

6. How should a registry for breast cancer treatments using thermal ablation devices be developed? What data analysis methods need to be considered when developing the registry data set?

7. Have you implemented some form of a registry for breast cancer thermal ablation treatments already? Please describe the extent of implementation, and type of data being collected.

8. Should a registry be considered for all thermal ablation device applications for cancer treatment? If yes, why? If not, what thermal ablation device uses should be considered for data capture in a registry?

9. What solutions have you developed or do you think could be developed for addressing the various technical use, pathological, imaging and other treatment assessment problems that might arise in developing and implementing a registry for breast cancer or other cancer treatments using thermal ablation devices? Criteria for Data Inclusion from Breast Cancer Treatments Using Thermal Ablation Devices

10. What is the minimum data set that should be associated with a device use session? Would this minimum data set differ for different devices? If so, how?

11. How would the data in the minimum data set be used to improve patient safety? What other data would improve patient safety?

12. How and by whom should the registry and its associated minimum data set be obtained and maintained?

13. What information should be accessible by the public, healthcare providers, professional organizations, FDA, other Federal Agencies, the industry, and individual manufacturers? How would the information be accessible?

14. What type of proprietary information needs to be excluded?

15. Should data from all thermal ablation device investigators be included or should the data be limited to include only investigators that have received a certain level of training for device use?

#### Registry Benefits and Costs

16. From your perspective, how could a registry be best used among competing manufacturers of similar product lines? What obstacles do you see in using such an approach for justifying marketing claims?

17. From your perspective, should data previously collected or currently being collected be incorporated by investigators studying the effects of thermal ablation treatment for breast cancer be included in the registry? If so,

why, and under what circumstances? If not, why not?

18. From your perspective, what specific public health and patient safety benefits could be gained from having a standardized registry for breast cancer treatments using thermal ablation devices? In addition, how would such a system contribute to meeting device recall and adverse event reporting requirements, and to reducing medical error? Please submit detailed data to support benefits you identify.

19. From your perspective, what are the startup costs measured in time and other resources associated with the development, implementation, and use of a registry for breast cancer treatments using thermal ablation devices? Please submit detailed data to support these cost estimates.

20. If you have already implemented a form of a registry for breast or other cancer treatments using thermal ablation devices, what investments in equipment, training, and other human and physical resources were necessary to implement the use of such a database? What factors influenced your decision to implement such a system?

21. From your perspective, what are the obstacles to implementing or using a registry for breast cancer treatments using thermal ablation devices?

#### IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic copies or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

#### V. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**) and may be seen between 9 a.m. and 4 p.m., Monday through Friday. (FDA has verified the Web site address, but is not responsible for subsequent changes to

the Web site after this document publishes in the **Federal Register**.)

1. Panel transcript and questions regarding percutaneous and thermal ablation treatment of breast cancer in lieu of operative resection (see [http://www.fda.gov/OHRMS/DOCKETS/AC/03/questions/3973q1\\_Breast%20ca%20Questions.htm](http://www.fda.gov/OHRMS/DOCKETS/AC/03/questions/3973q1_Breast%20ca%20Questions.htm) and <http://www.fda.gov/OHRMS/DOCKETS/AC/03/transcripts/3973t1.htm>).

2. Gliklich, R.E., N.A Dreyer, eds. "Registries for Evaluating Patient Outcomes: A User's Guide." (Prepared by Outcome DEcIDE Center [Outcome Sciences, Inc. dba Outcome] under Contract No. HHS290200500351 TO1.) AHRQ Publication No. 07-EHC001-1. Rockville, MD: Agency for Healthcare Research and Quality. April 2007.

3. Goldberg, S.N., et al. "Image Guided Tumor Ablation: Proposal for Standardization of Terms and Reporting Criteria," *Radiology* 2003; 228: 335-345.

4. Goldberg, S.N., et al. "Image Guided Tumor Ablation: Standardization of Terminology and Reporting Criteria," *Journal of Vascular and Interventional Radiology* 2005; 16: 765-778.

Dated: May 19, 2008.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy and Planning.*

[FR Doc. E8-11899 Filed 5-27-08; 8:45 am]

**BILLING CODE 4160-01-S**

## DEPARTMENT OF HOMELAND SECURITY

### Office of the Secretary

[Docket No. DHS-2008-0050]

### Data Privacy and Integrity Advisory Committee

**AGENCY:** Office of the Secretary, DHS.

**ACTION:** Notice of Federal Advisory Committee Meeting.

**SUMMARY:** The Data Privacy and Integrity Advisory Committee will meet on June 11, 2008 in Arlington, VA. This meeting will be open to the public.

**DATES:** The Data Privacy and Integrity Advisory Committee will meet on Wednesday, June 11, 2008 from 9 a.m. to 12 p.m. and 1:30 p.m. to 4 p.m. Please note that the meeting may close early if the committee has completed its business.

