

the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by November 26, 2009, and the final decision of the Commission shall be issued by March 26, 2010.

**Karen V. Gregory,**  
*Secretary.*

[FR Doc. E8-28638 Filed 12-2-08; 8:45 am]

BILLING CODE 6730-01-P

## FEDERAL MARITIME COMMISSION

[Petition No. P2-08]

**Petition of APM Terminals Pacific Ltd., California United Terminals, Inc.; Eagle Marine Services, Ltd.; International Transportation Services, Inc.; Long Beach Container Terminal, Inc.; Seaside Transportation Service LLC; Total Terminals LLC; West Basin Container Terminal LLC; Pacific Maritime Services, LLC; SSA Terminal (Long Beach), LLC Trans Pacific Container Service Corporation; Yusen Terminals, Inc.; and SSA Terminals, LLC, ("Marine Terminal Operators"); and Portcheck LLC; Notice of Filing and Request for Comments**

This is to provide notice of filing and to invite comments on or before December 15, 2008, with regard to the Petition described below.

The marine terminal operators as listed above and PortCheck LLC, parties to FMC Agreement No. 201199, the *Port Fee Services Agreement* ("Petitioners") have petitioned the Commission pursuant to 46 CFR 502.69 of the Commission's Rules of Practice and Procedure, for a review of a staff action taken concerning the effective date of Petitioners' agreement filed on November 3, 2008. In particular, Commission staff found that the agreement was not eligible for an exemption from the statutory 45-day agreement waiting period under Section 40304(c) of the Shipping Act of 1984 ("Shipping Act"), and the Commission's Rules at 46 CFR 535.308(a).

Certain interested parties have already submitted comments on this Petition. One letter, submitted by counsel on behalf of licensed motor carriers Swift Transportation Company and Knight Transportation, Inc., indicate that they have been "informed by the Ports" of the Commission staff action thereon. Accordingly, it appears that there may be broad public interest.

In order for the Commission to make a thorough evaluation of the Petition, interested persons are requested to submit views or arguments in reply to the Petition no later than December 15, 2008. Replies shall consist of an original and 15 copies, be directed to the Secretary, Federal Maritime Commission, 800 North Capitol Street, NW., Washington, DC 20573-0001, and be served on Petitioner's counsel, David F. Smith and Wayne R. Rohde, Sher and Blackwell LLP, Suite 900, 1850 M Street, NW., Washington, DC 20036. A copy of the reply shall be submitted in electronic form (Microsoft Word) by e-mail to [Secretary@fmc.gov](mailto:Secretary@fmc.gov).

The Petition will be posted on the Commission's Web site at <http://www.fmc.gov/reading/Petitions.asp>. Replies filed in response to this petition also will be posted on the Commission's Web site at this location.

Parties participating in this proceeding may elect to receive service of the Commission's issuances in this proceeding through e-mail in lieu of service by U.S. mail. A party opting for electronic service shall advise the Office of the Secretary in writing and provide an e-mail address where service can be made.

**Karen V. Gregory,**  
*Secretary.*

[FR Doc. E8-28637 Filed 12-2-08; 8:45 am]

BILLING CODE 6730-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1390-N2]

RIN 0938-AP15

### Medicare Program; Hospital Inpatient Prospective Payment Systems and Fiscal Year 2009 Rates: Fiscal Year 2009 Wage Index Changes Following Implementation of Section 124 of the Medicare Improvement for Patients and Providers Act of 2008

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

**ACTION:** Notice.

**SUMMARY:** This notice contains fiscal year (FY) 2009 revised final wage indices and hospital reclassifications for 27 hospitals. These revised final wage indices and hospital reclassifications were made according to special procedural rules set forth in the FY 2009 hospital inpatient prospective payment systems final rule (73 FR 48588-9).

**DATES:** *Effective Date:* The provisions of this notice are effective on December 3, 2008,

*Applicability Date:* The final wage indices and hospital reclassifications are applicable for discharges beginning October 1, 2008.

**FOR FURTHER INFORMATION CONTACT:** Tzvi Hefter, (410) 786-4487.

### SUPPLEMENTARY INFORMATION:

#### I. Background

On July 15, 2008 the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA) (Pub. L. 110-275) was enacted. Section 124 of Public Law 110-275 extends through FY 2009 wage index reclassifications under section 508 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (Pub. L. 108-173) and certain special exceptions (for example, those special exceptions contained in the final rule promulgated in the August 11, 2004 **Federal Register** (69 FR 49105 and 49107) and extended under section 117 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA) (Pub. L. 110-173)). Because of the timing of the enactment of Public Law 110-275, we were not able to recompute the fiscal year (FY) 2009 wage index values for any hospital reclassified under section 508 and special exception hospitals in time for inclusion in the FY 2009 hospital inpatient prospective payment system final rule published in the August 19, 2008 **Federal Register** (73 FR 48434) (hereinafter referred to as the FY 2009 IPPS final rule). Instead, we stated that we would issue the final FY 2009 wage index values and other related tables, in a separate **Federal Register** notice published subsequent to the final rule.

In the October 3, 2008 **Federal Register** (73 FR 57888), we published the FY 2009 IPPS final notice including the final wage indices and geographic reclassifications. The final notice reflects the reclassification withdrawal and termination decisions we made on behalf of hospitals in accordance with special procedural rules explained in the FY 2009 IPPS final rule (73 FR 48588).

In accordance with such rules, hospitals had until October 20, 2008 to notify us if they wished to revise the decision that we made on their behalf. We received requests from 31 hospitals. Of these hospitals, three hospitals were ineligible for a revision because the hospitals were not reclassified to or located in areas containing hospitals whose reclassifications or special exceptions were extended by section 124 of Public Law 110-275. A fourth

hospital was ineligible because we did not make a decision on behalf of the hospital.

**II. Provisions of This Notice**

This notice provides the revisions to the final wage index values and hospital reclassifications for 27 hospitals based on hospitals' requests. As stated in the

FY 2009 IPPS final rule (73 FR 48588) and the October 3, 2008 notice (73 FR 57888), we did not further recalculate the wage indices (including any rural floors or imputed rural floors) or standardized amounts based on the revisions for these 27 hospitals. Changes based on hospitals' requests affect the data presented in Tables 2, 4J, 9A, and

9B of the October 3, 2008 notice. Therefore, this notice provides the revisions to those tables for the specified providers.

*A. Wage Index Revisions for Table 2*

The wage data for the listed providers are revised as follows:

**TABLE 2—HOSPITAL CASE-MIX INDEXES FOR DISCHARGES OCCURRING IN FEDERAL FISCAL YEAR 2007; HOSPITAL WAGE INDEXES FOR FEDERAL FISCAL YEAR 2009; HOSPITAL AVERAGE HOURLY WAGES FOR FEDERAL FISCAL YEARS 2007 (2003 WAGE DATA), 2008 (2004 WAGE DATA), AND 2009 (2005 WAGE DATA); AND 3-YEAR AVERAGE OF HOSPITAL AVERAGE HOURLY WAGES**

