acquisition is the worldwide market for magnesium plates for photoengraving. At the time of the acquisition, MEL and Revere were the only manufacturers and sellers of magnesium plate for photoengraving, combining to account for 100 percent of the relevant market.

III. Entry

Entry is not likely to deter or counteract the anticompetitive effects of the acquisition. In order to be suitable for photoengraving applications, magnesium must be rolled and coated to exact and precise specifications. Accordingly, a new entrant would require substantial expertise in order to enter the market. In addition, the market is relatively small, which deters potential entrants from investing in the skill and expertise required for entry.

IV. Effects of the Acquisition

Absent the proposed Consent Agreement, the acquisition would result in further and ongoing competitive harm in the worldwide market for magnesium plates for photoengraving. Prior to the acquisition, MEL and Revere were the only providers of the relevant product. As a result, the acquisition eliminated actual, direct, and substantial competition between MEL and Revere, and resulted in a merger-to-monopoly in the market for magnesium plates for photoengraving.

V. The Consent Agreement

The proposed Consent Agreement remedies the competitive concerns raised by the acquisition by requiring MEL to sell the technology and know-how for manufacturing magnesium plates for photoengraving to Universal Engraving. This divestiture replaces competition that was eliminated as a result of MEL's acquisition of Revere.

Universal Engraving, based in Overland Park, Kansas, is a global leader in the manufacture and sale of products used in the photoengraving process, including brass and copper plates for photoengraving applications. Currently, Universal Engraving does not sell magnesium plates for the photoengraving process. However, under the terms of the proposed Consent Agreement, Universal Engraving will acquire the assets required to compete effectively in that market.

The proposed Consent Agreement also contains several provisions designed to ensure that the divestiture is successful. First, MEL must supply Universal Engraving with magnesium plate now, thereby allowing Universal Engraving to enter the relevant market immediately in competition with MEL. In addition, MEL must provide Universal Engraving with technical assistance related to the manufacture and sale of magnesium plates for photoengraving. Finally, MEL will supply Universal Engraving with chemicals that are used in the photoengraving process, particularly, chemicals that are used to engrave magnesium plates.

If, after the public comment period the Commission determines that Universal Engraving is not an acceptable acquirer of the assets to be divested, or that the manner of the divestitures is not acceptable, MEL must unwind the divestiture and divest the assets within 180 days of the date the Order becomes final to another Commission-approved acquirer. If MEL fails to divest the assets within the 180 days, the Commission may appoint a trustee to divest the relevant assets.

The purpose of this analysis is to facilitate public comment on the proposed Consent Agreement. This analysis is not intended to constitute an official interpretation of the proposed Consent Agreement or to modify its terms in any way.

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 2012–25960 Filed 10–19–12; 8:45 am]

BILLING CODE 6750–01–P

OFFICE OF GOVERNMENT ETHICS

Updated OGE Senior Executive Service Performance Review Board

AGENCY: Office of Government Ethics (OGE).

ACTION: Notice.

SUMMARY: Notice is hereby given of the appointment of members of the updated OGE Senior Executive Service (SES) Performance Review Board.

DATES: *Effective Date:* October 22, 2012.

FOR FURTHER INFORMATION CONTACT: Barbara Mullen-Roth, Deputy Director, Office of Government Ethics, Suite 500, 1201 New York Avenue NW., Washington, DC 20005–3917; Telephone: 202–482–9300; TYY: 800–877–8339; FAX: 202–482–9237.

SUPPLEMENTARY INFORMATION: 5 U.S.C. 4314(c) requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management at 5 CFR part 430, subpart C and § 430.310 thereof in particular, one or more Senior Executive Service performance review boards. As a small executive branch agency, OGE has just one board. In order to ensure an adequate level of staffing and to avoid a constant series of recusals, the designated members of OGE's SES Performance Review Board are being drawn, as in the past, in large measure from the ranks of other agencies. The board shall review and evaluate the initial appraisal of each OGE senior executive's performance by his or her supervisor, along with any recommendations in each instance to the appointing authority relative to the performance of the senior executive. This notice updates the membership of OGE's SES Performance Review Board as it was most recently published at 76 FR 60840 (September 30, 2011).

Approved: October 11, 2012.

Don W. Fox,

Acting Director, Office of Government Ethics.

The following officials have been appointed members of the SES Performance Review Board of the Office of Government Ethics:

Barbara Mullen-Roth [Chair], Deputy Director, Office of Government Ethics;

Justina Fugh, Senior Counsel for Ethics, Environmental Protection Agency;

Melinda Loftin, Director of Interior Ethics Office, Department of the Interior;

Robert Shapiro, Associate Solicitor for Legal Counsel, Department of Labor;

Edgar Swindell, Associate General Counsel, Department of Health and Human Services; and

Susan Winchell, Assistant General Counsel for Ethics, Department of Education.

