

appropriate agency meetings with medical product sponsors and investigators; and (2) exploring means to provide for identification of patient representatives who do not have any, or have minimal, financial interests in the medical products industry.”

FDA has formed an Agency-wide working group to explore approaches and procedures as well as to align strategies across the Agency for patient participation in accordance with the statute. Involvement of the patient community brings the unique perspective of patients, family members, caregivers, and patient advocates to the decision-making processes of the FDA, and FDA is currently using a variety of tools to help ensure that the patient community is involved in medical product discussions to enhance benefit-risk assessment. FDA assesses the benefit-risk of new drugs and certain devices on a case-by-case basis. In this assessment, FDA may consider, among other things, the degree of unmet medical need and the severity and morbidity of the condition or disease the drug or device is intended to treat or diagnose. This approach has been critical to increasing patient access to new treatments for cancer, other serious diseases, and rare diseases, where existing therapies have been few and limited in their effectiveness.

Currently, patient representatives can serve as Special Government Employees (SGEs) in order to participate as a member of an FDA's federal advisory committee meeting about medical products undergoing the FDA review process for marketing approval and other regulatory issues. Patient representatives serve as committee members on advisory committees managed by the Office of the Commissioner, Center for Drug Evaluation and Research, Center for Biological Evaluation and Research, and Center for Devices and Radiological Health. SGE patient representatives may also serve on special assignments to provide feedback and perspective on product reviews in progress. These SGE activities are in addition to the many other activities in which FDA obtains patient perspectives, such as open public hearings on specific diseases or drug development issues, and as speakers at FDA-sponsored conferences and workshops.

FDASIA includes the reauthorization of the Prescription Drug User Fee Act (PDUFA) that provides FDA with the necessary resources to maintain a predictable and efficient review process for human drug and biological products. This is the fifth authorization of PDUFA (otherwise known as “PDUFA V”),

which was, as directed by Congress, developed in consultation with drug industry representatives, patient and consumer advocates, health care professionals, and other public stakeholders. Under PDUFA V, FDA intends to conduct at least 20 public meetings that aim to more systematically gather patients' perspectives on their conditions and available therapies to treat those conditions (Patient Focused Drug Development). PDUFA V also includes an initiative to enhance FDA's review of patient-reported outcome study endpoints and endpoint assessment tools.

FDASIA also includes the reauthorization of the Medical Device User Fee Act (MDUFA) that provides FDA the necessary resources to increase the efficiency of regulatory processes in order to reduce the time it takes to bring safe and effective medical devices to the U.S. market. This third authorization of MDUFA (otherwise known as “MDUFA III”), was a result of more than a year of public input, negotiations with industry representatives, and discussions with patient and consumer stakeholders. Under MDUFA III, FDA has established the Patient Preference Initiative to provide the information, guidance, and framework necessary to incorporate patient preferences on the benefit-risk tradeoffs of medical devices into the full spectrum of medical device regulatory processes and to inform medical device innovation by the larger medical device community. In the process, the initiative aims to advance the science of measuring medical device preferences of patients, caregivers, and providers. Once the Patient Preference Initiative helps to define or refine the methods to measure patient preferences, FDA intends to incorporate patient views into the total product life cycle of medical devices.

FDA is opening a docket for 30 days to provide an opportunity for interested stakeholders to submit comments on “strategies to solicit the views of patients during the medical product development process and consider the perspectives of patients during regulatory discussions” under section 1137 of FDASIA. FDA is interested in comments on both current and new activities that would involve patient participation in regulatory discussions, as well as comments on ways to assess patient participation activities.

II. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of

Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments 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, and will be posted to the docket at <http://www.regulations.gov>.

Dated: October 29, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

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BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of HHS-Certified Laboratories and Instrumented Initial Testing Facilities Which Meet Minimum Standards To Engage in Urine Drug Testing for Federal Agencies

AGENCY: Substance Abuse and Mental Health Services Administration, HHS.

ACTION: Notice.

SUMMARY: The Department of Health and Human Services (HHS) notifies federal agencies of the laboratories and Instrumented Initial Testing Facilities (IITF) currently certified to meet the standards of the Mandatory Guidelines for Federal Workplace Drug Testing Programs (Mandatory Guidelines). The Mandatory Guidelines were first published in the **Federal Register** on April 11, 1988 (53 FR 11970), and subsequently revised in the **Federal Register** on June 9, 1994 (59 FR 29908); September 30, 1997 (62 FR 51118); April 13, 2004 (69 FR 19644); November 25, 2008 (73 FR 71858); December 10, 2008 (73 FR 75122); and on April 30, 2010 (75 FR 22809).