| Provider No. | Case mix index | FY 2009 wage index | Average hourly wage FY 2007 | Average hourly wage FY 2008 | Average hourly wage FY 2009 | Average hourly wage (3 years) |
|--------------|----------------|--------------------|-----------------------------|-----------------------------|-----------------------------|-------------------------------|
| 050069       | 1.7315         | 1.2032             | 34.6353                     | 35.3850                     | 38.1339                     | 36.1121                       |
| 050168       | 1.5718         | 1.2032             | 37.9784                     | 40.5973                     | 40.8362                     | 39.8630                       |
| 050173       | 1.3439         | 1.2032             | 29.0576                     | 31.6717                     | 32.3265                     | 30.9929                       |
| 050193       | 1.2326         | 1.2032             | 33.9520                     | 29.0623                     | 36.7240                     | 32.9059                       |
| 050224       | 1.6646         | 1.2032             | 32.5010                     | 35.7280                     | 37.3442                     | 35.2849                       |
| 050226       | 1.5109         | 1.2032             | 32.4411                     | 35.4597                     | 36.5354                     | 34.8258                       |
| 050230       | 1.5465         | 1.2032             | 34.0600                     | 35.8490                     | 38.8901                     | 36.2987                       |
| 050348       | 1.7778         | 1.2032             | 31.5156                     | 32.7107                     | 33.5276                     | 32.6288                       |
| 050426       | 1.4602         | 1.2032             | 33.2031                     | 34.9855                     | 37.6505                     | 35.2298                       |
| 050526       | 1.1838         | 1.2032             | 28.1997                     | 33.3964                     | 35.5457                     | 32.2794                       |
| 050543       | 0.7528         | 1.2032             | 29.4443                     | 24.4913                     | 32.8367                     | 28.6013                       |
| 050548       | 0.7102         | 1.2032             | 39.2234                     | 41.1075                     | *                           | 40.1570                       |
| 050551       | 1.3450         | 1.2032             | 34.0467                     | 37.2506                     | 37.6223                     | 36.3787                       |
| 050567       | 1.5114         | 1.2032             | 35.7063                     | 37.6384                     | 39.0114                     | 37.5242                       |
| 050570       | 1.5522         | 1.2032             | 34.5161                     | 38.4373                     | 40.6761                     | 37.8616                       |
| 050580       | 1.1501         | 1.2032             | 31.5806                     | 34.1531                     | 35.0966                     | 33.6235                       |
| 050589       | 1.2415         | 1.2032             | 34.5100                     | 37.6886                     | 37.2056                     | 36.5102                       |
| 050603       | 1.4514         | 1.2032             | 34.0275                     | 35.0279                     | 35.4809                     | 34.9113                       |
| 050609       | 1.3266         | 1.2032             | 41.7208                     | 39.7397                     | 43.4555                     | 41.6214                       |
| 050678       | 1.3259         | 1.2032             | 32.4473                     | 33.7633                     | 35.8411                     | 34.1151                       |
| 050693       | 1.3935         | 1.2032             | 34.5797                     | 39.6838                     | 42.8266                     | 38.9562                       |
| 050720       | 0.9629         | 1.2032             | 29.4726                     | 30.3595                     | 32.1173                     | 30.5950                       |
| 050744       | 1.7431         | 1.2032             | *                           | *                           | 48.4951                     | 48.4951                       |
| 050745       | 1.3420         | 1.2032             | *                           | *                           | 42.5523                     | 42.5523                       |
| 050746       | 1.8199         | 1.2032             | *                           | *                           | 43.2015                     | 43.2015                       |
| 050747       | 1.5410         | 1.2032             | *                           | *                           | 44.5887                     | 44.5887                       |
| 250078       | 1.5862         | 0.8418             | 22.1243                     | 22.8430                     | 23.9598                     | 22.9835                       |

*B. Revisions to Table 4J*

The entry in the second column titled, "Reclassified for FY 2009", for the

following listed providers has been revised to include an asterisk to indicate that the providers have been reclassified to CBSA 31084 Los Angeles-Long

Beach-Glendale, CA for FY 2009; and, therefore, are ineligible to receive an outmigration adjustment for FY 2009:

