activity has on the practice of medicine, including but not limited to the interpretation of testing results and performance of testing procedures; and

(4) The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.

In the Act, Congress defined the term ''confirming genetic diagnostic test activity'' to mean the performance of a genetic diagnostic test, by a genetic diagnostic test provider, on an individual solely for the purpose of providing the individual with an independent confirmation of results obtained from another test provider's prior performance of the test on the individual.

Recognizing the diversity and complexity of the public policy issues surrounding independent second opinion genetic diagnostic testing, the USPTO conducted a thorough review of the academic and scientific literature, took notice of several published reports, and actively sought diverse and sophisticated input from the public. In that last regard, the Office published a notice in the **Federal Register** and on the USPTO public Web site dedicated to AIA implementation (AIA micro-site), seeking written comments and announcing two public hearings for this study. *See Request for Comments and Notice of Public Hearings on Genetic Diagnostic Testing,* 77 FR 3748 (Jan. 25, 2012). The Office also provided the public with a dedicated email address and a contact person in the USPTO to receive comments.

As announced in the **Federal Register** and on the AIA micro-site, the Office held two public hearings dedicated to taking public comment for this report. The first occurred at the USPTO headquarters in Alexandria, Virginia, on Thursday, February 16, 2012, and the second took place at the University of San Diego School of Law in San Diego, California, on Friday, March 9, 2012. At the hearings, witnesses provided pre-scheduled testimony, and members of the audience provided spontaneous testimony. Representatives from the USPTO attended the hearings and actively questioned all witnesses. Also, witnesses exchanged comments with the audience.

In the final days before the deadline for receipt of written comments, the Supreme Court of the United States issued two rulings with potential ramifications for the present study. The first was a memorandum opinion in *Mayo Collaborative Services* v. *Prometheus Laboratories, Inc.,* 132 S. Ct. 1289 (2012). The second was an order in *Association for Molecular Pathology* v. *Myriad Genetics,* 132 S. Ct. 1794 (2012), granting the petition for a writ of certiorari, vacating the decision of the United States Court of Appeals for the Federal Circuit (CAFC), and remanding the case for reconsideration in light of the *Mayo* decision. Accordingly, the USPTO published a notice on the AIA micro-site seeking additional public input, within ten calendar days, regarding the impact of the Supreme Court's actions on independent second opinion genetic diagnostic testing.

Through the **Federal Register** notice and hearings, the Office received twenty-seven sets of written comments and testimony from eighteen witnesses. Respondents with written comments, many of whom also testified, included four U.S. intellectual property organizations, thirteen U.S. companies and organizations, three U.S. patent practitioners, and seven members of the public speaking as individuals.

On August 28, 2012, the Department of Commerce sent a letter to the House and Senate Judiciary Committee leadership updating them on the status of the genetic testing report. The letter stated in part: ''Given the complexity and diversity of the opinions, comments, and suggestions provided by interested parties, and the important policy considerations involved, we believe that further review, discussion, and analysis are required before a final report can be submitted to Congress.'' After this additional public roundtable, the USPTO will follow next steps and fulfill its obligation to Congress.

Issues for Comment: The USPTO seeks comments on how to address the issue of independent second opinion genetic diagnostic testing and its relationship to medical care and medical practice, the rights of innovators, and considerations relevant to medical costs and insurance coverage. The issues enumerated below are as posed in the AIA and serve as a preliminary guide to aid the USPTO in collecting further relevant information and to evaluate possible administrative or legislative recommendations that may be provided to Congress. The tenor of the following issues should not be taken as an indication that the USPTO has taken a position or is predisposed to any particular views. The public is invited to address any or all of these issues. The public also is invited to provide input on other issues believed to be relevant to the scope of the study in addition to those listed below.

(1) The impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients and recipients of genetic diagnostic testing, and on inhibiting innovation to existing testing and diagnoses;

(2) The effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test;

(3) The impact that current exclusive licensing and patents on genetic testing activity has on the practice of medicine, including but not limited to the interpretation of testing results and performance of testing procedures; and

(4) The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.

