services usually is the training level of the staff on board the vehicle. The industry standard is that the BLS-level ambulance is staffed with two people, each of whom is trained to provide basic first aid and certified as an emergency medical technician-basic (EMT-B). The ALS-level ambulance is staffed with two people trained to provide basic first aid, one of whom is also trained and certified at the advanced first aid level and certified either as a paramedic or as an emergency medical technician-advanced (EMT-A). The EMT-A has received additional training and certification to perform one or more ALS services. Paramedics and emergency medical technicians must be certified by the State or local authority in the area in which the services are furnished and be legally authorized to operate all life-saving and life-sustaining equipment that is on board. Section 410.40(a) does not describe the level of training necessary to provide either the basic or advanced level of care.

### D. Origins and Destinations

Section 410.40(c) sets forth our longstanding policy that coverage is not authorized for ambulance services to destinations other than those that were specified in the committee reports accompanying the 1965 Social Security Amendments (H.R. Rep. No. 213, 89th

Cong., 1st Sess. 37, and S. Rep. No. 404, 89th Cong., 1st Sess., Pt. I, at 43 (1965)). Thus, under §410.40(c), Medicare Part B covers ambulance services for a beneficiary only if other methods of transportation would be contraindicated and the transportation is to one of the following destinations:

- To a hospital, which includes a RPCH, or SNF from any point of origin.
- To the beneficiary's home from a hospital, RPCH, or SNF.
- To an outside supplier to obtain medically necessary diagnostic or therapeutic services not available in the hospital, RPCH, or SNF where the beneficiary is an inpatient from a hospital, RPCH, or SNF (including the return trip).

Transporting hospital or RPCH inpatients to and from an outside supplier to obtain medically necessary diagnostic or therapeutic services is a Medicare Part A service and the cost is paid in the appropriate ancillary cost center of the hospital or RPCH where the beneficiary is an inpatient.

Section 410.40(e) limits Medicare payment to the destinations described in §410.40(c).

Sections 410.40(c) and (e) do not permit routine coverage of, or payment for, transportation to nonhospital-based or independent diagnostic and treatment facilities. Currently, we pay for transportation to these types of facilities only if the beneficiary is an inpatient at a hospital, RPCH, or SNF and the treatment needed is not available at that inpatient facility. We do not cover round trip transportation to nonhospital-based facilities from the beneficiary's home.

### E. Basic Life Support and Advanced Life Support Services

When section 1861(s)(7) of the Act was passed, only one level of ambulance service was being furnished; that is, BLS. The vehicle was equipped with basic first aid equipment such as a stretcher, linens, and emergency lights and sirens. The staff was trained to provide basic first aid treatment, for example, to stop bleeding, splint fractures, or administer cardio-pulmonary resuscitation to restore breathing or heartbeat. Since ambulance services were first covered under Medicare, the advancement of first aid techniques assisted in the creation of the ALS level of ambulance services. These techniques included the ability to treat severe trauma and to administer drugs and biologicals, as well as to perform other more advanced lifesaving and/or lifesustaining treatments.

Since 1982, we have recognized different payment levels for ambulance

services depending on whether the services furnished are described as a BLS or ALS level of service. However, our regulations have not kept up with the changing use of technology, and so we have no way of ensuring that we are paying properly for the services that are furnished.

### F. Location and Availability of Ambulance Suppliers

Ambulance services are furnished by for-profit companies and non-profit companies. The for-profit ambulance companies charge an amount sufficient to cover costs and a return on investment. The non-profit companies, once the predominant suppliers of these services, are largely volunteer organizations. Many of these volunteer organizations are located in areas that were considered rural. Although increases in population have changed some rural areas into urban areas, many of the suppliers continue to be volunteer organizations. Still other areas remain largely underpopulated; however, the services furnished have increased because of the level of training and technology available.

Other non-profit ambulance suppliers are local governments, either cities or other incorporated entities. Until recently, within the last 10 to 15 years, the non-profit volunteer companies and the municipal organizations did not charge Medicare for their services. Because the cost of furnishing services has become increasingly more expensive and the level of training and certification more sophisticated, many of these organizations have begun to charge for part or all of the services that they furnish.

### III. Proposed Changes to Medicare Policy and Regulations

There is a need to make policy changes so that the Medicare coverage criteria are consistent and clear and reflect the advances that have occurred in the health care and ambulance industries. Our current regulations inadequately address technological advances. We believe it is appropriate at this time to establish criteria under which Medicare carriers can determine when the ALS level of service is necessary and covered and when the condition of the beneficiary requires only the BLS level of service.

We propose to amend our regulations to clarify that the basis for covering ambulance services is the medical condition of the beneficiary for transportation furnished by an ambulance. To accomplish this clarification of determining the level of medically necessary services for

coverage and payment purposes, we propose that the suppliers use diagnostic codes designated by HCFA that would describe the nature of the beneficiary's medical condition. We propose to designate the International Classification of Diseases, 9th revision, Clinical Modification (ICD-9-CM) diagnostic codes that would describe the nature of the beneficiary's medical condition. The use of these codes would also assist the ambulance suppliers in billing the medically necessary BLS or ALS level of ambulance service.

#### *A. Medicare Coverage of Ambulance Services*

As a means of distinguishing ambulance services covered under Part B from other modes of patient-related transportation, we propose revising existing § 410.40. In § 410.40(a), we would provide for Part B coverage of ambulance services only if the supplier meets the applicable vehicle, staff, and billing and reporting requirements in § 410.41, and the medical necessity and origin and destination requirements in § 410.40. Also, even when all other coverage requirements are met, Medicare Part B would cover the services as ambulance services only if they are not services that can be paid for directly or indirectly under Part A. The cost of the transportation paid for under Part A is ordinarily considered part of the cost related to the hospital's care of the beneficiary as a patient. If the hospital is paid under the prospective payment system (PPS), payment is made under the appropriate diagnosis-related group (DRG). If the hospital is not paid under PPS, payment is made on a reasonable cost basis per hospital stay, subject to the Tax Equity and Fiscal Responsibility Act (TEFRA). If the beneficiary's stay is covered under Medicare Part A, payment for the stay will reflect the transportation and that transportation cannot be covered under the Part B ambulance services benefit.

#### *B. Levels of Services*

We propose in § 410.40(b) to cover ambulance services in the United States at either the BLS or ALS level of services. We would determine the level of payment based on the level of services medically necessary to treat a beneficiary's condition as described by the ICD-9-CM diagnostic codes used to bill for ambulance services. We would make an exception to the BLS/ALS distinction for certain non-Metropolitan Statistical Areas (non-MSA) and cover ALS services if certain criteria in § 410.40(e) are met.

#### *C. Medical Necessity*

We propose in § 410.40(c)(1) that ambulance services are covered by Medicare based on the beneficiary's medical condition. A listing of medical conditions and the proposed corresponding ICD-9-CM diagnostic codes is included in Addendum 1 of this proposed rule.