A notice listing all currently HHS-certified laboratories and IITFs is published in the **Federal Register** during the first week of each month. If any laboratory or IITF certification is suspended or revoked, the laboratory or IITF will be omitted from subsequent lists until such time as it is restored to full certification under the Mandatory Guidelines.

If any laboratory or IITF has withdrawn from the HHS National Laboratory Certification Program (NLCP) during the past month, it will be listed at the end and will be omitted from the monthly listing thereafter.

This notice is also available on the Internet at <http://beta.samhsa.gov/workplace>.

FOR FURTHER INFORMATION CONTACT: Giselle Hersh, Division of Workplace Programs, SAMHSA/CSAP, Room 7-1051, One Choke Cherry Road, Rockville, Maryland 20857; 240-276-2600 (voice), 240-276-2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were initially developed in accordance with Executive Order 12564 and section 503 of Public Law 100-71. The "Mandatory Guidelines for Federal Workplace Drug Testing Programs," as amended in the revisions listed above, requires strict standards that laboratories and IITFs must meet in order to conduct drug and specimen validity tests on urine specimens for federal agencies.

To become certified, an applicant laboratory or IITF must undergo three rounds of performance testing plus an on-site inspection. To maintain that certification, a laboratory or IITF must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

Laboratories and IITFs in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A HHS-certified laboratory or IITF must have its letter of certification from HHS/SAMHSA (formerly: HHS/NIDA), which attests that it has met minimum standards.

In accordance with the Mandatory Guidelines dated November 25, 2008 (73 FR 71858), the following HHS-certified laboratories and IITFs meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

HHS-Certified Instrumented Initial Testing Facilities

Gamma-Dynacare Medical Laboratories, 6628 50th Street NW., Edmonton, AB Canada T6B 2N7, 780-784-1190

HHS-Certified Laboratories

ACM Medical Laboratory, Inc., 160 Elmgrove Park, Rochester, NY 14624, 585-429-2264

Aegis Analytical Laboratories, Inc., 345 Hill Ave., Nashville, TN 37210, 615-255-2400 (Formerly: Aegis Sciences Corporation, Aegis Analytical Laboratories, Inc., Aegis Analytical Laboratories)

Alere Toxicology Services, 1111 Newton St., Gretna, LA 70053, 504-361-8989/800-433-3823 (Formerly: Kroll Laboratory Specialists, Inc., Laboratory Specialists, Inc.)

Alere Toxicology Services, 450 Southlake Blvd., Richmond, VA

23236, 804-378-9130 (Formerly: Kroll Laboratory Specialists, Inc., Scientific Testing Laboratories, Inc.; Kroll Scientific Testing Laboratories, Inc.)

Baptist Medical Center-Toxicology Laboratory, 11401 I-30, Little Rock, AR 72209-7056, 501-202-2783 (Formerly: Forensic Toxicology Laboratory Baptist Medical Center) Clinical Reference Lab, 8433 Quivira Road, Lenexa, KS 66215-2802, 800-445-6917

DrugScan, Inc., 200 Precision Road, Suite 200, Horsham, PA 19044, 800-235-4890

ElSohly Laboratories, Inc., 5 Industrial Park Drive, Oxford, MS 38655, 662-236-2609

Fortes Laboratories, Inc., 25749 SW Canyon Creek Road, Suite 600, Wilsonville, OR 97070, 503-486-1023

Gamma-Dynacare Medical Laboratories,* A Division of the Gamma-Dynacare Laboratory Partnership, 245 Pall Mall Street, London, ONT, Canada N6A 1P4, 519-679-1630

Laboratory Corporation of America Holdings, 7207 N. Gessner Road, Houston, TX 77040, 713-856-8288/800-800-2387

Laboratory Corporation of America Holdings, 69 First Ave., Raritan, NJ 08869, 908-526-2400/800-437-4986 (Formerly: Roche Biomedical Laboratories, Inc.)

Laboratory Corporation of America Holdings, 1904 Alexander Drive, Research Triangle Park, NC 27709, 919-572-6900/800-833-3984 (Formerly: LabCorp Occupational Testing Services, Inc., CompuChem Laboratories, Inc.; CompuChem Laboratories, Inc., A Subsidiary of

Roche Biomedical Laboratory; Roche CompuChem Laboratories, Inc., A Member of the Roche Group) Laboratory Corporation of America Holdings, 1120 Main Street, Southaven, MS 38671, 866-827-8042/800-233-6339 (Formerly: LabCorp Occupational Testing Services, Inc.; MedExpress/National Laboratory Center)

LabOne, Inc. d/b/a Quest Diagnostics, 10101 Renner Blvd., Lenexa, KS 66219, 913-888-3927/800-873-8845 (Formerly: Quest Diagnostics Incorporated; LabOne, Inc.; Center for Laboratory Services, a Division of LabOne, Inc.)

