

application. Cumulatively, these organizations report the total burden to applicants to be 2,863 hours.

*Frequency:* Recordkeeping, Reporting, on occasion.

*Affected:* Individuals.

*Total Annual Respondents:* 5,827.

*Total Annual Responses:* 6,949.

*Average Burden Per Response:* 25 minutes.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access the HHS Web site address at <http://www.hhs.gov/oirm/infocollect/pending/> or e-mail your request, including your address, phone number, OMB number, and OS document identifier, to [naomi.cook@hhs.gov](mailto:naomi.cook@hhs.gov), or call the Reports Clearance Office on (202) 690-6162.

Written comments and recommendations for the proposed information collections must be mailed within 60 days of this notice directly to the OS Paperwork Clearance Officer designated at the following address: Department of Health and Human Services, Office of the Secretary, Assistant Secretary for Budget, Technology, and Finance, Office of Information and Resource Management, Attention: Naomi Cook (4040-0005), Room 531-H, 200 Independence Avenue, SW., Washington DC 20201.

Dated: August 18, 2005.

**Robert E. Polson,**

*Office of the Secretary, Paperwork Reduction Act Reports Clearance Officer.*

[FR Doc. 05-17430 Filed 8-31-05; 8:45 am]

**BILLING CODE 4151-17-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### National Center for Injury Prevention and Control Initial Review Group: Notice of Charter Renewal

This gives notice under the Federal Advisory Committee Act (Pub. L. 92-463) of October 6, 1972, that the National Center for Injury Prevention and Control Initial Review Group, Centers for Disease Control and Prevention of the Department of Health and Human Services, has been renewed for a 2-year period extending through August 20, 2007.

For further information, contact Gwen Cattledge, Executive Secretary, National Center for Injury Prevention and Control Initial Review Group, Centers for Disease Control and Prevention of the Department of Health and Human

Services, 4770 Buford Highway, NE., M/ S K02, Atlanta, Georgia 30341-3717, telephone 770-488-4655.

The Director, Management and Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: August 26, 2005.

**B. Kathy Skipper,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.*

[FR Doc. 05-17399 Filed 8-31-05; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Disease Control and Prevention

#### Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Epidemiologic Study of Inflammatory Bowel Disease, Request for Applications Number DP-05-130; Correction

*Correction:* This notice was published in the **Federal Register** on August 18, 2005, Volume 70, Number 159, page 48574. The meeting time and date has been changed.

*Time and Date:* 2:30 p.m.-4 p.m., September 27, 2005 (Closed).

**FOR FURTHER INFORMATION CONTACT:** J. Felix Rogers, PhD, MPH, Scientific Review Administrator, National Center for Chronic Disease Prevention and Health Promotion, 4770 Buford Highway, MS-K92, Atlanta, GA 30341, Telephone 404.639.6101.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: August 26, 2005.

**B. Kathy Skipper,**

*Acting Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).*

[FR Doc. 05-17410 Filed 8-31-05; 8:45 am]

**BILLING CODE 4163-18-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1308-NC]

RIN 0938-AN94

#### Medicare Program; Withdrawal of Ambulance Fee Schedule Issued in Accordance With Federal District Court Order in *Lifestar Ambulance, Inc. v. United States*, No. 4:02-CV-127-1 (M.D. Ga., Jan. 16, 2003)—Medicare Covered Ambulance Services

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice with comment period.

**SUMMARY:** This notice with comment period withdraws the fee schedule that was put in place in 2003 to effect compliance with the Order in *Lifestar Ambulance, Inc. v. United States*. [211 F.R.D. 688 (M.D. Ga. 2003)] That Order was vacated on January 10, 2005 by the U.S. Court of Appeals for the Eleventh Circuit and is no longer in force.

**DATES:** To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on October 31, 2005.

**ADDRESSES:** In commenting, please refer to file code CMS-1308-NC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments to <http://www.cms.hhs.gov/regulations/ecomments> or to <http://www.regulations.gov> (attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word).

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1308-NC, P.O. Box 8011, Baltimore, MD 21244-1850.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By express or overnight mail.* You may send written comments (one original and two copies) to the following address ONLY: Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS-1308-NC, Mail Stop C4-26-05, 7500 Security Boulevard, Baltimore, MD 21244-1850.

4. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-7197 in advance to schedule your arrival with one of our staff members.

Room 445-G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244-1850.

(Because access to the interior of the Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

**EFFECTIVE DATE:** This notice is effective on September 1, 2005.

**FOR FURTHER INFORMATION CONTACT:** Anne Tayloe, (410) 786-4546.

**SUPPLEMENTARY INFORMATION:**

*Submitting Comments:* We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS-1308-NC and the specific "issue identifier" that precedes the section on which you choose to comment.

*Inspection of Public Comments:* All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. CMS posts all electronic comments received before the close of the comment period on its public Web site as soon as possible after they have been received. Hard copy comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to

4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

**I. Background**

[If you choose to comment on issues in this section, please include the caption "BACKGROUND" at the beginning of your comments.]

Section 4531 of the Balanced Budget Act of 1997 (BBA) required the Secretary of the Department of Health and Human Services (HHS) (the Secretary) to establish a national fee schedule (FS) for payment of ambulance services through a negotiated rulemaking process. The statute provides that the Secretary phase in the application of payment rates under the FS in a fair and efficient manner and that the aggregate amount of payment for the services under the new FS not exceed the amount that would be paid under the old system as stated in section 1834(l) of the Social Security Act (the Act). The BBA provided that the FS would apply to services furnished on or after January 1, 2000.

The proposed and final FS rules both provided for payment for ambulance services to be made in two parts: (1) A base rate; and (2) a payment for mileage. Section 423 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA), which was passed after the publication of the proposed FS rule and prior to the publication of the final rule, provided that during the phase-in of the FS there would be full payment of any national mileage rate for ambulance services furnished by suppliers in States where the Medicare carrier did not previously pay separately for all mileage within the county from which the beneficiary is transported ("BIPA mileage provision"). Two States were identified as qualifying under this provision: North Carolina (NC) and Tennessee (TN). BIPA specifies that this provision applies to services furnished on or after July 1, 2001.

This FS was implemented on April 1, 2002 by a final rule published in the **Federal Register** on February 27, 2002 (67 FR 9100). As stated in the final rule, the phase-in is accomplished over five years by blending a percentage of the payment that is based on the old payment system with a percentage of the payment based on the FS according to the following schedule:

| Year                | Old (percent) | FS (percent) |
|---------------------|---------------|--------------|
| 4/1/2002-12/31/2002 | 80            | 20           |
| 2003                | 60            | 40           |
| 2004                | 40            | 60           |

| Year | Old (percent) | FS (percent) |
|------|---------------|--------------|
| 2005 | 20            | 80           |
| 2006 | 0             | 100          |

The full national FS mileage rate in those States that qualify for BIPA provision section 423 (NC, TN) was paid as of April 1, 2002.

In *Lifestar Ambulance Service, Inc. v. United States*, 211 F.R.D. 688 (M.D. Ga. 2003), three ambulance suppliers seeking to represent a nationwide class of ambulance suppliers sued the Secretary, arguing that he had no discretion to give the FS an effective date other than January 1, 2000. The district court agreed with the plaintiff suppliers and issued an order certifying a nationwide class of ambulance suppliers and requiring the Secretary to adopt a FS for the January 1, 2000, through March 31, 2002 period. The court's decision also required the Secretary to pay full mileage under the BIPA provision for the July 1, 2001 through March 31, 2002 period.

On April 16, 2003, the Secretary issued a notice in compliance with the district court's order. (68 FR 18654) The Secretary established a FS based on the FS as described in the **Federal Register** (67 FR 9100), with a modified phase-in as follows:

| Year               | Old (percent) | FS (percent) |
|--------------------|---------------|--------------|
| 2000               | 95            | 5            |
| 2001               | 90            | 10           |
| 1/1/2002-3/31/2002 | 80            | 20           |

Additionally, under the district court's order, the notice stated that the Medicare program would pay full BIPA mileage for services provided on or after July 1, 2001. The notice stated that the Secretary had appealed the decision in *Lifestar* and that any FS or BIPA mileage payment made under the notice for the January 1, 2000 through March 31, 2002 period would be subject to recoupment if the district court's decision was reversed on appeal. The Secretary has not made any payments under this FS. In addition, we are not aware of any ambulance suppliers seeking payment under this FS prior to the Eleventh Circuit's reversal of the district court decision, although some were seeking full mileage under the BIPA mileage provision.

On appeal, the Eleventh Circuit found that the district court had lacked jurisdiction over the case because the plaintiffs had not gone through the administrative process before filing suit. See *Lifestar Ambulance Service, Inc. v.*

*United States*, 365 F.3d 1293 (11th Cir. 2004), *cert. denied*, -US-, 125 S.Ct. 866 (Jan 10, 2005). It reversed and vacated the district court decision and remanded the case with instructions to dismiss for lack of subject-matter jurisdiction. Plaintiffs unsuccessfully sought rehearing *en banc* and Supreme Court review. The district court dismissed the complaint in accordance with the Eleventh Circuit's mandate on February 2, 2005.

## II. Provisions of the Notice With Comment Period

[If you choose to comment on issues in this section, please include the caption "PROVISIONS" at the beginning of your comments.]

The purpose of this notice is to withdraw the FS covering the period of January 1, 2000 through March 31, 2002 that was published in the April 16, 2003 notice. As we stated explicitly in the April 16, 2003 notice, we only issued this ambulance fee schedule to comply with the *Lifestar* district court order and that order was vacated and the *Lifestar* case dismissed. Although the April 16, 2003 notice clearly states that payment under the FS for the January 1, 2000 through March 31, 2002 period is dependent on the district court opinion not being reversed by the Eleventh Circuit Court of Appeals, refraining from formally withdrawing the FS for this period could create unnecessary confusion.

In light of our inability to issue a fee schedule by January 1, 2000, we continue to believe that giving the fee schedule prospective application clearly meets the intent of the Congress. The Congress made no indication that it wanted us to apply the base rate or the mileage provisions of the FS retroactively in the event that we were unable to issue the final FS by January 1, 2000. Also, given ample opportunity, the Congress did not provide specific direction regarding this issue after the January 1, 2000 date passed. The Congress itself took no further action on the issue (such as directing the implementation of its own version of an ambulance fee schedule).

Furthermore, the BBA directed the Secretary to phase in the application of the payment rates under the fee schedule in an efficient and fair manner and required that payments under the schedule in the year 2000 not exceed the inflation-adjusted expenditures that were made under the prior statute as stated in section 1834(l) of the Act. The FS was to reallocate expenditures among ambulance providers and suppliers in a manner that did not result in an increase in aggregate payments for

ambulance services (for example, some providers and suppliers would have received higher payments, others would have received lower payments, and the changes would have offset each other.) Only additional payments made under the BIPA mileage provision were not required to meet this criteria. Applying the FS to the January 1, 2000 through March 31, 2002 period would violate this principle unless the FS applied to all ambulance providers and suppliers, not just those seeking additional payment under it. Accordingly, we may have to recoup monies paid to those providers and suppliers whose payments were greater under the pre-existing "reasonable charge" and "reasonable cost" system when compared to what they would have received under the FS for the January 1, 2000 through March 31, 2002 period. Applying the FS retroactively to the providers and suppliers would arguably not constitute a fair phase-in of the FS provisions.

## III. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substance of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

The FS being withdrawn by this notice was only put in place pursuant to the court's order in *Lifestar*, and explicitly provided that it would not be effective in the event the *Lifestar* decision was overturned on appeal. The *Lifestar* decision has been vacated, and the case in district court dismissed. To our knowledge no payments have been made under the FS to date and, had they been, such payments would be subject to recoupment pursuant to the provisions of the April 16, 2003, notice. Accordingly, there is no reason to keep a FS in place that CMS is no longer required to promulgate, and under which it would make no payments in light of the appellate court decision. To leave the FS in place while awaiting comments would only generate confusion on the part of ambulance providers and suppliers.

Therefore, we find good cause to waive the notice of proposed

rulemaking with respect to the issuance of this notice.

## IV. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 35).

## V. Regulatory Impact Statement or Analysis

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

Because the FS for the January 1, 2000 through March 31, 2002 is not one under which we are required to make payments in light of the Eleventh Circuit reversal of the district court decision, withdrawing the FS will have no financial impact on providers and suppliers, or on government spending.

Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects (\$100 million or more in any 1 year). Because the FS being withdrawn is not one under which we are required to make payments, in light of the Eleventh Circuit decision, withdrawing it will have no financial impact on program spending. Therefore, this notice is not a major notice as defined in Title 5, United States Code, section 804(2) and is not an economically significant notice under Executive Order 12866.

The RFA requires agencies to analyze options for regulatory relief of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small governmental jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of \$6 million to \$29 million in any 1 year. Individuals and States are not considered to be small entities. We have determined that this notice will not

have a significant economic impact on a substantial number of small entities. Therefore, we are not preparing an analysis for the RFA.

In addition, section 1102(b) of the Social Security Act (the Act) requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. We have determined that this notice will not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing an analysis for section 1102(b) of the Act.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditures in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of \$110 million. This notice has no consequential effect on State, local, or tribal governments or on the private sector.

Executive Order 13132 establishes certain requirements that an agency must meet when it publishes a rule that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. This notice will not have a substantial effect on State or local governments. There are no other alternatives at this time.

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

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

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

Dated: May 17, 2005.

**Mark B. McClellan,**

*Administrator, Centers for Medicare & Medicaid Services.*

Approved: August 25, 2005.

**Michael O. Leavitt,**

*Secretary.*

[FR Doc. 05–17278 Filed 8–26–05; 9:46 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Administration for Children and Families

#### Family and Youth Services Bureau; Positive Youth Development State and Local Collaboration Demonstration Projects

**AGENCY:** Family and Youth Services Bureau, Administration for Children and Families (ACF), Department of Health and Human Services (HHS).

**ACTION:** Award announcement.

**CFDA#:** The Catalog of Federal Domestic Assistance (CFDA) number for this program is 93.623. The title is the Positive Youth Development State and Local Collaboration Demonstration Projects.

**Legislative Authority:** Grants for Runaway and Homeless Youth programs are authorized by the Runaway and Homeless Youth Act (title III of the Juvenile Justice and Delinquency Prevention Act of 1974), as amended by the Missing, Exploited, and Runaway Children Protection Act of 1999, (Pub. L. 106–71).

**Amount of Award:** \$100,000 per grantee.

**Project Period:** 9/30/04–9/29/05.

**SUMMARY:** Notice is hereby given that a noncompetitive grant supplement is being made to the following state agencies: State of Nebraska Health & Human Services, University of Kentucky Research Foundation, State of Oregon, New York Office of Children & Family Services, State of Louisiana, Iowa Dept. of Human Rights Criminal & Juvenile Justice, Commonwealth of Massachusetts, Illinois Department of Human Services, Governor's Office for Children Youth & Families. The purpose of this supplement is to support collaborations between state-level agencies and local community jurisdictions regarding positive development opportunities available to young people as approved in their original planning grant.

#### FOR FURTHER INFORMATION CONTACT:

Administration for Children and Families, Family and Youth Services Bureau, 330 C Street, SW., Washington, DC 20447, Courtney Workman—(202) 205–8657, [cworkman@acf.hhs.gov](mailto:cworkman@acf.hhs.gov).

Dated: August 22, 2005.

**Joan E. Ohl,**

*Commissioner, Administration on Children, Youth and Families.*

[FR Doc. 05–17371 Filed 8–31–05; 8:45 am]

**BILLING CODE 4184–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2005N–0343]

#### Agency Emergency Processing Under Office of Management and Budget Review; Guidance for Requesting an Extension to Use Existing Label Stock After the Trans Fat Labeling Effective Date of January 1, 2006

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for emergency processing under the Paperwork Reduction Act of 1995 (the PRA). FDA is preparing a guidance document to notify the public of procedures being implemented by the agency to assist firms that wish to request, on a case-by-case basis upon an appropriate showing, an extension to use existing label stock after the effective date of the *trans* fat labeling final rule. This notice solicits comments on the proposed collection of information associated with the guidance document entitled “Guidance for Requesting an Extension to Use Existing Label Stock After the *Trans* Fat Labeling Effective Date of January 1, 2006.”

**DATES:** Fax written comments on the collection of information by October 3, 2005. FDA is requesting approval of this emergency processing by September 8, 2005.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

#### FOR FURTHER INFORMATION CONTACT:

Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

**SUPPLEMENTARY INFORMATION:** FDA has requested emergency processing of this proposed collection of information under section 3507(j) of the PRA (44 U.S.C. 3507(j)) and 5 CFR 1320.13. FDA issued a final rule (the *trans* fat final rule) on July 11, 2003 (68 FR 41434) to