The codes would indicate the need for medically necessary BLS or ALS level of ambulance services. More specifically, the ICD-9-CM diagnostic codes would be used as indicators of medical necessity by describing the nature of the symptoms or injury; that is, they describe the beneficiary's medical condition that makes the ambulance transportation necessary. If more specific information about the beneficiary's condition is available, that information would also be coded using ICD-9-CM diagnostic codes. More specific information might be available, for instance, when a beneficiary is transferred from one facility to another and the physician provides the ambulance personnel with pertinent information about the beneficiary's condition. While this list is not exhaustive, it does represent what we have identified, through discussions with the industry and carrier representatives, as a range of the types of medical conditions to which ambulance suppliers currently respond.

The ICD-9-CM diagnostic list includes the code v49.8, Other Specified Problems Influencing Health Status. For example, this code would be applicable when a beneficiary with end-stage renal disease needs regular dialysis treatment and cannot use regular transportation because he or she is bed-confined. To assist in determining medical necessity as it relates to this code, we are proposing that for purposes of Medicare Part B, the term bed-confined is defined as follows: "bed-confined" denotes the inability to get up from bed without assistance, the inability to ambulate, and the inability to sit in a chair or wheelchair. This definition also applies to the terms "bedridden" and "stretcher-bound". Bed-confined is not synonymous with non-ambulatory since a paraplegic or quadriplegic person is non-ambulatory but spends a significant amount of time in a wheelchair. Bed-confined is also not synonymous with bed rest, a recommended state of affairs that does not exclude an occasional ambulation to the commode or time spent in a chair.

We recognize that unusual circumstances exist that warrant the need for ambulance services. In these circumstances, the publication of the

list does not preclude the Carrier from accepting other ICD-9-CM diagnostic codes to describe a medical condition that is not included on the list. However, we believe that these circumstances will be rare. The codes in Addendum 1 of this proposed rule would enable the supplier to know whether a claim may be paid at the BLS or ALS level of ambulance services. The use of ICD-9-CM diagnostic codes is intended to promote consistency in claims processing. Use of the ICD-9-CM diagnostic codes, however, does not make the claim payable if the beneficiary could have been transported by other means. Proposed § 410.40(c)(3) provides that we will establish guidelines on the use of the designated codes that would ensure medical necessity of ambulance services, coverage at the appropriate level, and consistency in claims filing. We will, in the event that there are subsequent revisions to the listing of ICD-9-CM diagnostic codes to describe the medical condition of the beneficiary, publish the updated listing of codes used for ambulance services as a Notice in the **Federal Register**.

Proposed § 410.40(c)(2) provides for coverage of non-emergency services (including, but not limited to, transportation for an ESRD beneficiary) if the ambulance supplier, before furnishing services to the beneficiary, obtains a current written physician's order certifying that the beneficiary must be transported in an ambulance because other means of transportation would be contraindicated. The physician's order must be dated no earlier than 60 days before the date a service is furnished. The ambulance supplier would also be responsible for obtaining additional written certifications for each subsequent 60-day period.

We believe the requirement for physician's certification for scheduled ambulance services would ensure that scheduled ambulance services are necessary as other means of transportation would be contraindicated. Adding the requirement is consistent with the Secretary's authority to ensure that all claims for services are reasonable and necessary in accordance with section 1862(a)(1) of the Act.

The requirement that this certification be renewed every 60 days is consistent with the Secretary's authority under section 1835(a)(2)(B) of the Act. This section ensures, that, in the case of medical and other health services furnished by a provider, a physician certifies that such services, including

those furnished over a period of time, are medically necessary.

#### *D. Origins and Destinations*

In § 410.40(d), we propose to modify the limits on origins and destinations that currently appear in § 410.40(c). We would also remove reference to round-trip ambulance transportation of inpatients of hospitals and RPDs to outside facilities from this section since this is a Part A benefit and more properly belongs in another section. We will consider the appropriate placement of this text and place it in the proper section in the final rule. We would add a provision that, under Part B, ambulance transportation is permitted from an SNF to the nearest supplier of medically necessary services not available at the SNF where the beneficiary is an inpatient, including the return trip. We would also add a provision that would cover medically necessary ambulance services for an ESRD beneficiary living at home to the nearest dialysis facility capable of furnishing the necessary dialysis services without regard to whether that dialysis facility is hospital-based. Thus, round-trip ambulance services furnished to a beneficiary from his or her residence would be covered. Our purpose in proposing this modification is to make § 410.40(d) consistent with our policy of transporting beneficiaries to the nearest appropriate facility.

#### *E. Consideration of a Coverage Exception for ALS services in Non-Metropolitan Statistical Areas*

We are concerned that our policy determining the level of Medicare payment based on the level of medically necessary services may have some negative impact on an ambulance supplier's ability to furnish services in communities with small populations. In addition, several industry representatives have voiced their concerns that this proposed change could possibly decrease access to service or, in extreme circumstances, lead to the collapse of some emergency medical systems. Additional discussions have led us to look further at the need for any exception to these rules. To help us to better understand the extent to which a problem exists, or could potentially exist, we are soliciting information from interested parties on the need for an exception and the areas where it may apply. We are requesting information that would help identify the sole suppliers of ambulance services in non-MSAs and other suppliers that may qualify for an exception. The information could include a list of sole suppliers in rural counties of a State, a

description of the level of services offered by these suppliers, the size of the community they serve, the population of the service area, the distance to the nearest carrier, the number of vehicles operated by the supplier(s), time and distance factors related to providing service, and any other information, including relevant economic information that would have a bearing on the need for an exception to our proposed coverage and payment policy.

The solicitation of information is not to determine whether an individual supplier meets eligibility requirements for an exception. This is solely a request for information that will assist us in making the final determination as to whether an exception process is warranted. If we do not receive compelling information regarding the need for an exception, we may choose not to provide an exception to the rule that suppliers bill for the level of services furnished. If we implement an exception to our general ambulance coverage policy, we would review the need for the policy within 5 years after we implement it. We would want to ensure that there is a continued need for an exception and consider any changes that may be needed to reflect current trends in population and the ambulance industry.

To further facilitate our understanding of this issue, we have especially involved the Department's Office of Rural Health Policy and consulted with various industry representatives in an effort to address this issue and consider alternatives that would mitigate negative impact on communities. With these special circumstances in mind, we have examined what special considerations may be warranted for communities.

Absent the detailed information we are requesting through our solicitation, we have developed two alternatives that we could use if we decide that an exception is warranted.