**TABLE 4J—OUT-MIGRATION ADJUSTMENT—FY 2009**

| Provider No. | Reclassified for FY 2009 | Out-migration adjustment | Qualifying county name | County code |
|--------------|--------------------------|--------------------------|------------------------|-------------|
| 050069       | *                        | 0.0013                   | Orange                 | 05400       |
| 050168       | *                        | 0.0013                   | Orange                 | 05400       |
| 050173       | *                        | 0.0013                   | Orange                 | 05400       |
| 050193       | *                        | 0.0013                   | Orange                 | 05400       |
| 050224       | *                        | 0.0013                   | Orange                 | 05400       |
| 050226       | *                        | 0.0013                   | Orange                 | 05400       |
| 050230       | *                        | 0.0013                   | Orange                 | 05400       |
| 050348       | *                        | 0.0013                   | Orange                 | 05400       |
| 050426       | *                        | 0.0013                   | Orange                 | 05400       |
| 050526       | *                        | 0.0013                   | Orange                 | 05400       |
| 050543       | *                        | 0.0013                   | Orange                 | 05400       |
| 050548       | *                        | 0.0013                   | Orange                 | 05400       |
| 050551       | *                        | 0.0013                   | Orange                 | 05400       |

TABLE 4J—OUT-MIGRATION ADJUSTMENT—FY 2009—Continued

| Provider No. | Reclassified for FY 2009 | Out-migration adjustment | Qualifying county name | County code |
|--------------|--------------------------|--------------------------|------------------------|-------------|
| 050567       | *                        | 0.0013                   | Orange                 | 05400       |
| 050570       | *                        | 0.0013                   | Orange                 | 05400       |
| 050580       | *                        | 0.0013                   | Orange                 | 05400       |
| 050589       | *                        | 0.0013                   | Orange                 | 05400       |
| 050603       | *                        | 0.0013                   | Orange                 | 05400       |
| 050609       | *                        | 0.0013                   | Orange                 | 05400       |
| 050678       | *                        | 0.0013                   | Orange                 | 05400       |
| 050693       | *                        | 0.0013                   | Orange                 | 05400       |
| 050720       | *                        | 0.0013                   | Orange                 | 05400       |
| 050744       | *                        | 0.0013                   | Orange                 | 05400       |
| 050745       | *                        | 0.0013                   | Orange                 | 05400       |
| 050746       | *                        | 0.0013                   | Orange                 | 05400       |
| 050747       | *                        | 0.0013                   | Orange                 | 05400       |

C. Revisions to Table 9A

The geographic reclassification data for listed providers have been revised as specified in the following table:

TABLE 9A—HOSPITAL RECLASSIFICATIONS AND REDESIGNATIONS—FY 2009

| Provider No. | Geographic CBSA | Reclassified CBSA | LUGAR |
|--------------|-----------------|-------------------|-------|
| 050069       | 42044           | 31084             |       |
| 050168       | 42044           | 31084             |       |
| 050173       | 42044           | 31084             |       |
| 050193       | 42044           | 31084             |       |
| 050224       | 42044           | 31084             |       |
| 050226       | 42044           | 31084             |       |
| 050230       | 42044           | 31084             |       |
| 050348       | 42044           | 31084             |       |
| 050426       | 42044           | 31084             |       |
| 050526       | 42044           | 31084             |       |
| 050543       | 42044           | 31084             |       |
| 050548       | 42044           | 31084             |       |
| 050551       | 42044           | 31084             |       |
| 050567       | 42044           | 31084             |       |
| 050570       | 42044           | 31084             |       |
| 050580       | 42044           | 31084             |       |
| 050589       | 42044           | 31084             |       |
| 050603       | 42044           | 31084             |       |
| 050609       | 42044           | 31084             |       |
| 050678       | 42044           | 31084             |       |
| 050693       | 42044           | 31084             |       |
| 050720       | 42044           | 31084             |       |
| 050744       | 42044           | 31084             |       |
| 050745       | 42044           | 31084             |       |
| 050746       | 42044           | 31084             |       |
| 050747       | 42044           | 31084             |       |
| 250078       | 25620           | 25060             |       |

D. Revisions to Table 9B

In Table 9B, entitled “Hospital Reclassifications and Redesignations by Individual Hospital under Section 508 of Public Law 108–173 and Special Exceptions Wage Index Assignments—FY 2009”, provider 25–0078 is removed because the provider is now listed in Table 9A (see section II.C. of this notice) as reclassified to CBSA 25060, Gulfport-Biloxi, MS.