[FR Doc. 2012–25882 Filed 10–19–12; 8:45 am]

BILLING CODE 6345–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Announcement of Requirements and Registration for ''Health Design Challenge''

AGENCY: Office of the National Coordinator for Health Information Technology, HHS.

Award Approving Official: Farzad Mostashari, National Coordinator for Health Information Technology.

ACTION: Notice.

SUMMARY: Blue Button for America is a collaborative Federal effort led by the Department of Health and Human Services and the Department of Veterans Affairs to ensure everyone across the country gets access to their medical records. By clicking on a Blue Button icon, patients can get their personal health information in an electronic

format—a service that has not been available to most people until very recently. Because of Blue Button, over 1 million Americans have already downloaded their health records from their medical providers and insurance companies, and the number is expected to increase dramatically in the near future.

Being able to access your health information on demand can be lifesaving in an emergency situation, can help prevent medication errors, and can improve care coordination so everyone who is caring for you is on the same page. However, too often health information is presented in an unwieldy and unintelligible way that makes it hard for patients, their caregivers, and their physicians to use. There is an opportunity for talented designers to reshape the way health records are presented to create a better patient experience.

The statutory authority for this challenge competition is Section 105 of the America COMPETES Reauthorization Act of 2010 (Pub. L. 111–358).

DATES: Effective on October 16, 2012. Challenge submission period ends November 30, 2012, 11:59 p.m. et.

FOR FURTHER INFORMATION CONTACT: Adam Wong, 202–720–2866 and Ryan Panchadsaram, 202–690–0099

SUPPLEMENTARY INFORMATION:

Subject of Challenge Competition:

The purpose of this challenge is to improve the design of the medical record so it is more usable by and meaningful to patients, their families, and others who take care of them. This is an opportunity to take the plain-text Blue Button file and enrich it with visuals and a better layout. Innovators will be invited to submit their best designs for a medical record that can be printed and viewed digitally.

This challenge will focus on the content defined by a format called the Continuity of Care Document (CCD). A CCD is a common template used to describe a patient's health history and can be output by electronic medical record (EMR) software. Submitted designs should use the sections and fields found in a CCD. See the resources section on Challenge.gov for a sample CCD.

Challenge entrants will submit a design that:

- Improves the visual layout and style of the information from the medical record.
- Makes it easier for a patient to manage his/her health.
- Enables a medical professional to digest information more efficiently
- Aids a caregiver such as a family member or friend in his/her duties and responsibilities with respect to the patient

Entrants should be conscious of how the wide variety of personas will affect their design. Our healthcare system takes care of the following types of individuals:

- An underserved inner-city parent with lower health literacy.
- A senior citizen that has a hard time reading.
- A young adult who is engaged with technology and mobile devices.
- An adult whose first language is not English.
- A patient with breast cancer receiving care from multiple providers.
- A busy mom managing her kids' health and helping her aging parents.

This challenge is an opportunity for talented individuals to touch the lives of Americans across the country through design. The most innovative designs will be showcased in an online gallery and in a physical exhibit at the Annual ONC Meeting in Washington DC. Winning submissions will receive monetary prizes.

A panel of curators will select a final design (that may combine elements of numerous winning designs) that will be built and open-sourced on the code sharing community Github. Open sourcing the final product will enable EHR developers to improve on it by adding new functionality or creating new styles that serve different patient populations, and to integrate it into actual products.

The Department of Veterans Affairs enthusiastically supports the open-source development of the design because it could enable them to improve MyHealth*e*Vet, the patient portal used by veterans and their families across the country.

Because of the collaborative and open source nature of the challenge, all entries are required to be submitted under a Creative Commons license. This license allows the community to use and adapt the designs while ensuring that the designer receives attribution. More details on the license can be found at *http://creativecommons.org*.

In order for an entry to be eligible to win this Challenge, it must meet the following requirements:

- Deliverable: Must be an image or browser viewable file. The acceptable image formats: .PNG, .JPG, .GIF, .TIFF, .PSD, .AI, and .PDF. The acceptable browser viewable format is .HTML.
- Feasibility: This challenge requires only that the design of the medical record to be submitted. It is not the responsibility of the entrant to build or code a working version of the design. However, the design must be ultimately implementable using HTML, CSS, and JavaScript.
- Data: The design must be built off the data fields found in a Continuity of Care Document (CCD).

Eligibility Rules for Participating in the Competition:

To be eligible to win a prize under this challenge, an individual or entity—

(1) Shall have registered to participate in the competition under the rules promulgated by the Office of the National Coordinator for Health Information Technology.

(2) Shall have complied with all the requirements under this section.

(3) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States.

(4) May not be a Federal entity or Federal employee acting within the scope of their employment.

(5) Shall not be an HHS employee working on their applications or submissions during assigned duty hours.

(6) Shall not be an employee of Office of the National Coordinator for Health IT.

(7) Federal grantees may not use Federal funds to develop COMPETES Act challenge applications unless consistent with the purpose of their grant award.