Under our first, and preferred alternative, we would propose in § 410.40(e) to pay ambulance suppliers in non-MSAs for the ALS level of services in all cases if the State Emergency Medical Services (EMS) Director annually makes one of the following certifications:

- The ambulance supplier serves a non-MSA, is the sole supplier of ground ambulance services in the area, owns and operates ambulance vehicles, and furnishes only ALS ambulance vehicles and staff.
- If there is more than one ground ambulance supplier in the non-MSA area, the ambulance supplier seeking

the exception is located more than 40 miles from the nearest available ground ambulance supplier in the area.

In order to qualify for this exception, the supplier would submit to the carrier, on an annual basis, financial information demonstrating that without payment at the ALS level, the financial impact would jeopardize beneficiary access to ambulance services in the area. The supplier would also submit information showing Medicare utilization of ambulance services compared to total service; total volume of services furnished by the supplier; and any other specific, pertinent information documenting the impact on beneficiaries' access to ambulance services that might result from payments at the BLS level for suppliers that have ALS ambulances only. On an annual basis, the ambulance supplier would also be responsible for submitting to the State EMS Director information demonstrating that it meets the established geographic exception criteria. Based on the State EMS Director's certification of the geographic criteria and the carrier's review of the financial information, the carrier would determine if the ambulance supplier meets the requirements to qualify for an exception.

We chose the 40-mile standard because, after consultation with the National Highway Traffic Safety Administration, we determined that 40 miles is a reasonable indicator of access to services. It assumes that 20 minutes is an acceptable maximum response time in most areas. The establishment of a distance criteria is consistent with other access standards used for rural areas, including Medicare's criteria for designating Sole Community Hospitals (42 CFR 412.92). In addition, the use of a distance criterion would be relatively easy to administer compared with other possible criteria. We believe ease of implementation is important because the proposed exception would require active participation by the State EMS Directors in certifying the ambulance suppliers that would qualify for the exception. The National Highway Traffic Safety Administration has suggested that in many cases, while distance may be an acceptable criteria, time factors also are important. We did not propose time factors in our first alternative because they would be difficult to administer. Nevertheless, we recognize that time factors may be more appropriate than distance in some areas and we would like to receive comments on this issue.

The second alternative we have considered would be to create an exception with criteria similar to those

used for the sole community hospitals under Medicare's prospective payment system for hospitals. Under this alternative, we would require that the State EMS Director certify that the ambulance supplier is the sole supplier of ambulance services, or is located in an urban or rural area (as defined in § 412.62(f)(1)(ii) and (f)(1)(iii)) and meets one of the following conditions:

- The ambulance supplier is located between 25 and 35 miles from other like ambulance suppliers.
- The ambulance supplier is located between 15 and 25 miles from other like ambulance suppliers, but because of distance, local topography, and weather conditions, the travel time between the supplier and the other nearest ambulance supplier is at least 45 minutes.

These criteria are much more complex than the first alternative and would be difficult to administer. The amount of data that would need to be collected and evaluated would be considerable. It is for this reason that we do not favor this alternative.

#### *F. Limitation on Services Outside the United States*

We would redesignate § 410.40(d) as § 410.40(f), "Specific limits on coverage of ambulance services outside the United States," without changing the policy.

#### *G. Limitation on Liability*

In considering changes to Medicare coverage of ambulance services, we are mindful of the effect any changes may have on beneficiaries, particularly on beneficiary liability for payment of services. We intend that a beneficiary not pay for an ambulance service for which we deny payment because of a lack of medical necessity, when a beneficiary did not know that the service is not covered. Existing regulations concerning limitations on liability under Medicare in §§ 411.400, 411.402, and 411.406 (part 411, subpart K) would apply to ambulance services. Under the limitation on liability, Medicare payment may be made for certain claims for a service if we exclude the service from coverage in accordance with § 411.15(k) and section 1862(a)(1) of the Act as not medically necessary. A beneficiary who did not know and could not reasonably have been expected to know that payment would be denied for a service under section 1862(a)(1) of the Act generally receives protection from financial liability in accordance with the limitation on liability provisions of section 1879 of the Act as implemented by part 411, subpart K of our

regulations. Similarly, when the beneficiary is protected and the ambulance supplier also did not know and could not reasonably have been expected to know that payment would be denied, the supplier also receives protection from financial liability in accordance with the limitation on liability provision. In this case, Medicare payment may be made to the supplier.

A Medicare payment reduction from the ALS to BLS level of services would constitute a partial denial of payment for the ALS level of services. If we reduce payment from the ALS to the BLS level of service on the basis of a lack of medical necessity in accordance with § 411.15(k) and section 1862(a)(1) of the Act, the beneficiary and supplier protections under the limitation on liability provisions in part 411, subpart K and section 1879 of the Act would apply to the payment reduction.

With respect to ambulance services, the limitation on liability applies only in a narrow range of cases in which the denial is made under section 1862(a)(1) of the Act; that is, because the service furnished was not reasonable or necessary. Most denials of Medicare payment for ambulance services are made on the basis of section 1861(s)(7) of the Act and implementing regulations in existing § 410.40 because the services do not meet the definition of ambulance services. When, for example, ambulance services do not meet the rule that other means of transportation would be inappropriate for the beneficiary's condition (proposed § 410.40(c)), or when they violate the limits on origin and destination or the nearest appropriate facility rule (proposed § 410.40(d)), the statutory basis for denial is section 1861(s)(7) of the Act, and the limitation on liability provisions do not apply.

In proposed § 410.40(g), we specify the narrow class of medical necessity denials to which the limitation on liability provisions of part 411, subpart K apply. We state, however, that § 411.404 concerning criteria for determining that a beneficiary knew that services are excluded from Medicare coverage does not apply to medical necessity payment denials for ambulance services.

Under this proposed rule, the use by suppliers of written advance notices to the beneficiaries of the likelihood of noncoverage by Medicare of ambulance services would not be permitted. We believe it would be inappropriate to allow an ambulance supplier to give written advance notice of the likelihood of noncoverage or to attempt to obtain an agreement from a beneficiary to pay

for ambulance services when the circumstances surrounding the need for ambulance services usually do not permit a beneficiary to make a rational, informed consumer decision. Nonetheless, if a supplier could not have been expected to know that a particular ambulance service was not medically necessary, the supplier would also not be held liable.

If, upon review, the carrier determines that the services furnished were not reasonable and necessary, and denies coverage of the services, partially or in full, the ambulance supplier has the right to appeal the determination as stated in part 405 subpart H. Consistent with existing policy, the right to appeal applies only to those ambulance suppliers that accept assignment. (This would not be an appropriate application when the supplier does not accept assignment and payment is made directly to the beneficiary. If the supplier does not accept assignment, the beneficiary has the right to appeal.) It is our belief, however, that proposed use of the ICD-9-CM diagnostic codes to describe the condition of the beneficiary would provide suppliers and ambulance personnel with additional knowledge that they need to make the correct decision when submitting a claim for payment. Therefore, we expect that there would be few instances when there would be appeals.

