

FEDERAL MARITIME COMMISSION**Notice of Agreements Filed**

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (www.fmc.gov) or by contacting the Office of Agreements at (202)–523–5793 or tradeanalysis@fmc.gov.

Agreement No.: 012339–001.

Title: Sealand/APL West Coast of Central America Slot Charter Agreement.

Parties: APL Co. Pte Ltd; and American President Lines, Ltd. (collectively “APL”); Maersk Line A/S dba Sealand.

Filing Party: Wayne R. Rohde, Esq.; Cozen O’Conner; 1627 I Street NW., Suite 1100; Washington, DC 20006–4007.

Synopsis: The amendment would add ports on the Pacific Coast of Guatemala, El Salvador, and Nicaragua to the agreement.

Agreement No.: 012429.

Title: CMA CGM/APL Panama—USEC Space Charter Agreement.

Parties: APL Co. Pte Ltd; and American President Lines, Ltd. (collectively “APL”); CMA CGM, S.A.

Filing Party: Draughn B. Arbona, Esq.; CMA CGM (America) LLC; 5701 Lake Wright Drive; Norfolk, VA 23502.

Synopsis: The agreement authorizes APL to charter space to CMA CGM in the trade between Panama and the U.S. East Coast.

Agreement No.: 012430.

Title: CMA CGM/APL Colombia/Panama—USEC Space Charter Agreement.

Parties: APL Co. Pte Ltd; and American President Lines, Ltd. (collectively “APL”)

Filing Party: Draughn B. Arbona, Esq.; CMA CGM (America) LLC; 5701 Lake Wright Drive; Norfolk, VA 23502.

Synopsis: The agreement authorizes APL to charter space to CMA CGM in the trade between Colombia and Panama on the one hand, and the U.S. East Coast on the other hand.

Agreement No.: 0123431.

Title: HSDG/Zim Asia US East Coast Slot Charter Agreement.

Parties: Hamburg Sud Amerikanische Dampfschiffahrts-Gesellschaft KG and Zim Integrated Shipping Services, Ltd.

Filing Party: Mark E. Newcomb; ZIM American Integrated Shipping Services Co., LLC; 5801 Lake Wright Dr.; Norfolk, VA 23508.

Synopsis: The Agreement would authorize Zim to charter space to Hamburg Sud in the trade between China and Korea on one hand, and Panama, Jamaica and the U.S. East Coast on the other hand. The parties have requested Expedited Review.

Agreement No.: 012432.

Title: APL/ANL Asia—USWC Space Charter Agreement.

Parties: APL Co. Pte Ltd; and American President Lines, Ltd. (collectively “APL”); and ANL Singapore Pte Ltd.

Filing Party: Draughn B. Arbona, Esq.; CMA CGM (America) LLC; 5701 Lake Wright Drive; Norfolk, VA 23502.

Synopsis: The Agreement authorizes APL to charter space to ANL in the trade between Asia and the U.S. West Coast.

Agreement No.: 012433.

Title: HLAG/MOL Slot Charter Agreement.

Parties: Hapag-Lloyd AG and Mitsui O.S.K. Lines, Ltd.

Filing Party: Wayne Rohde, Esq.; Cozen O’Connor; 1200 Nineteenth Street NW; Washington, DC 20036.

Synopsis: The Agreement authorizes Hapag-Lloyd to charter space to MOL in the trade between Puerto Rico, the Dominican Republic, and Panama.

By Order of the Federal Maritime Commission.

Dated: July 29, 2016.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2016–18388 Filed 8–2–16; 8:45 am]

BILLING CODE 6731-AA-P

FEDERAL RESERVE SYSTEM**Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company**

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board’s Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices

of the Board of Governors. Comments must be received not later than August 18, 2016.

A. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *Theresa Dawley, Richfield, Minnesota, Kathryn Appold, Burnsville, Minnesota, and Delbert Dawley, Shakopee, Minnesota*, as a group acting in concert, to retain shares of Munich Bancshares, Inc., Munich, North Dakota, and thereby indirectly retain shares of Horizon Financial Bank, both in Munich, North Dakota.

Board of Governors of the Federal Reserve System, July 29, 2016.

Michele T. Fennell,

Assistant Secretary of the Board.

[FR Doc. 2016–18380 Filed 8–2–16; 8:45 am]

BILLING CODE 6210-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Agency for Healthcare Research and Quality****Agency Information Collection Activities: Proposed Collection; Comment Request**

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: “*The Patient-Centered Medical Home (PCMH) Items Demonstration Study*.” In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by October 3, 2016.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT:

Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

The Patient-Centered Medical Home (PCMH) Items Demonstration Study

This study is being conducted by AHRQ through its contractor, RAND, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

Method of Collection

The patient-centered medical home (PCMH) is a model for delivering primary care that is patient-centered, comprehensive, coordinated, accessible, and continuously improved through a systems-based approach to quality and safety.

As primary care practices across the United States seek National Committee for Quality Assurance (NCQA) recognition as patient-centered medical homes (PCMH), they can choose to administer the Consumer Assessment of Healthcare Providers and Systems (CAHPS®) Clinician and Group (CG–CAHPS) survey with or without the PCMH supplemental item set (AHRQ, 2010; Hays et al., 2014; Ng et al., 2016; Scholle et al., 2012). NCQA offers a special patient experience distinction to practices that opt to use the PCMH CAHPS items set in their CG–CAHPS survey tool. While over 11,000 practices, representing an estimated 15–18% of primary care physicians, are currently recognized for PCMH by NCQA (NCQA, 2015), fewer than 3% of them submit patient experience surveys to NCQA when applying for recognition under NCQA's PCMH recognition program.

Despite the rapid movement toward PCMH primary care transformation and the increasing use of PCMH CAHPS items, little is known about the ways in which practices are using these CAHPS data and the PCMH supplemental item information (about access, comprehensiveness, self-management, shared decision making, coordination of care, and information about care and appointments) to understand and improve their patients' experiences during PCMH transformation. The PCMH Items Demonstration Study will investigate:

- How practices across the U.S. use CAHPS and the PCMH item set during PCMH transformation,
- How practices assemble and select items for inclusion in their patient

experience surveys (e.g. core, PCMH, supplemental, and custom items),

- Primary care practice leaders' perspectives on NCQA PCMH Recognition and CAHPS Patient Experience Distinction,
- Effects of changes made during PCMH transformation on patient experiences reported on CAHPS surveys and any PCMH items, and
- Associations between PCMH transformation and patient experience scores.

To achieve the goals of this project the following data collections will be implemented:

(1) Office Manager Questions administered via phone about the participating practice's characteristics to describe the type of practices in the study and to understand how practice characteristics influence PCMH transformation and patient experience.

(2) Physician Interviews administered via phone with the lead PCMH clinical expert about the details, decisions and processes of PCMH transformation, NCQA PCMH Recognition and CAHPS Patient Experience Distinction and their use of patient experience data during the transformation process.

(3) PCMH–A Assessment Tool to be completed by the lead PCMH clinical expert (before or after the interview on the standardized form via fax or email) to collect validated metrics on the “PCMH-ness” of the practice.

(4) CAHPS Patient Experience Data Files, which are patient-level, de-identified CAHPS patient experience data covering the period of PCMH transformation for the participating practice. These data are collected independently of this study by the practice (or network) via its current vendor. We will work with the PCMH clinical expert, or a designated person who handles data, in each of the participating practices to submit these CAHPS data files securely to RAND to understand CAHPS patient experience trends and associations with PCMH implementation during the practice's PCMH journey.

Characterizing the use of CAHPS and PCMH items by primary care practices will provide important insight into the activities practices conduct during PCMH transformation to improve patient experience scores. This information may be useful in supporting practices that lag behind their peers, learning from practices with outstanding records of patient experience, and providing recommendations that may be used to refine the content of the CAHPS survey items.

Estimated Annual Respondent Burden

Table 1 shows the estimated annualized burden and cost for the respondents' time to participate in this data collection. These burden estimates are based on tests of data collection conducted on nine or fewer entities. As indicated below, the annual total burden hours are estimated to be 179 hours. The annual total cost associated with the annual total burden hours is estimated to be \$16,899.

