

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.

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]

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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]

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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