#### *H. Requirements for Ambulance Services*

##### *1. Vehicle*

We propose in § 410.41(a) that a vehicle used as an ambulance must be designed and equipped to respond to medical emergencies and, in non-emergency situations, be capable of transporting beneficiaries with acute medical conditions. The vehicle must also comply with all relevant State and local laws governing licensing and certification of an emergency medical transportation vehicle.

We would also require that, at a minimum, an ambulance 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.

##### *2. Vehicle Staff*

We propose in § 410.41(b)(1) the staffing requirements for the BLS level of services. We propose that the vehicle 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.

In § 410.41(b)(2), we propose the staffing requirements for the ALS level of services. The ALS-level ambulance would include at least two staff members. One of the staff members must be trained to provide basic first aid at the EMT B level and another member who must be trained and certified as a paramedic or as an emergency medical technician-advanced (EMT-A) who must also be trained and certified to perform one or more ALS services. Paramedics and emergency medical technicians must be certified by the State in which the services are furnished and legally authorized to operate all lifesaving equipment on board.

### 3. Billing and Reporting Requirements

We propose in § 410.41(c) that a supplier must use diagnostic and procedure codes designated by HCFA. We propose to designate the HCFA Common Procedure Coding System (HCPCS) codes describing the origin and destination of the services and ICD-9-CM diagnostic codes describing the beneficiary's medical condition (see Addendum 1 of this rule) to bill for covered ambulance services. We also would require that a supplier must, at the carrier's request, complete and return an ambulance supplier form established by HCFA and provide Medicare carriers with documentation of its compliance with State and local emergency vehicle and staff licensure and certification requirements (see Addendum 2 of this rule). In this paragraph, we also would require, upon the carriers request, that the supplier provide any additional information as required, for example when a supplier does not submit the required form and documentation or whenever there is a question about the supplier's documentation or there is a question

about the supplier's compliance with any of the requirements for vehicle and staff.

To be covered ambulance services, the services must be medically necessary in accordance with section 1862(a)(1) of the Act. Medical necessity is usually established on the basis of the description of the beneficiary's condition at the time of the transportation. Currently, we require the use of International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) diagnostic codes on Part B claims submitted by physicians as well as by other providers. Forty-six of the 53 Medicare carriers require the ambulance suppliers to include ICD-9-CM diagnostic codes to confirm medical necessity.

As stated above, we intend that all suppliers who bill Medicare for ambulance services use the HCPCS codes describing origin and destination, and the ICD-9-CM diagnostic codes to describe a beneficiary's condition, based on the information from the emergency medical technician or paramedic who furnishes treatment at the scene and during transportation.

The documentation required from each supplier would ensure that the vehicles used to furnish ambulance services are equipped and staffed to respond to emergency situations and in scheduled situations to be able to properly respond to acute care needs. The ambulance supplier form requirement would ensure that the documentation requirements are met.

### IV. Other Information

#### A. Paperwork 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.

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

The information collection requirements in § 410.40(c)(2) require the ambulance supplier to obtain certification from the beneficiary's physician to document the beneficiary's need for non-emergency, scheduled transportation by ambulance. We believe it is necessary to ensure that the ambulance services are medically necessary. The requirement for the physician's certification does not require a particular form or format and can be simply a letter written to describe the beneficiary's condition that supports the need for ambulance services. This could take as little as 10 minutes of the physician's time per patient and could be used by the supplier for a 60-day period. The burden on the supplier is to send in the certification with the first claim to the Medicare carrier or intermediary to validate the need for the transportation. We do not know how many suppliers or beneficiaries would be affected by this requirement; however, we do not believe the number to be substantial, nor do we believe the burden to be significant. The following chart shows the potential paperwork burden that may be imposed on physicians by this proposed rule.

ESTIMATED PAPERWORK BURDEN ON PHYSICIANS

CFR Section	Estimated annual number of ambulance trips requiring certification statements	Estimated average time in minutes to complete each statement	Estimated total annual burden hours
410.40(c)(2) .....	3,000	10	500

The information collection requirements in § 410.41(c)(1) concern treatment furnished to beneficiaries transported by ambulance. Suppliers

would be required to use ICD-9-CM diagnostic codes describing the beneficiary's condition to complete the claims form to bill the Medicare

program for payment for ambulance services. The diagnostic coding system we propose to use is a system of ICD-9-CM diagnostic codes and therefore



the transition from the coding system used by the great majority of suppliers to the new system would be seamless. In addition, the use of the new diagnostic codes would eliminate the narrative description of the beneficiary's condition currently required. Therefore, we believe this requirement would lessen the existing information collection burden on the supplier. The time estimated to place the correct codes on the form is approximately 1 minute. We do, however, acknowledge that using the ICD-9-CM diagnostic coding system may initially require more time than the estimated 1 minute. We would like to solicit comments from those contractors who do not require suppliers to submit claims with diagnostic codes. Specifically, we would like to receive information that will assist us in determining how problematic, if at all, required use of diagnostic codes will be to the contractor and its suppliers and the costs associated with the implementation of such a requirement.

Section 410.41(c)(2) requires the supplier to complete an ambulance supplier form and to provide documentation of vehicle and staff licensure and certification to the Medicare carrier. This simply requires photocopying documentation already required by the State or local law and

in the possession of the supplier and sending those copies, along with the form, to the carrier. We would 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 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. The supplier is also required to notify the carrier when a new vehicle or staff member is added to the business. Suppliers will not be required to complete a new form. Carriers may accept the supplier's statement and accompanying documentary evidence that vehicle and personnel requirements are met. We believe receipt of this documentation is necessary to ensure that newly acquired vehicles that will be used to furnish ambulance services are properly equipped and that newly hired EMS personnel are trained and certified to provide the appropriate level of emergency medical service to

respond to emergency situations and, in non-emergency situations, are able to respond to the acute care needs of the beneficiary. It is estimated that the time to complete this form is no more than 32 minutes.

Section 410.41(c)(3) requires that the supplier provide any additional information necessary to ensure that the carriers records are complete and up-to-date. Although we are unable to estimate the time that may be necessary to meet this requirement, we do not believe it will take the supplier longer than a couple of minutes to copy and send the additional documentation.

Section 410.40(e) provides for the criteria for our preferred alternative of an exception to the ALS and BLS payment criteria which will allow all payments to a supplier that met the criteria to be made at the ALS level. We may not include an exception in the final rule unless documentation is furnished convincing us that an exception process is necessary, but we have shown the potential paperwork burden associated with our preferred alternative and an alternative that is spelled out in the preamble to this rule.