MedTox Laboratories, Inc., 402 W. County Road D, St. Paul, MN 55112, 651-636-7466/800-832-3244

MetroLab-Legacy Laboratory Services, 1225 NE 2nd Ave., Portland, OR 97232, 503-413-5295/800-950-5295

Minneapolis Veterans Affairs Medical Center, Forensic Toxicology Laboratory, 1 Veterans Drive, Minneapolis, MN 55417, 612-725-2088

National Toxicology Laboratories, Inc., 1100 California Ave., Bakersfield, CA 93304, 661-322-4250/800-350-3515

One Source Toxicology Laboratory, Inc., 1213 Genoa-Red Bluff, Pasadena, TX 77504, 888-747-3774 (Formerly: University of Texas Medical Branch, Clinical Chemistry Division; UTMB Pathology-Toxicology Laboratory)

Pacific Toxicology Laboratories, 9348 DeSoto Ave., Chatsworth, CA 91311, 800-328-6942 (Formerly: Centinela Hospital Airport Toxicology Laboratory)

Pathology Associates Medical Laboratories, 110 West Cliff Dr., Spokane, WA 99204, 509-755-8991/800-541-7891x7

Phamatech, Inc., 10151 Barnes Canyon Road, San Diego, CA 92121, 858-643-5555

Quest Diagnostics Incorporated, 1777 Montreal Circle, Tucker, GA 30084, 800-729-6432 (Formerly: SmithKline Beecham Clinical Laboratories;

SmithKline Bio-Science Laboratories) Quest Diagnostics Incorporated, 400 Egypt Road, Norristown, PA 19403, 610-631-4600/877-642-2216 (Formerly: SmithKline Beecham Clinical Laboratories; SmithKline Bio-Science Laboratories)

Quest Diagnostics Incorporated, 8401 Fallbrook Ave., West Hills, CA 91304, 818-737-6370 (Formerly: SmithKline Beecham Clinical Laboratories)

Redwood Toxicology Laboratory, 3700650 Westwind Blvd., Santa Rosa, CA 95403, 800-255-2159

Southwest Laboratories, 4625 E. Cotton Center Boulevard, Suite 177, Phoenix,

* The Standards Council of Canada (SCC) voted to end its Laboratory Accreditation Program for Substance Abuse (LAPSA) effective May 12, 1998. Laboratories certified through that program were accredited to conduct forensic urine drug testing as required by U.S. Department of Transportation (DOT) regulations. As of that date, the certification of those accredited Canadian laboratories will continue under DOT authority. The responsibility for conducting quarterly performance testing plus periodic on-site inspections of those LAPSA-accredited laboratories was transferred to the U.S. HHS, with the HHS' NLCP contractor continuing to have an active role in the performance testing and laboratory inspection processes. Other Canadian laboratories wishing to be considered for the NLCP may apply directly to the NLCP contractor just as U.S. laboratories do.

Upon finding a Canadian laboratory to be qualified, HHS will recommend that DOT certify the laboratory (**Federal Register**, July 16, 1996) as meeting the minimum standards of the Mandatory Guidelines published in the **Federal Register** on April 30, 2010 (75 FR 22809). After receiving DOT certification, the laboratory will be included in the monthly list of HHS-certified laboratories and participate in the NLCP certification maintenance program.

AZ 85040, 602-438-8507/800-279-0027
 STERLING Reference Laboratories, 2617
 East L Street, Tacoma, Washington
 98421, 800-442-0438
 US Army Forensic Toxicology Drug
 Testing Laboratory, 2490 Wilson St.,
 Fort George G. Meade, MD 20755-
 5235, 301-677-7085

Summer King,
 Statistician.

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BILLING CODE 4160-20-P

DEPARTMENT OF HOMELAND SECURITY

[Docket No. DHS-2014-0048]

President's National Security Telecommunications Advisory Committee

AGENCY: National Protection and Programs Directorate, DHS.

ACTION: Committee Management; Notice of Partially Closed Federal Advisory Committee Meeting.

SUMMARY: The President's National Security Telecommunications Advisory Committee (NSTAC) will meet on Wednesday, November 19, 2014, in Washington DC. The meeting will be partially closed to the public.