(8) Federal contractors may not use Federal funds from a contract to develop COMPETES Act challenge applications or to fund efforts in support of a COMPETES Act challenge submission.

An individual or entity shall not be deemed ineligible because the individual or entity used Federal facilities or consulted with Federal employees during a competition if the facilities and employees are made available to all individuals and entities participating in the competition on an equitable basis.

Entrants must agree to assume any and all risks and waive claims against the Federal Government and its related entities, except in the case of willful misconduct, for any injury, death, damage, or loss of property, revenue, or profits, whether direct, indirect, or consequential, arising from my participation in this prize contest, whether the injury, death, damage, or loss arises through negligence or otherwise.

Entrants must also agree to indemnify the Federal Government against third

party claims for damages arising from or related to competition activities.

Registration Process for Participants:

To register for this challenge participants should either:

- Access the *www.challenge.gov* Web site and search for the ''Health Design Challenge''.
- Access the ONC Investing in Innovation (i2) Challenge Web site at:
  - *http://www.health2con.com/devchallenge/challenges/onc-i2-challenges/.*
  - A registration link for the challenge can be found on the landing page under the challenge description.

Amount of the Prize:

Each submission will be considered for all four prize categories listed below. A review panel will select winners based on defined criteria (below). An individual submission can win multiple awards.

- Overall Design: $16,000 (1st), $6,000 (2nd), and $4,000 (3rd).
- Best Medication Section—$5,000 (1st), $3,000 (2nd), and $1,000 (3rd).
- Best Medical/Problem History Section—$5,000 (1st), $2,000 (2nd), and $1,000 (3rd).
- Best Lab Summaries—$5,000 (1st), $2,000 (2nd), and $1,000 (3rd).

Awards may be subject to Federal income taxes and HHS will comply with IRS withholding and reporting requirements, where applicable.

Payment of the Prize:

Prize will be paid by contractor.

Basis Upon Which Winners Will Be Selected:

The review panel will make selections based upon the following criteria:

- Overall Appeal.
- Patient Usefulness—Does it address the needs of a patient?
- Caregiver Usefulness—Does it ease the responsibilities of a caregiver?
- Physician Usefulness—Can a physician integrate it into their workflow?
- Visual Hierarchy—Can the most important information be easily found?
- Information Density—Is it easy to digest the information that is presented?
- Accessibility—Can a varied population make use of this document?

Additional Information:

Authority: 15 U.S.C. 3719.

Dated: October 15, 2012.

Farzad Mostashari,

National Coordinator for Health Information Technology.

[FR Doc. 2012–25954 Filed 10–19–12; 8:45 am]

BILLING CODE 4150–45–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0471]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Prescription Drug User Fee Cover Sheet; Form FDA 3397

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by November 21, 2012.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0297. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850, 301–796–7726, *Ila.Mizrachi@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Prescription Drug User Fee Cover Sheet; Form FDA 3397—(OMB Control Number 0910–0297)—Extension

Under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (sections 735 and 736 (21 U.S.C. 379g and 379h)), as amended, FDA has the authority to assess and collect user fees for certain drug and biologics license applications and supplements to those applications. Under this authority, pharmaceutical companies pay a fee for certain new drug applications (NDAs), biologics license applications (BLAs), or supplements submitted to the Agency for review. Because the submission of user fees concurrently with applications and supplements is required, review of an application by FDA cannot begin until the fee is submitted. The Prescription Drug User Fee Cover Sheet, Form FDA 3397, is designed to provide the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to account for and track user fees. The form provides a cross-reference of the fee submitted for an application by using a unique number tracking system. The information collected is used by FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) to initiate the administrative screening of NDAs, BLAs, and/or supplemental applications to those applications.

Respondents to this collection of information are new drug and biologics manufacturers. Based on FDA's database system for fiscal year (FY) 2011, there are an estimated 260 manufacturers of products subject to the Prescription Drug User Fee Act (Pub. L. 105–115). The total number of annual responses is based on the number of submissions received by FDA in FY 2011. CDER received 3,363 annual responses that include the following submissions: 114 NDAs; 4 BLAs; 1,900 manufacturing supplements; 1,209 labeling supplements; and 136 efficacy supplements. CBER received 768 annual responses that include the following submissions: 6 BLAs; 698 manufacturing supplements; 44 labeling supplements; and 20 efficacy supplements. The estimated hours per response are based on past FDA experience with the various submissions.

FDA is revising Form FDA 3397 in the following ways: (1) By updating the applicable Web sites; (2) by adding a Privacy Act Notice pursuant to the Privacy Act of 1974, 5 U.S.C. 552a(3)j; (3) by adding 351(k) applications to the CDER and CBER lists of applications and supplements for which Form FDA 3397 need not be submitted; (4) by adding ''or proper name'' to instruction number 3; and (5) by making minor editorial changes.

In the **Federal Register** of May 18, 2012 (77 FR 29663), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows: