30269. Officer: Joshua Wolf, Member/Manager (QI). Application Type: New NVO & OFF License.

Pegasus Logistics Group, Inc. (NVO & OFF), 615 Freeport Pkwy, Suite 100, Coppell, TX 75019. Officer: Kenneth C. Beam, President (QI). Application Type: Add NVO Service.


Santa Fe Group Americas, Inc. (NVO & OFF), 1001 S. Daisy Ashford Street, Suite 100, Houston, TX 77077. Officers: Francesca A. Vollaro, Vice President (QI), Lars L. Iversen, President. Application Type: New NVO License.

SH Transport, Inc. (NVO), 1975 Charles Willard Street, Rancho Dominguez, CA 90220. Officer: Steven Park, President (QI). Application Type: New NVO License.

Transport Partner (USA), Inc. (NVO & OFF), 2006 Cherry Hill Lane, Charleston, SC 29405. Officers: Adam Adaway, Secretary (QI), Wim Spinhoven, President, Application Type: Add NVO Service.

Transports P. Fatton Inc. dba Fatton USA (NVO), 145 Hook Creek Blvd., Bldg. A5, Valley Stream, NY 11581. Officers: Renaud Mellier, Treasurer (QI), Henri Ducasse, CEO. Application Type: QI Change.

Dated: November 16, 2012.

By the Commission.

Karen V. Gregory,
Secretary.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Recognition of Entities for the Accreditation of Qualified Health Plans

AGENCY: Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This notice announces the recognition of the National Committee for Quality Assurance (NCQA) and URAC as recognized accrediting entities for the purposes of fulfilling the accreditation requirement as part of qualified health plan certification.

DATES: This notice is effective on November 20, 2012.


SUPPLEMENTARY INFORMATION:

I. Background

Section 1311(c)(1)(D) of the Affordable Care Act specifies that to be certified as a qualified health plan (QHP) and operate in the Exchange, a health plan must be accredited by a recognized accrediting entity on a uniform timeline established by the applicable Exchange. On July 20, 2012, we published a final rule in the Federal Register (77 FR 42658) titled, “Patient Protection and Affordable Care Act; Data Collection To Support Standards Related to Essential Health Benefits; Recognition of Entities for the Accreditation of Qualified Health Plans.” In that rule, we finalized 45 CFR 156.275(c), which specified the requirements for accrediting entities to be recognized for the purposes of fulfilling the accreditation requirement as part of QHP certification. We also established that, effective upon completion of the conditions at § 156.275 in paragraphs (c)(2) through (c)(4), that the National Committee for Quality Assurance (NCQA) and URAC will be recognized as accrediting entities for the purposes of QHP certification and that the Department of Health and Human Services (HHS) will notify the public of this recognition in the Federal Register. As discussed in the preamble to the final rule published on July 20, 2012, the recognition of accrediting entities in phase one is effective until it is rescinded or this interim phase one process is replaced by the phase two process.

II. Provisions of the Final Notice

NCQA and URAC met the requirements and criteria described in the final rule to be recognized as an accrediting entity (77 FR 42662 through 42668). Therefore, this notice serves as public notification that NCQA and URAC are recognized by the Secretary of HHS as accrediting entities for the purposes of QHP certification.

III. 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.

Dated: November 8, 2012.

Marilyn Tavenner,
Acting Administrator, Centers for Medicare & Medicaid Services.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Medicare Program; Town Hall Meeting on FY 2014 Applications for New Medical Services and Technology Add-On Payments

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

ACTION: Notice of meeting.

SUMMARY: This notice announces a Town Hall meeting in accordance with section 1886(d)(3)(A)(vi) of the Social Security Act (the Act) to discuss fiscal year (FY) 2014 applications for add-on payments for new medical services and technologies under the hospital inpatient prospective payment system (IPPS). Interested parties are invited to this meeting to present their comments, recommendations, and data regarding whether the FY 2014 new medical services and technologies applications meet the substantial clinical improvement criterion.

1 Delegated to CCIIO, 76 FR 53903 through 53906 2011–11–30.
DATES: Meeting Date: The Town Hall Meeting announced in this notice will be held on Tuesday, February 5, 2013. The Town Hall Meeting will begin at 9:00 a.m. Eastern Standard Time (e.s.t.) and check-in will begin at 8:30 a.m. e.s.t. Only one check-in is required to enter the building.

Deadline for Registration for Participants (not Presenting) at the Town Hall Meeting and Submitting Requests for Special Accommodations: The deadline to register to attend the Town Hall Meeting and requests for special accommodations must be received no later than 5:00 p.m., e.s.t. on Monday, January 21, 2013.