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

ESTIMATED ANNUAL SUPPLIER REPORTING BURDEN

CFR Sections	Estimated number of ambulance suppliers	Estimated average burden per response	Estimated annual burden hours
410.41(c)(1) ICD-9-CM diagnostic codes ALS/BLS .....	9,000 .....	1 min.	150
410.41(c)(2) ambulance supplier form and documentation .....	9,000 .....	32 min.	4,530
410.41(c)(3) any additional information .....	9,000 .....	2 min.	300
410.40(e) Annual submission of supporting financial documentation for an ALS exception. OPTION #1.	(Potential) 3,000.	60 min.	3,000
OPTION #2 FOUND IN THE PREAMBLE .....	(Potential) 3,000.	60 min.	3,000

We have submitted a copy of this proposed rule to OMB for its review of the information collection requirements in §§410.40 and 410.41.

For comments that relate to information collection requirements, mail comments to:

Health Care Financing Administration, Office of Financial and Human Resources, Management Planning and Analysis Staff, 7500 Security Boulevard, Room #C2-26-17 Baltimore, Maryland, 21244-1850.

Mail a copy of your comments to: 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.

#### 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. We will consider all comments we receive by the date and time specified in the "DATES" section of this preamble, and, if we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

#### V. Regulatory Impact Statement

Consistent with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 through 612), we prepare a regulatory flexibility analysis unless the Secretary certifies that a rule would 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 603 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 E.O. 12866 to require a regulatory impact analysis; however, the following information, together with information provided elsewhere in this preamble constitute a voluntarily analysis and moot the requirements of the RFA. First, this proposed 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:

- A greater number of ambulance suppliers provide only the more expensive ALS level of services even if only a BLS level of services is warranted.
- High costs for equipment, supplies, and trained personnel incurred by all ambulance suppliers are passed on to the public.
- Provision of 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 of non-emergency vehicles that transport beneficiaries whose medical condition is such that transportation in an ambulance is unnecessary.

Second, we believe the proposals contained in this rule would 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 would 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 proposed 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 proposal primarily provide transportation services, such as wheelchair van transportation, we do not believe the number to be substantial. In an effort to determine the impact of this proposed change, we are requesting information from those suppliers of ambulance services who will potentially be affected by this proposal.

- The requirement for suppliers to use ICD-9-CM diagnostic codes to bill ambulance services would promote consistency in Medicare carrier processing of claims for ambulance services. The use of these codes would also reduce the uncertainty currently experienced by suppliers concerned about whether they will receive payment for their claims for specific types of services, because using the codes would assist suppliers in filing claims properly. The use of the appropriate ICD-9-CM diagnostic code to describe a beneficiary's medical condition would justify the need for ambulance services and determine the appropriate level of coverage. However, use of the appropriate diagnostic code does not make the claim payable if the beneficiary could have been transported by other means.

- The application of the limitation on liability protections would provide a safeguard to beneficiaries who must use ambulance services by ensuring that they would not be required to pay for differences in the amounts paid for BLS and ALS services. These same limitation on liability protections provide safeguards for the suppliers as well. For example, if the supplier erred on the side of caution by furnishing an (ALS level of) ambulance service that was more costly than was necessary because the medical situation was less severe than was first thought to have existed, the supplier would not bear the adverse economic burden of that decision.

- The requirement for physicians to certify the need for scheduled ambulance services of beneficiaries who are inpatients to outside facilities to receive therapy or treatment would ensure that those beneficiaries receiving the services actually need them. Also, the provision permitting ESRD beneficiaries to be transported to nonhospital-based facilities nearest their home would be more convenient, since they would 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 further from their homes would be more costly.

Third, if we are convinced that an exception to the ALS/BLS rule is necessary, the non-Metropolitan Statistical Area exception that would permit coverage of the more costly ALS level of services in non-Metropolitan Statistical Areas could assure access to ambulance services where there is only one ambulance supplier. However we will create an exception only if we believe that the rule would impose financial hardship on isolated suppliers that cannot maintain both BLS and ALS vehicles.

Last, the overall savings that this rule would generate are listed below:

MEDICARE PROGRAM SAVINGS

[In millions]

Fiscal Years				
1997	1998	1999	2000	2001
\$50 .....	\$55	\$60	\$65	\$75

A primary concern in basing coverage and payment on medical necessity is the issue of ambulance services in sparsely populated areas. We realize that there are areas where multiple ambulances, a

mix of BLS and ALS, are not economical and, as such, acknowledge that the distributive effect of this regulation may be perceived as uneven because billing for ALS only services occurs only in

some areas. In terms of expenditure cutbacks the estimated \$50 million in spending reductions in the first year out of a total of \$1.83 billion has been determined to result in a national

reduction of about 2.7 percent of the total expenditures for ambulances services. Through further analysis of this circumstance we have determined that we can expect to see that a limited impact of one half of the anticipated cutback in payments (approximately \$25 million) would take place in northern California, Florida, Mississippi, Texas, and Ohio, and one-fourth of the cutback (another \$12.5 million) would take place in Alabama, Arkansas, Georgia, Louisiana, Oklahoma, and Oregon. We are able to identify these areas on the basis of regional patterns that reflect areas where there is use of predominately ALS services. There are, however, no national data identifying communities that mandate using ALS services exclusively. The program used to determine this impact is aggregated by locality and does not contain provider specific information. Therefore, while we are unable to determine exactly how many suppliers in the aforementioned areas will be affected, we have estimated the dollar impact by State if the areas furnished a mix of BLS/ALS services approximating the national average.

In determining what special considerations may be warranted to mitigate the possible negative impact on non-Metropolitan Statistical Areas of the country, we considered two alternatives as a possible solution. Under the first and preferred alternative we would propose to continue to reimburse ambulance suppliers in a non-Metropolitan Statistical Area for the ALS level of service if the State EMS Director can certify that the ambulance supplier meets established criteria. The second alternative we considered would be to create an exception with criteria similar to those used for sole community hospitals under Medicare's prospective payment system for hospitals. The specifics of both alternatives are discussed at length in the preamble. We also had to take into consideration questions that were raised that have led us to doubt the need for any exception to the proposed rules. To foster better understanding of this problem or potential problem, we have issued a request for information from interested parties on the need for an exception and to help identify areas where it might apply. This aspect of our analysis is also discussed at length in the preamble.

If an exception is implemented, this perceived "uneven" impact may not be as significant in the States listed above. Also, we may find that the overall national impact is less than anticipated. In any event, our clarification of the

criteria for coverage of ambulance services should reduce allowances only to those suppliers now receiving payments incorrectly. The limitation on liability provisions will protect both beneficiaries and suppliers where they are "without fault."

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

#### List of Subjects

##### 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 would be amended as set forth below:

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

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.* (1) Medicare Part B covers ambulance services if the supplier meets the applicable vehicle, staff, and billing and reporting requirements of §410.41 and the medical necessity and origin and destination requirements of this section.

