

respective approval/clearance and coverage processes.)

12. It is CMS' policy to inform the public when it begins an NCD process for a particular product. However, under applicable statutes and FDA's regulations, the existence of a premarket application is considered confidential commercial information prior to approval or clearance unless the sponsor has publicly acknowledged the application. With the consent of the sponsor, should CMS make public that it has begun the NCD process, as part of parallel review, for a product still undergoing FDA premarket review? As a condition of the agencies' agreement to initiate parallel review, should a sponsor have to inform the public, or consent to the agencies informing the public, that the product will be evaluated under parallel review? If the sponsor declines to consent to disclosure, should it be permitted to request parallel review anyway, which would prevent CMS from disclosing the NCD process until after the product is approved by the FDA? How can the transparency of CMS' NCD process be reconciled with the need to retain confidentiality of certain commercial information?

13. At present, sponsors whose medical products will undergo both FDA premarket review and CMS national coverage review submit separate application packages to FDA and CMS that, in part, contain the same data, and, in part, contain different data. Keeping in mind the limited resources available to the agencies, what steps can the agencies take to minimize duplication of data submissions? Would the use of electronic submissions reduce submission burdens and facilitate data transfers? Are there other steps the agencies can take to streamline a parallel review process without modifying the regulatory standards and evidentiary requirements of both agencies? Would the transparency of CMS' NCD process subject the FDA to additional public pressure regarding marketing authorization?

14. Should the agencies convene a joint advisory committee to consider common issues needing public discussion and advice during the parallel review process?

15. What other concerns or considerations should the agencies take into account when developing a process for parallel review?

16. Once FDA and CMS have opened a parallel review should a sponsor be able to terminate or withdraw the request for parallel review? If this happens, should that information be made public?

17. Sponsors who submit a PMA or 510(k) to the FDA generally must pay a user fee. One key advantage of parallel review is to streamline the current process by allowing engagement by a sponsor with both FDA and CMS concurrently. Earlier engagement could shorten the time between FDA approval or clearance of the PMA or 510(k) and a coverage decision from CMS. Parallel review could, however, entail additional costs for the agencies (for example, if the product ultimately does not receive FDA approval or clearance). Changes to a user fee would also require legislative changes. Given these factors, should the current Medical Device User Fee be restructured to support the FDA and CMS costs of this parallel review and if so, how?

Dated: September 10, 2010.

**Margaret A. Hamburg,**  
*Commissioner of Food and Drugs.*

Dated: July 29, 2010.

**Donald M. Berwick,**  
*Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2010-23252 Filed 9-16-10; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

#### Patient Safety Organizations: Voluntary Delisting

**AGENCY:** Agency for Healthcare Research and Quality (AHRQ), HHS.

**ACTION:** Notice of delisting.

**SUMMARY:** AHRQ has accepted a notification of voluntary relinquishment from the Coalition for Quality and Patient Safety of Chicagoland (CQPS) of its status as a Patient Safety Organization (PSO). The Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act), Public Law 109-41, 42 U.S.C. 299b-21-b-26, provides for the formation of PSOs, which collect, aggregate, and analyze confidential information regarding the quality and safety of health care delivery. The Patient Safety and Quality Improvement Final Rule (Patient Safety Rule), 42 CFR Part 3, authorizes AHRQ, on behalf of the Secretary of HHS, to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be "delisted" by the Secretary if it is found to no longer meet the requirements of the Patient Safety Act and Patient Safety Rule, including when a PSO chooses to

voluntarily relinquish its status as a PSO for any reason.

**DATES:** The directories for both listed and delisted PSOs are ongoing and reviewed weekly by AHRQ. The delisting was effective at 12 Midnight ET (2400) on May 25, 2010.

**ADDRESSES:** Both directories can be accessed electronically at the following HHS Web site: <http://www.pso.AHRQ.gov/index.html>.

**FOR FURTHER INFORMATION CONTACT:** Diane Cousins, RPh., Center for Quality Improvement and Patient Safety, AHRQ, 540 Gaither Road, Rockville, MD 20850; Telephone (toll free): (866) 403-3697; Telephone (local): (301) 427-1111; TTY (toll free): (866) 438-7231; TTY (local): (301) 427-1130; E-mail: [psos@AHRQ.hhs.gov](mailto:psos@AHRQ.hhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### Background

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity is to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule (PDF file, 450 KB PDF Help) relating to the listing and operation of PSOs. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes a PSO from listing. AHRQ has accepted a notification from the Coalition for Quality and Patient Safety of Chicagoland (CQPS), PSO number P0027, to voluntarily relinquish its status as a component PSO of the Institute of Medicine of Chicago. CQPS' notification stated that the Institute of Medicine of Chicago has relinquished its ownership of CQPS and transferred all of its assets to a successor organization, Project Patient Care, Inc. Accordingly, CQPS was delisted effective 12 Midnight ET (2400) on May 25, 2010. AHRQ has received and accepted certification from the Coalition for Quality and Patient Safety of Chicagoland PSO (CQPS PSO), PSO Number P0090, for listing as a component PSO of Project Patient Care, Inc. The listing was effective at 12:01 a.m. ET (2401) on May 26, 2010.