III. Regulatory Impact Statement

We do not consider this notice to constitute a rule under 5 U.S.C. 553(b). The notice announces wage index values and reclassifications based upon policies already adopted in the FY 2009 IPPS final rule. Thus, we do not believe that reviews under Executive Order 12866 on Regulatory Planning and Review (September 30, 1993, as further amended), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L.

96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2)) are required. Nevertheless, we have examined the impact of this notice under the aforementioned authorities.

Executive Order 12866 (as amended by Executive Orders 13258 and 13422)

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 one year). We estimate that FY 2009 IPPS payments will increase approximately \$3 million based on the changes included in this notice. Therefore, we note that not only does this notice not constitute a substantive rule, but it also does not reach the economic threshold and thus is not considered a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. 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 \$7.0 million to \$34.5 million in any one year. Individuals and States are not included in the definition of a small entity. We are not preparing an analysis for the RFA because the notice is not a substantive rule, and we have determined, and the Secretary certifies, that this notice will not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of 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 for Medicare payment regulations and has fewer than 100 beds. We are not preparing an analysis for section 1102(b) of the Act because we have determined, and the Secretary certifies, that this notice will not have a significant impact on the operations of a substantial number of small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any one year of \$100 million in 1995 dollars, updated annually for inflation. In 2008, that threshold is approximately \$130 million. This notice will have 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 promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on State and local governments, preempts State law, or otherwise has Federalism implications. Since this notice does not impose any costs on State or local governments, the requirements of Executive Order 13132 are not applicable.

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

Dated: November 20, 2008.

**Kerry Weems,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

Approved: November 25, 2008.

**Michael O. Leavitt,**

*Secretary.*

[FR Doc. E8-28619 Filed 12-2-08; 8:45 am]

**BILLING CODE 4120-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2008-D-0609]

#### Draft Guidance for Industry on the Submission of Patent Information for Certain Old Antibiotics; Availability

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled “Submission of Patent Information for Certain Old Antibiotics.” The draft guidance describes the agency’s current thinking on the implementation of certain provisions of the Q1 Program Supplemental Funding Act (the Q1 Act) that concern old antibiotics and addresses which sponsors of new drug applications (NDAs) must submit patent information under the Q1 Act by December 5, 2008.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by February 2, 2009.

**ADDRESSES:** Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 2201, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

#### FOR FURTHER INFORMATION CONTACT:

Mary Ann Holovac, Center for Drug Evaluation and Research (HFD-615), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8971.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

FDA is announcing the availability of a draft guidance for industry entitled “Submission of Patent Information for Certain Old Antibiotics.” The draft guidance provides information regarding FDA’s current thinking on the implementation of section 4(b)(1) of the Q1 Act (Public Law 110-379).

The Q1 Act amends section 505 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 355) by adding subsection (v), which establishes, among other things, certain conditions under which the patent listing, patent certification, and marketing exclusivity provisions of sections 505(c) and (j) of the FD&C Act, and the patent term extension provisions of 35 U.S.C. 156 apply to marketing applications for drugs that contain an antibiotic that was the subject of any marketing application received by FDA on or before November 20, 1997 (an old antibiotic). The transitional rules at section 4(b) of the Q1 Act provide for the submission of the patent information by sponsors of certain NDAs, the publication of such patent information by FDA, and the certification to such patents by applicants of pending abbreviated new drug applications to be deemed “a first applicant” (as defined in section 505(j)(5)(B)(iv) the FD&C Act), not later than 60, 90, and 120 days after enactment of the Q1 Act, respectively.

Specifically, section 4(b)(1) of the Q1 Act requires the submission to FDA of patent information by sponsors of certain NDAs for drugs (including