The PCMH Items Demonstration Study will recruit 150 practices including the participating practices' office managers and one physician/lead PCMH clinical expert. We will recruit and administer the Office Manager Questions by phone to 150 office managers, recruit all sampled physicians by sending them a recruitment packet that includes a cover letter, an AHRQ endorsement letter and an information sheet, and then administer the Physician Interview protocol questions by phone to 150 physicians, and 150 physicians will self-administer the PCMH–A Assessment Tool.

We have calculated our burden estimate for Office Manager Questions asked during physician recruitment using an estimate of 3–5 questions a minute as the Office Manager Questions are closed-ended survey questions. The Office Manager Questions contains 17 questions and is estimated to require an average of 5 minutes; this estimate is supported by the information gathered during a pilot of these questions. For the Physician Interview, we have calculated the burden estimate to require an average of 40 minutes per interview. For the PCMH–A Assessment Tool, we calculated our burden using a conservative estimate of 4.5 items per minute. Prior work suggests that 3–5 items on an assessment tool can typically be completed per minute, depending on item complexity and respondent characteristics (Berry, 2009; Hays & Reeve, 2010). The PCMH–A Assessment tool contains 36 items and is estimated to require an average completion time of 8–10 minutes.

Participating practices will be asked to submit any available CAHPS Patient Experience data files (e.g. submission of de-identified data including a data dictionary via encrypted transfer) for the period of time covering their NCQA PCMH Recognition history. Each practice will have an average estimate of 3 CAHPS Patient Experience data files to submit per one submission, which we based on the average number of years of PCMH history of the sample. In addition, we conservatively estimate

that half of the control practices (25/50) administer CG-CAHPS data, as this percentage is unknown; while 90% of

the participating current and past CAHPS practices (90/100) will submit CAHPS data, yielding 115 submissions

of CAHPS patient experience data files. As indicated below, the annual total burden is estimated to be 179 hours.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection task	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Office Manager Questions	150	1	5/60	12.5
Physician Interview	150	1	40/60	100
PCMH-A Assessment Tool	150 (same physicians as above).	1 (same person as above)	15/60	37.5
CAHPS Patient Experience Data Files	115	1 per practice	15/60	28.75
Total	415	1	75/60	178.75

+ The same respondent completes the Physician Interview and PCMH-A Assessment Tool and submits the CAHPS Patient Experience Data Files.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection task	Number of requests	Total burden hours	Average hourly wage rate *	Total cost burden
Office Manager Questions	150	12.5	^a \$57.44	\$718.00
Physician Interview	150	100	^b 97.33	9,733.00
PCMH-A Assessment Tool	150	37.5	^b 97.33	3,649.88
CAHPS Patient Experience Data Files	115	28.75	^b 97.33	2,798.24
Total	300	178.75	55.48	16,899.12

+ The same respondent completes the Physician Interview and PCMH-A Assessment Tool and submits the CAHPS Patient Experience Data Files.

* Occupational Employment Statistics, May 2015 National Occupational Employment and Wage Estimates United States, U.S. Department of Labor, Bureau of Labor Statistics. http://www.bls.gov/oes/current/oes_nat.htm.

^aBased on the mean wages for *General and Operations Managers, 11-1021 within Healthcare Support Occupations*, the occupational group most likely tasked with completing the Office Manager Questions.

^bBased on the mean wages for *Physicians and Surgeons, 29-1060*, the occupational group most likely tasked with completing the Physician Interview, PCMH-A Assessment Tool, and submitting the CAHPS Patient Experience Data Files.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All

comments will become a matter of public record.

Sharon B. Arnold,
Deputy Director.

[FR Doc. 2016-18392 Filed 8-2-16; 8:45 am]

BILLING CODE 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-2049]

Medical X-Ray Imaging Devices Conformance With International Electrotechnical Commission Standards; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "Medical X-Ray Imaging Devices Conformance With IEC Standards." This draft guidance

describes FDA's policy regarding the regulation of medical x-ray imaging equipment that are subject to requirements in the Federal Food, Drug, and Cosmetic Act (the FD&C Act) and FDA's regulations that apply to medical devices and electronic products. The draft guidance also provides recommendations to industry on how to comply with the applicable requirements. This draft guidance is not final nor is it in effect at this time.

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 either electronic or written comments on the draft guidance by November 1, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.