**ADDRESSES:** The meeting will be held in Galleries I and II of the Hilton Arlington Hotel, 950 North Stafford Street, Arlington, Virginia 22203. Send written materials, comments, and requests to make oral presentations to Ken Hunt, Executive Director, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, Washington, DC 20528. Written

materials, comments, and requests to make oral presentations at the meeting should reach the contact person listed by June 5, 2008. Requests to have a copy of your material distributed to each member of the committee prior to the meeting should reach the persons listed under **FOR FURTHER INFORMATION CONTACT**, below, by June 5, 2008.

Persons wishing to make comments or who are unable to attend or speak at the meeting may submit comments at any time. All submissions received must include the docket number: DHS-2008-0050 and may be submitted by any one of the following methods:

- *Federal Rulemaking Portal:* <http://www.regulations.gov>. Follow instructions for submitting comments on the Web site.

- *E-mail:* [PrivacyCommittee@dhs.gov](mailto:PrivacyCommittee@dhs.gov). Include docket number in the subject line of the message.

- *Fax:* (866) 466-5370.

- *Mail:* Mr. Ken Hunt, Executive Director, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, Washington, DC 20528.

*Instructions:* All submissions received must include the words "Department of Homeland Security Data Privacy and Integrity Advisory Committee" and the docket number: DHS-2008-0050. Comments received will also be posted without alteration at <http://www.regulations.gov>, including any personal information provided.

*Docket:* For access to the docket to read background documents or comments received by the DHS Data Privacy and Integrity Committee, go to <http://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:**

Hugo Teufel III, Chief Privacy Officer, or Ken Hunt, Executive Director, Data Privacy and Integrity Advisory Committee, Department of Homeland Security, Washington, DC 20528, by telephone (703) 235-0780 or by fax (703) 235-0442, or by e-mail [PrivacyCommittee@dhs.gov](mailto:PrivacyCommittee@dhs.gov).

**SUPPLEMENTARY INFORMATION:** Notice of this meeting is given under the Federal Advisory Committee Act, 5 U.S.C. App. (Pub. L. 92-463).

During the meeting, the DHS Chief Privacy Officer will provide an update on the activities of the DHS Privacy Office. In the morning session, invited speakers will discuss the Privacy and Civil Liberties Oversight Board and the DHS Office for Civil Rights and Civil Liberties. The Subcommittees will update the Committee on their current work. In the afternoon session, speakers will discuss privacy protections and concerns within E-Verification. A

tentative agenda is posted on the Privacy Advisory Committee Web site at <http://www.dhs.gov/privacy>.

At the discretion of the Chair, members of the public may make brief (i.e., no more than three minutes) oral presentations from 3:30 p.m.—4 p.m. If you would like to make an oral presentation at the meeting, please register in advance or sign up on the day of the meeting. If you would like a copy of your material(s) distributed to each member of the committee in advance, please submit 22 copies to Ken Hunt by June 5, 2008.

**Information on Services for Individuals With Disabilities**

For information on facilities or services for individuals with disabilities or to request special assistance at the meeting, contact Ken Hunt as soon as possible.

Dated: May 20, 2008.

**Hugo Teufel,**

*Chief Privacy Officer.*

[FR Doc. E8-11875 Filed 5-27-08; 8:45 am]

**BILLING CODE 4410-10-P**

**DEPARTMENT OF HOMELAND SECURITY**

**U.S. Citizenship and Immigration Services**

**Agency Information Collection Activities: Form N-300, Extension of a Currently Approved Information Collection; Comment Request**

**ACTION:** 30-Day Notice of Information Collection Under Review: Form N-300, Application to File Declaration of Intention; OMB Control No. 1615-0078.

The Department of Homeland Security, U.S. Citizenship and Immigration Services (USCIS) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and clearance in accordance with the Paperwork Reduction Act of 1995. The information collection was previously published in the **Federal Register** on March 3, 2008, at 73 FR 11431 allowing for a 60-day public comment period. USCIS did not receive any comments for this information collection.

The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until June 27, 2008. This process is conducted in accordance with 5 CFR 1320.10.

Written comments and/or suggestions regarding the item(s) contained in this

notice, 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 Management Division, Clearance Office, 111 Massachusetts Avenue, Suite 3008, Washington, DC 20529. 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 202-395-6974 or via email at [kastrich@omb.eop.gov](mailto:kastrich@omb.eop.gov).

When submitting comments by e-mail please make sure to add OMB Control Number 1615-0078. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information 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 agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(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 through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, e.g., permitting electronic submission of responses.

*Overview of this information collection:*

(1) *Type of Information Collection:* Extension of a currently approved information collection.

(2) *Title of the Form/Collection:* Application to File Declaration of Intention.

(3) *Agency form number, if any, and the applicable component of the Department of Homeland Security sponsoring the collection:* Form N-300. U.S. Citizenship and Immigration Services.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract:* Primary: Individuals or Households. This form will be used by permanent residents to file a declaration of intention to become a citizen of the United States. This collection is also used to satisfy documentary requirements for those seeking to work