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

(b) *Levels of services.* Except as provided in paragraph (e) of this section (concerning ALS services furnished in non-MSA areas) and based on the level of services needed to treat a beneficiary's condition (as described by diagnostic codes that HCFA designates for ambulance services), Medicare covers ambulance services within the United States as one of the following levels of services:

- (1) Basic life support (BLS) services.
- (2) Advanced life support (ALS) services.

(c) *Medical necessity requirements.* (1) Except as provided in paragraph (c)(2) of this section, Medicare covers ambulance services if they are furnished to a beneficiary whose medical condition is such that other means of

transportation would be contraindicated.

(2) Medicare covers non-emergency transportation services if the ambulance supplier, before furnishing services to the beneficiary, obtains a current written physician's order certifying that the beneficiary must be transported in an ambulance because other means of transportation would be contraindicated. The physician's order must be dated no earlier than 60 days before the date the service is furnished.

(3) In accordance with section 1861(s)(7) of the Act, HCFA:

(i) Establishes guidelines on the use of diagnostic codes that ensure the medical necessity of ambulance services, coverage at the appropriate level of service (BLS or ALS), and consistency in claims filing.

(ii) Updates the guidelines and codes as necessary.

(d) *Origin and destination requirements.* The following transportation is covered:

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

(2) From a hospital, RPCH, 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 an inpatient, including the return trip.

(4) For a beneficiary who is receiving renal dialysis for treatment of ESRD if the requirements of paragraph (c)(2) of this section are met, from the beneficiary's home to the nearest facility that supplies renal dialysis, including the return trip.

(e) *Coverage exception for ALS services in non-MSA areas.* Medicare covers ambulance services as ALS level of services if the following conditions are met:

(1) The State Emergency Medical Services Director makes, on an annual basis, the following certification:

(i) The ground ambulance supplier serves a county or comparable New England entity that is not designated as a Metropolitan Statistical Area by the Office of Management and Budget (that is, a non-MSA area).

(ii) The supplier is either the sole supplier of ground ambulance services in the area, or is located more than 40 miles from any other available ground emergency services vehicle in the area.

(iii) The supplier owns and operates ambulance vehicles.

(iv) The supplier furnishes only ALS ambulance vehicles and staff.

(2) The supplier submits annually to the carrier financial information demonstrating that without payment at the ALS level, beneficiary access to ambulance services in the area would be jeopardized.

(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.

(g) *Limitation on beneficiary liability.* (1) If the supplier furnishes BLS level of ambulance services to an individual, but uses an ALS-level vehicle and submits a bill for Medicare payment of ALS level of services, HCFA partially denies coverage of the services under § 411.15(k) of this chapter because the services are not reasonable or necessary and reduces payment from the ALS level of services to the BLS level of services.

(2) For amounts denied under paragraph (g)(1) of this section, the provisions of § 411.404 notwithstanding, HCFA considers beneficiaries to meet the conditions of § 411.400(a)(2) of this chapter, that is, not to have known or been expected to know that the services are not covered under Medicare.

3. Section 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.

(3) Be equipped with telecommunications equipment to send and receive voice and data transmissions.

(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 who meet the following requirements:

(i) Are certified as emergency medical technicians-basic (EMT-B) by the State or local authority where the services are furnished.

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

(2) *ALS vehicles.* In addition to meeting the 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-advanced (EMT-A) who is certified 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 HCFA designated diagnostic codes to describe the beneficiary's medical condition.

(2) Upon a carrier's request, complete and return the ambulance supplier form developed by HCFA and provide the Medicare carrier with documentation of emergency vehicle and staff licensure and certification requirements in keeping 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 is revised to read as follows:

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

**§ 424.124 [Amended]**

2. In § 424.124, paragraph (c)(2) is amended by removing the citation “§ 410.140” and adding in its place the citation “§ 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: January 8, 1997.

**Bruce C. Vladeck,**

*Administrator, Health Care Financing Administration.*

Dated: January 29, 1997.

**Donna E. Shalala,**

*Secretary.*

**Addendum 1**

We would assign International Classification of Diseases 9th revision, Clinical Modification (ICD-9-CM) diagnostic codes to each of the following conditions:

(Listed in the first column are the medical conditions that are encountered most frequently by ambulance crews. The second column contains the corresponding ICD-9-CM code(s). In the third column we have placed an “A” denoting “ALS”, “B” denoting “BLS”, or “B/A” denoting both “BLS/ALS”. If only an “A” or “B” is in the column, it means that the trip will be paid as only as ALS or BLS. If both “B/A” appear, while it is expected that most trips will be BLS, the determination regarding which level of service is medically necessary will be made, based on documentation submitted by the supplier, at the discretion of the carrier. Please note that this list is not exhaustive. In unusual circumstances that warrant the need for ambulance services, the Carrier may accept the use of other ICD-9-CM codes to describe a medical condition that is not on this list).

Condition	ICD-9-CM Code	BLS/ ALS Level
Abdominal Pain .....	789.00, 789.07	B/A
	789.09	
Abnormal Electrocardiogram (EKG) .....	794.31	A
Asphyxiation and Strangulation .....	994.7	A
Backache, unspecified .....	724.5	B
Burns .....	949.0, 949.1,	B/A
	949.2, 949.3,	
	949.4, 949.5	
Cardiac Arrest .....	427.5	A
Chest Pain, unspecified .....	786.50	A
Coma .....	780.01	B

Condition	ICD-9-CM Code	BLS/ ALS Level
Contracture of Multiple Joints .....	718.49	B
Convulsions .....	780.3	B
Delirium, acute .....	293.0	B
Dead on Arrival (DOA) (Cause unknown; death occurring in less than 24 hours from onset of symptoms) .....	798.2	B
Drowning .....	994.1	A
Drug Overdose; Unspecified Drug or Medicinal Substance .....	977.9	A
Effects of Lightning .....	994.0	A
Electrocution and nonfatal effects caused by electric current .....	994.8	A
Food Poisoning; unspecified .....	005.9	B/A
Head Injury, closed .....	854.0	A
Head Injury, open .....	854.1	A
Hemorrhage of Gastrointestinal Tract, unspecified .....	578.9	B/A
Hemorrhage, unspecified .....	459.0	B/A
Hypothermia .....	991.6	A
Injuries, multiple .....	959.8	A
Injury to Elbow, Forearm and Wrist .....	959.3	B
Injury to Face and Neck .....	959.0	B/A
Injury to Hand .....	959.4	A
Injury to Hip and Thigh .....	959.6	B
Injury to Knee, Ankle, Leg and Foot .....	959.7	B
Injury to Shoulder and Upper Arm .....	959.2	B
Injury to Trunk .....	959.1	A
Instantaneous Death .....	798.1	B
Joint Pain, multiple .....	719.40	B
Open Wound, Unspecified Eye Ball .....	871.9	B
Other Artificial Opening (e.g., presence of chest tubes) .....	v44.48	B
Other Specified Problems Influencing Health Status (e.g., bed-confined) .....	v49.8	B
Pelvis Pain, female .....	625.9	B/A
Pelvis Pain, male .....	789.0	B/A
Pelvis Stiffness .....	719.55	B/A
Poisoning, unspecified noxious substance eaten as food .....	989.9	B/A
Respiratory Arrest .....	799.1	A
Respiratory Distress .....	786.09	A
Shock .....	785.50	A
Smoke Inhalation, Symptomatic .....	987.9	A
Stroke .....	436	A
Transient Alteration of Awareness .....	780.02	B/A
Unconscious .....	780.09	B
Unspecified Complication of Labor and Delivery .....	669.9	A
Wound Disruption of (Dehiscence) .....	998.3	B/A

**Addendum 2**

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 Carriers discretion so that our agents will be assured that they have the latest documentation on file 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).