Deadline for Registration of Presenters of the Town Hall Meeting: The deadline to register to present at the Town Hall Meeting must be received no later than 5:00 p.m., e.s.t. on Monday, January 14, 2013.

Deadline for Submission of Agenda Item(s) or Written Comments for the Town Hall Meeting: Written comments and agenda items for discussion at the Town Hall Meeting, including agenda items by presenters, must be received by Monday, January 14, 2013. In addition to materials submitted for discussion at the Town Hall Meeting, individuals may submit written comments after the Town Hall Meeting, as specified in the ADDRESSES section of this notice, on whether the service or technology represents a substantial clinical improvement. These comments must be received by Tuesday, February 26, 2013, for consideration in the FY 2014 IPPS proposed rule.

ADDRESSES: Meeting Location: The Town Hall Meeting will be held in the main Auditorium in the central building of the Centers for Medicare and Medicaid Services located at 7500 Security Boulevard, Baltimore, MD 21244–1850.

In addition, we are providing two alternatives to attending the meeting in person—(1) there will be an open toll-free phone line to call into the Town Hall Meeting; or (2) participants may view and participate in the Town Hall Meeting via live stream technology and/or webinar. Information on these options are discussed in section II.B. of this notice.

Registration and Special Accommodations: Individuals wishing to participate in the meeting must register by following the on-line registration instructions located in section III. of this notice or by contacting staff listed in the FOR FURTHER INFORMATION CONTACT section of this notice. Individuals who need special accommodations should contact staff listed in the FOR FURTHER INFORMATION CONTACT section of this notice.

Submission of Agenda Item(s) or Written Comments for the Town Hall Meeting: Each presenter must submit an agenda item(s) regarding whether a FY 2014 application meets the substantial clinical improvement criterion. Agenda items, written comments, questions or other statements must not exceed three single-spaced typed pages and may be sent via email to newtech@cms.hhs.gov.

FOR FURTHER INFORMATION CONTACT:
Michael Treitel, (410) 786–4552, michael.treitel@cms.hhs.gov, or Celeste Beauregard, (410) 786–8102, celeste.beauregard@cms.hhs.gov. Alternatively, you may forward your requests via email to newtech@cms.hhs.gov.

SUPPLEMENTARY INFORMATION:
I. Background on the Add-On Payments for New Medical Services and Technologies Under the IPPS
Sections 1886(d)(5)(K) and (L) of the Social Security Act (the Act) require the Secretary to establish a process of identifying and ensuring adequate payments to acute care hospitals for new medical services and technologies under Medicare. Effective for discharges beginning on or after October 1, 2001, section 1886(d)(5)(K)(i) of the Act requires the Secretary to establish (after notice and opportunity for public comment) a mechanism to recognize the costs of new services and technologies under the hospital inpatient prospective payment system (IPPS). In addition, section 1886(d)(5)(K)(vi) of the Act specifies that a medical service or technology will be considered “new” if it meets criteria established by the Secretary (after notice and opportunity for public comment). (See the FY 2002 IPPS proposed rule (66 FR 22693, May 4, 2001) and final rule (66 FR 46912, September 7, 2001) for a more detailed discussion.)

In the September 7, 2001 final rule (66 FR 46914), we noted that we evaluated a request for special payment for a new medical service or technology against the following criteria in order to determine if the new technology meets the substantial clinical improvement requirement:
- The device offers a treatment option for a patient population unresponsive to, or ineligible for, currently available treatments.
- The device offers the ability to diagnose a medical condition earlier in a patient population than allowed by currently available methods. There must also be evidence that use of the device to make a diagnosis affects the management of the patient.
- Use of the device significantly improves clinical outcomes for a patient population as compared to currently available treatments. Some examples of outcomes that are frequently evaluated in studies of medical devices are the following:
  - Reduced mortality rate with use of the device.
  - Reduced rate of disease-related complications.
  - Decreased rate of subsequent diagnostic or therapeutic interventions (for example, due to reduced rate of recurrence of the disease process).
  - Decreased number of future hospitalizations or physician visits.
  - More rapid beneficial resolution of the disease process because of use of the device.
  - Decreased pain, bleeding or other quantifiable symptoms.
  - Reduced recovery time.

In addition, we indicated that the requester is required to submit evidence that the technology meets one or more of these criteria.

Section 503 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1886(d)(5)(K)(viii) of the Act to revise the process for evaluating new medical services and technology applications by requiring the Secretary to do the following:
- Provide for public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of Medicare beneficiaries before publication of a proposed rule.
- Make public and periodically update a list of all the services and technologies for which an application is pending.
- Accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial improvement.
- Provide for a meeting at which organizations representing hospitals, physicians, manufacturers and any other interested party may present comments, recommendations, and data to the clinical staff of CMS as to whether the service or technology represents a substantial improvement before publication of a proposed rule.

The opinions and alternatives provided during this meeting will assist us as we evaluate the new medical
services and technology applications for fiscal year (FY) 2014. In addition, they will help us to evaluate our policy on the IPPS new technology add-on payment process before the publication of the FY 2014 IPPS proposed rule.

II. Town Hall Meeting and Conference Calling/Live Streaming Information

A. Format of the Town Hall Meeting

As noted in section I. of this notice, we are required to provide for a meeting at which organizations representing hospitals, physicians, manufacturers and any other interested party may present comments, recommendations, and data to the clinical staff of CMS concerning whether the service or technology represents a substantial clinical improvement. This meeting will allow for a discussion of the substantial clinical improvement criteria on each of the FY 2014 new medical services and technology add-on payment applications. Information regarding the applications can be found on our Web site at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html.

The majority of the meeting will be reserved for presentations of comments, recommendations, and data from registered presenters. The time for each presenter’s comments will be approximately 10 to 15 minutes and will be based on the number of registered presenters. Presenters will be scheduled to speak in the order in which they register and grouped by new technology applicant. Therefore, individuals who wish to present must register and submit their agenda item(s) via email to newtech@cms.hhs.gov by the date specified in the DATES section of this notice.

In addition, written comments will also be accepted and presented at the meeting if they are received via email to newtech@cms.hhs.gov by the date specified in the DATES section of this notice. Written comments may also be submitted after the meeting for our consideration. If the comments are to be considered before the publication of the proposed rule, the comments must be received via email to newtech@cms.hhs.gov by the date specified in the DATES section of this notice.

B. Conference Call, Live Streaming, and Webinar Information

For participants who cannot attend the Town Hall Meeting in person, an open toll-free phone line, (877) 267–1577, has been made available. The conference code is “7702.” Also, there will be an option to view and participate in the Town Hall Meeting via live streaming technology and/or a webinar. Information on the option to participate via live streaming technology and/or a webinar will be provided through an upcoming listerv notice and posted on the New Technology Web site at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html. Continue to check the Web site for updates.

Disclaimer: Because this is the first year that we are providing an option for live streaming technology and/or a webinar, we cannot guarantee the reliability of these technologies.

III. Registration Instructions

The Division of Acute Care in CMS is coordinating the meeting registration for the Town Hall Meeting on substantial clinical improvement. While there is no registration fee, individuals planning to attend the Town Hall Meeting in person must register to attend.

Registration may be completed online at the following web address: http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/newtech.html. Select the link at the bottom of the page “Register to Attend the New Technology Town Hall Meeting”. After completing the registration, on-line registrants should print the confirmation page(s) and bring it with them to the meeting(s).

If you are unable to register online, you may register by sending an email to newtech@cms.hhs.gov. Please include your name, address, telephone number, email address and fax number. If seating capacity has been reached, you will be notified that the meeting has reached capacity.

IV. Security, Building, and Parking Guidelines

Because these meetings will be located on Federal property, for security reasons, any persons wishing to attend these meetings must register by the date specified in the DATES section of this notice. Please allow sufficient time to go through the security checkpoints. It is suggested that you arrive at 7500 Security Boulevard no later than 8:30 a.m. e.s.t. if you are attending the Town Hall Meeting so that you will be able to arrive promptly for the meeting. Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.

- Passing through a metal detector and inspection of items brought into the building. We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, set-up, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

Note: Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting in person. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting(s).

All visitors must be escorted in areas other than the lower and first floor levels in the Central Building. Seating capacity is limited to the first 250 registrants.

Authority: Section 503 of Public Law 108–173.

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

Dated: November 14, 2012.

Marilyn Tavenner,
Acting Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 2012–28478 Filed 11–21–12; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects


Description: This is a financial report submitted following the end of each fiscal quarter by each State or Tribe with an approved title IV–E plan administering any of three title IV–E entitlement grant programs—Foster Care, Adoption Assistance or Guardianship Assistance.

The purpose of this form is to enable each State or Tribe to meet its statutory and regulatory requirement to report program expenditures made in the