DATES: The NSTAC will meet in a closed session on Wednesday, November 19, 2014, from 8:30 a.m. to 10:30 a.m. and in an open session on Wednesday, November 19, 2014, from 10:40 a.m. to 2:40 p.m.

ADDRESSES: The open, public session will be held at the Department of Homeland Security Immigration and Customs Enforcement facility, 500 12th Street SW., Washington DC, and will begin at 10:40 a.m. For information on facilities or services for individuals with disabilities, to request special assistance at the meeting, or to attend in person contact nstac@dhs.gov as soon as possible.

We are inviting public comment on the issues the NSTAC will consider, as listed in the **SUPPLEMENTARY INFORMATION** section below. Associated briefing materials that will be discussed at the meeting will be available at www.dhs.gov/nstac for review as of November 5, 2014. Comments must be identified by docket number DHS-2014-0048 and may be submitted by one of the following methods:

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

- Email: NSTAC@dhs.gov. Include the docket number in the subject line of the message.

- Fax: 703-235-5962, Attn: Sandy Benevides.

- Mail: Designated Federal Officer, National Security Telecommunications Advisory Committee, National Protection and Programs Directorate, Department of Homeland Security, 245 Murray Lane, Mail Stop 0615, Arlington VA 20598-0615.

Instructions: All submissions received must include the words "Department of Homeland Security" and the docket number for this action. Comments received will 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 NSTAC, go to <http://www.regulations.gov>, referencing docket number DHS-2014-0048.

A public comment period will be held during the open portion of the meeting on Wednesday, November 19, 2014, from 1:35 p.m. to 2:05 p.m., and speakers are requested to limit their comments to three minutes. Please note that the public comment period may end before the time indicated, following the last call for comments. Contact Sandy Benevides at 703-235-5408 or Sandra.Benevides@dhs.gov to register as a speaker by close of business on November 17, 2014. Speakers will be accommodated in order of registration within the constraints of the time allotted to public comment.

FOR FURTHER INFORMATION CONTACT: Helen Jackson, NSTAC Designated Federal Officer, Department of Homeland Security, telephone (703) 235-5321 or Helen.Jackson@dhs.gov.

SUPPLEMENTARY INFORMATION: Notice of this meeting is given under the *Federal Advisory Committee Act*, 5 U.S.C. Appendix. The NSTAC advises the President on matters related to national security and emergency preparedness (NS/EP) telecommunications policy.

Agenda: The committee will meet in the open session to engage in an update of the Federal Communications Commission's current priorities; a discussion of the Department of Justice's Anti-Trust Guidelines; the current priorities and accomplishments of the First Responder Network Authority; a panel discussion of the interdependencies between the Communications and Electric Power Sector. The NSTAC members will deliberate and vote on the *NSTAC Report to the President on the Cybersecurity Implications of the*

Internet of Things and the *NSTAC Report to the President on Information and Communications Technology Mobilization*. Both reports will be available at www.dhs.gov/nstac as of November 5, 2014.

The NSTAC will meet in a closed session to hear a classified briefing regarding emerging threats to the communications infrastructure and to discuss the potential future NSTAC study topics.

Basis for Closure: In accordance with 5 U.S.C. § 552b(c), *The Government in the Sunshine Act*, it has been determined that two agenda items require closure as the disclosure of the information would not be in the public interest.

The first of these agenda items, the classified briefing, will provide members with information on national-state capabilities and strategic threats. Such threats target national communications infrastructure and impact industry's long-term competitiveness and growth, as well as the Government's ability to mitigate threats. Malicious actors continue to advance their techniques to exploit critical infrastructure networks and poses serious challenges for the communications sector. Disclosure of these threats would provide criminals who wish to intrude into commercial and Government networks with information on potential vulnerabilities and mitigation techniques, also weakening existing cybersecurity defense tactics. This briefing will be classified at the top secret level, thereby exempting disclosure of the content by statute. Therefore, this portion of the meeting is required to be closed pursuant to 5 U.S.C. § 552b(c)(1)(A).

The second agenda item, the discussion of potential NSTAC study topics, will address areas of critical cybersecurity vulnerabilities and priorities for Government. Government officials will share data with NSTAC members on initiatives, assessments, and future security requirements across public and private networks. The data to be shared includes specific vulnerabilities within cyberspace that affect the Nation's communications and information technology infrastructures and proposed mitigation strategies. Disclosure of this information to the public would provide criminals with an incentive to focus on these vulnerabilities to increase attacks on our cyber and communications networks. Therefore, this portion of the meeting is likely to significantly frustrate implementation of proposed DHS actions and is required to be closed pursuant to 5 U.S.C. 552b(c)(9)(B).