BILLING CODE 4120-01-P

**Addendum 2****AMBULANCE SUPPLIER FORM**

1. Name of Ambulance Company \_\_\_\_\_  
**Please list the legal business name**

Medicare Provider Number \_\_\_\_\_

2. Business Address \_\_\_\_\_

Mailing Address \_\_\_\_\_

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

3. Owner's Name(s) \_\_\_\_\_  
**Identify all individuals and their social security numbers or entities who have ownership or controlling interest. For each owner, fill in all of the requested information.**

Owner's Address \_\_\_\_\_

Telephone Number(s) \_\_\_\_\_

4. Business Telephone Number(s) \_\_\_\_\_  
**List Telephone Numbers for all locations. The business telephone number(s) must be numbers where patients or customers can reach you or register complaints.**

5. Federal Tax Identification Number \_\_\_\_\_

6. License Number \_\_\_\_\_  
**A copy of your current license/certificate must be submitted with this form. The effective date and expiration date must be stated on the license/certificate. Program payment will be made based on these dates. You must provide this office with a copy of the renewal license/certificate in order to receive payment after the expiration date.**

**All of the following criteria must be met in order to be approved by Medicare. If additional space is needed, please add an attachment.**

**7. What is the total number of licensed/certified ambulances in your fleet ?****Identify all of the ambulances in your fleet and their location**

# 1. Make \_\_\_\_\_ Model \_\_\_\_\_ Year \_\_\_\_\_

Location \_\_\_\_\_

#2. Make \_\_\_\_\_ Model \_\_\_\_\_ Year \_\_\_\_\_

Location \_\_\_\_\_

**8. Do your ambulances have the following: please respond accordingly for each ambulance in your fleet**

(A) First Aid Supplies ?

#1: Yes \_\_\_\_ No \_\_\_\_

#2: Yes \_\_\_\_ No \_\_\_\_

(B) Oxygen Equipment ?

#1: Yes \_\_\_\_ No \_\_\_\_

#2: Yes \_\_\_\_ No \_\_\_\_

(C) Other Safety and Lifesaving Equipment ?

#1 Yes \_\_\_\_ No \_\_\_\_

#2 Yes \_\_\_\_ No \_\_\_\_

**Provide a list of equipment with which each ambulance is equipped.**

#1 \_\_\_\_\_

\_\_\_\_\_

#2 \_\_\_\_\_

\_\_\_\_\_

**Do your ambulances have the following communications devices ?**

Please respond accordingly for each ambulance in your fleet

(A) Two-way telecommunications radio ? #1 Yes \_\_\_\_ No \_\_\_\_



#2 Yes \_\_\_\_ No \_\_\_\_

(B) Portable Communication ?

#1 Yes \_\_\_\_ No \_\_\_\_

#2 Yes \_\_\_\_ No \_\_\_\_

(C ) Warning Lights ?

#1 Yes \_\_\_\_ No \_\_\_\_

#2 Yes \_\_\_\_ No \_\_\_\_

(D) Sirens ?

#1 Yes \_\_\_\_ No \_\_\_\_

#2 Yes \_\_\_\_ No \_\_\_\_

9. **Do you provide the following level of service:**

(A) Basic Life Support (BLS)

Yes \_\_\_\_ No \_\_\_\_

How many of your ambulances are licensed/certified to provide this level of service ? \_\_\_\_

(B) Advanced Life Support (ALS)

Yes \_\_\_\_ No \_\_\_\_

How many of your ambulances are licensed/certified to provide this level of service ? \_\_\_\_

(C ) Air Ambulance Service

Yes \_\_\_\_ No \_\_\_\_

**\* Please provide written documentation of certification from the authorized State or local licensing and regulatory agency for each vehicle.**

10. How many crew members do you send on each run ? Please respond accordingly for each ambulance in your fleet

#1 \_\_\_\_\_

#2 \_\_\_\_\_

11. Please list the name of each crew member and their individual training (i.e., CPR, First Aid, ACLS etc.). A copy of their certificate(s) of training **must** be attached.

Name: \_\_\_\_\_

Training: \_\_\_\_\_

Name: \_\_\_\_\_

Training: \_\_\_\_\_

**\*\* QUESTION 12 SHOULD BE COMPLETED BY CERTIFIED BLS COMPANIES ONLY**

12. Do you bill Method 1, an all inclusive base rate ? Yes \_\_\_\_ No \_\_\_\_

Do you bill Method 2, base rate plus a separate charge for mileage ?

Yes \_\_\_\_ No \_\_\_\_

Do you bill Method 3, base rate plus a separate charge for supplies ?

Yes \_\_\_\_ No \_\_\_\_

Do you bill Method 4, separate charges for services, mileage, and supplies ?

Yes \_\_\_\_ No \_\_\_\_

Are you certified to perform defibrillation ?

Yes \_\_\_\_ No \_\_\_\_

(If yes, a copy of the certification must be attached)

**\*\* QUESTION 13 SHOULD BE COMPLETED BY CERTIFIED ALS COMPANIES ONLY**

13. Do you bill Method 1, an all-inclusive base rate ? Yes \_\_\_\_ No \_\_\_\_

Do you bill Method 2, base rate plus a separate charge for mileage ?

Yes \_\_\_\_ No \_\_\_\_

Do you bill Method 3, base rate plus a separate charge for supplies ?

Yes \_\_\_\_ No \_\_\_\_

Do you bill Method 4, separate charges for services, mileage, and supplies ?

Yes \_\_\_\_ No \_\_\_\_

Are you certified to perform defibrillation ?

Yes \_\_\_\_ No \_\_\_\_

**(If yes, a copy of the certification must be attached)**

Name of Medical Director: \_\_\_\_\_

14. What geographic area do you serve ? \_\_\_\_\_

15. Has your company, any owner or employee **ever** been excluded from participation in the Medicare/Medicaid program ? Yes \_\_\_\_ No \_\_\_\_

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

\_\_\_\_\_  
\_\_\_\_\_

Please list prior Medicare Identification Number(s) \_\_\_\_\_

Please list name of prior Carrier \_\_\_\_\_

**(If service was provided to Medicaid program please list prior Medicaid number and the State where service was provided.)**

16. You agree to notify this office of any change in operation, ownership or revocation of license. It is also understood that representatives from the Medicare Office may make on-site inspections at any time.