Dated: November 21, 2012.

David J. Kappos,

Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 2012–28890 Filed 11–28–12; 8:45 am]

BILLING CODE 3510–16–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2012–HA–0142]

Proposed Collection; Comment Request

AGENCY: Office of the Assistant Secretary of Defense for Health Affairs, DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the Office of the Assistant Secretary of Defense for Health Affairs announces the proposed extension of a public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 28, 2013.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

• *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, 2nd Floor, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to TRICARE Management Activity (TMA), Portfolio Management Division, ATTN: Karen Saddoris, CDFM–A, Project Officer, 5202 Leesburg Pike, Suite 1100, Falls Church, VA 22041, or call TMA, at (703) 681–8448.

Title; Associated Form; and OMB Number: Military Health Systems DHSS/DHIMS Information Systems User Satisfaction Survey, 0720–TBD.

Needs and Uses: The information collection requirement is necessary to enable the Military Health Systems (MHS) Chief Information Officer (CIO) to employ a standardized approach to gather and report data across 20 to 25 MHS-deployed systems/applications, for both Defense Military Health Systems (DHSS) and Defense Health Information Management Systems (DHIMS) in a repeatable process for continued monitoring of user satisfaction using established quantifiable outcome-based performance measures. Parallel efforts include the need to meet the National Defense Authorization Act (NDAA) requirement imposed by Congress in bill H.R. 6523.

Affected Public: Business or other for profit; Not-for-profit institutions.

Annual Burden Hours: 350.

Number of Respondents: 3,000.

Responses per Respondent: 1.

Average Burden per Response: 7 minutes.

Frequency: Annually.

SUPPLEMENTARY INFORMATION:

Summary of Information Collection

Respondents are staff contracted to the Department of Defense who use any of the approximately 20–25 MHS-deployed systems/applications. These systems/applications are used by the Army, Navy, and Air Force at their respective Command Headquarters, Surgeon's General Office, Bureau of Medicine, Military Treatment Facilities, and at TMA Headquarters. The survey will determine user satisfaction with overall ease of use, access to information needed to perform their job, level of training, system response time when entering or accessing the information, and system availability/minimal downtime. In addition to the quantitative measures, the survey will gather qualitative data to help identify customer ''pain points'' concerning each system. Final analysis will provide insight to the MHS organization on how best to improve the quality of care through existing health care systems.

Dated: November 26, 2012.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2012–28860 Filed 11–28–12; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DoD–2012–HA–0144]

Proposed Collection; Comment Request

AGENCY: TRICARE Management Activity, DoD.

ACTION: Notice.

In compliance with Section 3506(c)(2)(A) of the *Paperwork Reduction Act of 1995,* the TRICARE Management Activity announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by January 28, 2013.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

• *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the TRICARE Management Activity (TMA), Beneficiary Education & Support, ATTN: Lennya Bonivento, 7700 Arlington Boulevard, Suite 5101, Falls Church, VA 22042–5101, or call TMA Beneficiary Education & Support, at 703–681–1770.

Title; Associated Form; and OMB Number: Assistance Reporting Tool (ART), OMB Control Number: 0720–TBD.

Needs and Uses: The ART is a secure web-based system that captures feedback on and authorization related to TRICARE benefits. Users are comprised of Military Health System (MHS) customer service personnel, to include Beneficiary Counseling and Assistance Coordinators, Debt Collection Assistance Officers, personnel, family support, recruiting command, case managers, and others who serve in a customer service support role. The ART is also the primary means by which Military Medical Support Office (MMSO) staff capture medical authorization determinations and claims assistance information for remotely located service members, line of duty care, and for care under the Transitional Care for Service-related Conditions benefit. ART data reflects the customer service mission within the MHS: it helps customer service staff users prioritize and manage their case workload; it allows users to track beneficiary inquiry workload and resolution, of which a major component is educating beneficiaries on their TRICARE benefits. Personal health information (PHI) and personally identifiable information (PII) entered into the system is received from