More information on PSOs can be obtained through AHRQ's PSO Web site at <http://www.pso.AHRQ.gov/index.html>.

Dated: September 3, 2010.

**Carolyn M. Clancy,**  
Director.

[FR Doc. 2010-23077 Filed 9-16-10; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### Transportation Security Administration

#### Extension of Agency Information Collection Activity Under OMB Review: Office of Law Enforcement/Federal Air Marshal Service Mental Health Certification

**AGENCY:** Transportation Security Administration, DHS.

**ACTION:** 30-day notice.

**SUMMARY:** This notice announces that the Transportation Security Administration (TSA) has forwarded the Information Collection Request (ICR), Office of Management and Budget (OMB) control number 1652-0043, abstracted below to OMB for review and approval of an extension of the currently approved collection under the Paperwork Reduction Act (PRA). The ICR describes the nature of the information collection and its expected burden. TSA published a **Federal Register** notice, with a 60-day comment period soliciting comments, of the following collection of information on June 16, 2010, 75 FR 34148. The collection involves a certification form that applicants for the Federal Air Marshal positions are required to complete regarding their mental health history.

**DATES:** Send your comments by October 18, 2010. A comment to OMB is most effective if OMB receives it within 30 days of publication.

**ADDRESSES:** Interested persons are invited to submit written comments on the proposed information collection to the Office of Information and Regulatory Affairs, OMB. Comments should be addressed to Desk Officer, Department of Homeland Security/TSA, and sent via electronic mail to [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov) or faxed to (202) 395-6974.

**FOR FURTHER INFORMATION CONTACT:** Joanna Johnson, TSA PRA Officer, Office of Information Technology (OIT), TSA-11, Transportation Security Administration, 601 South 12th Street, Arlington, VA 20598-6011; telephone (571) 227-3651; e-mail [TSAPRA@dhs.gov](mailto:TSAPRA@dhs.gov).

#### SUPPLEMENTARY INFORMATION:

### Comments Invited

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), an agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB control number. The ICR documentation is available at <http://www.reginfo.gov>. Therefore, in preparation for OMB review and approval of the following information collection, TSA is soliciting comments to—

(1) Evaluate whether the proposed information requirement is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including using appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

### Information Collection Requirement

**Title:** Office of Law Enforcement/Federal Air Marshal Service Mental Health Certification.

**Type of Request:** Extension of a currently approved collection.

**OMB Control Number:** 1652-0043.

**Form(s):** TSA Form 1164.

**Affected Public:** Law Enforcement Officers/Air Marshal Applicants.

**Abstract:** TSA policy requires that applicants for Federal Air Marshal (FAM) positions meet certain medical standards, including whether the individual has an established medical history or clinical diagnosis of psychosis, neurosis, or any other personality or mental disorder that clearly demonstrates a potential hazard to the performance of FAM duties or the safety of self or others.

**Number of Respondents:** 10,000.

**Estimated Annual Burden Hours:** An estimated 10,000 hours annually.

Issued in Arlington, Virginia, on September 13, 2010.

**Joanna Johnson,**

TSA Paperwork Reduction Act Officer, Office of Information Technology.

[FR Doc. 2010-23193 Filed 9-16-10; 8:45 am]

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## DEPARTMENT OF HOMELAND SECURITY

### U.S. Citizenship and Immigration Services

#### Agency Information Collection Activities: Form I-777, Application for Replacement of Northern Mariana Card

**ACTION:** Correction to 30-day notice of Information Collection Under Review: Form I-777, Application for Replacement of Northern Mariana Card; OMB Control No. 1615-0042.

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On August 26, 2010, USCIS published a 30-day notice in the **Federal Register** at 75 FR 52540. The 30-day notice contained a spelling error in the title of Form I-777 throughout the document. This notice advises the public that the title of the Form I-777 should read "Application for Replacement of Northern Mariana Card", instead of "Application for Replacement of Northern *Marina* Card".

Written comments and/or suggestions regarding the item(s) contained in the 30-day notice published on August 26, 2010, especially regarding the estimated public burden and associated response time, should be directed to the Department of Homeland Security (DHS), and to the Office of Management and Budget (OMB) USCIS Desk Officer. Comments may be submitted to: USCIS, Chief, Regulatory Products Division, 111 Massachusetts Avenue, Washington, DC 20529-2210. Comments may also be submitted to DHS via facsimile to 202-272-8352 or via e-mail at [rfs.regs@dhs.gov](mailto:rfs.regs@dhs.gov), and to the OMB USCIS Desk Officer via facsimile at 202-395-5806 or via e-mail at [oir\\_submission@omb.eop.gov](mailto:oir_submission@omb.eop.gov).

When submitting comments by e-mail please make sure to add OMB Control Number 1615-0042 in the subject box.

If you need a copy of the information collection instrument, please visit the Web site at: <http://www.regulations.gov>.

We may also be contacted at: USCIS, Regulatory Products Division, 111 Massachusetts Avenue, NW., Washington, DC 20529-2210; Telephone 202-272-8377.

Dated: September 14, 2010.

**Sunday Aigbe,**

Chief, Regulatory Products Division, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2010-23344 Filed 9-16-10; 8:45 am]

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