**I have read and agree to the above by signing below on this \_\_\_\_ day of \_\_\_\_\_  
In the year of \_\_\_\_\_.**

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Signature: \_\_\_\_\_

[FR Doc. 97-15829 Filed 6-16-97; 8:45 am]

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## DEPARTMENT OF THE INTERIOR

## Fish and Wildlife Service

## 50 CFR Part 17

RIN 1018-AB73

**Endangered and Threatened Wildlife and Plants, Notice of Second Reopening of Comment Period on Proposed Endangered Status for the Peninsular Ranges Population of the Desert Bighorn Sheep****AGENCY:** Fish and Wildlife Service, Interior.**ACTION:** Proposed rule, notice of second reopening of comment period.

**SUMMARY:** The Fish and Wildlife Service (Service), pursuant to the Endangered Species Act of 1973, as amended (Act), provides notice of a second reopening of the comment period on the proposed endangered status for the Peninsular Ranges population of desert bighorn sheep (*Ovis canadensis*). On April 7, 1997, the Service reopened the comment period to acquire additional information from interested parties, and to resume the proposed listing action (62 FR 16518). In addition, the Service sought public comment on various articles and reports concerning the distinctiveness and status of bighorn sheep in the Peninsular Ranges. Because of a request to allow for further development of biological, distributional, and status information on the bighorn sheep, the comment period is reopened again for another 15 days.

**DATES:** The public comment period closes July 2, 1997. Any comments received by the closing date will be considered in the final decision on this proposal.

**ADDRESSES:** Written comments, materials and data, and available reports and articles concerning this proposal should be sent directly to the Field Supervisor, Carlsbad Field Office, U.S. Fish and Wildlife Service, 2730 Loker Avenue West, Carlsbad, California 92008. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address.

**FOR FURTHER INFORMATION CONTACT:** Peter Sorensen, at the address listed above (telephone 760/431-9440, facsimile 760/431-9618).

## SUPPLEMENTARY INFORMATION:

**Background**

The Peninsular Ranges population of the desert bighorn sheep occurs along desert slopes of the Peninsular Ranges from the vicinity of Palm Springs, California, into northern Baja California, Mexico. Depressed recruitment, habitat loss and degradation, disease, loss of dispersal corridors, and random events (e.g., drought) affecting small populations threaten the desert bighorn sheep in the Peninsular Ranges.

On May 8, 1992, the Service published a rule proposing endangered status for the Peninsular Ranges population of the desert bighorn sheep (57 FR 19837). The original comment period closed on November 4, 1992. The Service was unable to make a final listing determination regarding the bighorn sheep because of a limited budget, other endangered species assignments driven by court orders, and higher listing priorities. In addition, a moratorium on listing actions (Public Law 104-6), which took effect on April 10, 1995, stipulated that no funds could be used to make final listing or critical habitat determinations. Now that funding has been restored, the Service is proceeding with a final determination for the Peninsular Ranges population of the desert bighorn sheep.

Due to the length of time that has elapsed since the close of the initial comment period, changing procedural and biological circumstances and the need to review the best scientific information available during the decision-making process, the Service reopened the comment period for 30 days on April 7, 1997 (62 FR 16518). Moreover, the Service reopened the comment period to ensure that this proposed listing of a population of desert bighorn sheep is consistent with Service policy published on February 7, 1996, regarding the recognition of distinct vertebrate population segments (61 FR 4722). This policy requires that distinct population segments be discrete from other populations of the species, be biologically and/or ecologically significant to the species, and meet the standards of an endangered or threatened species under section 4(a) of the Act. On May 6, 1997, the Service received a request from Mr. Francis D. Logan, Jr., a representative of a landowner potentially affected by this proposal, to hold a public hearing and to extend the comment period to allow for the development of further biological, distributional, and status information on the bighorn sheep. Though the Service will not hold a hearing, the Service reopens the

comment period for 15 days. In this regard, the following recent articles and reports contained in Service files, including other non-cited information, remain available for public review:

- Berger, J.* 1990. Persistence of different-sized populations: An empirical assessment of rapid extinctions. *Conservation Biology* 4:91-98.
- Bleich, V., C., J. D. Wehausen, and S. A. Holl.* 1990. Desert-dwelling mountain sheep: Conservation implications of a naturally fragmented distribution. *Conservation Biology* 4:383-390.
- Bleich, V., C., J. D. Wehausen, R. R. Ramey II, and J. L. Rechel.* 1997. Metapopulation theory and mountain sheep: Implications for conservation. Pages 353-373 in D. R. McCullough, editor. *Metapopulations and Wildlife Conservation*, Island Press, Washington, D.C.
- Bighorn Institute.* 1996. Summary of the San Jacinto Mountains helicopter survey of Peninsular bighorn sheep. unpublished report, 2 pp.
- Bighorn Institute.* 1996. Summary of the Santa Rosa Mountains helicopter survey of Peninsular bighorn sheep. unpublished report, 3 pp.
- Boyce, W. M., P. W. Hedrick, N. E. Muggli-Cockett, S. Kalinowski, M. C. T. Penedo, and R. R. Ramey II.* 1997. Genetic variation of major histocompatibility complex and microsatellite loci: A comparison in bighorn sheep. *Genetics* 145:421-433.
- DeForge, J. R., E. M. Barrett, S. D. Ostermann, M. C. Jorgensen, and S. G. Torres.* 1995. Population dynamics of Peninsular bighorn sheep in the Santa Rosa Mountains, California. *Desert Bighorn Council Trans.* 39:50-57.
- R. R. Ramey II.* 1995. Mitochondrial DNA variation, population structure, and evolution of mountain sheep in the south-western United States and Mexico. *Molecular Ecology* 4:429-439.
- Rubin, E., and W. Boyce.* 1996. Results of helicopter survey conducted in Anza-Borrego Desert State Park. unpublished memo to Steve Torres (CDFG Bighorn Sheep Coordinator) and project collaborators. 6 pp.
- Wehausen, J. D., and R. R. Ramey II.* 1993. A morphometric reevaluation of the Peninsular bighorn subspecies. *Desert Bighorn Council Trans.* 37:1-10.

Regarding the above articles and reports, the Service particularly seeks information concerning:

- (1) the biological and ecological distinctiveness of bighorn sheep in the Peninsular Ranges from other populations of bighorn sheep;
- (2) other biological, commercial, or other relevant data on any threat (or lack thereof) to bighorn sheep in the Peninsular Ranges; and
- (3) the current size, number, or distribution of bighorn sheep populations in the Peninsular Ranges.