

access information after October 7, 2013. If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit http://www.adobe.com/go/connectpro_overview. (FDA has verified the Web site addresses in this document, but FDA is not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

Transcripts: Please be advised that as soon as a transcript is available, it will be accessible at <http://www.regulations.gov>. It may be viewed at the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. A transcript will also be available in either hardcopy or on CD-ROM, after submission of a Freedom of Information request. Written requests are to be sent to the Division of Freedom of Information (ELEM-1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857. A link to the transcript will also be available approximately 45 days after the public workshop on the Internet at <http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm>. (Select this public workshop from the posted events list).

SUPPLEMENTARY INFORMATION:

I. Background

Cataract surgery is the most commonly performed elective procedure in the United States with over 3 million patients being implanted with an IOL. Over the past two decades, IOLs have undergone significant design changes allowing them to correct for a spectrum of visual distances and refractive errors. As IOL technology evolves, some endpoints for the evaluation of the technology are also evolving. Endpoints and strategies for assessing the relative safety and effectiveness of these innovative lens designs are in various stages of development. At this workshop, not only will some of these novel endpoints and the challenges with assessments of these endpoints be identified, but these endpoints also will be prioritized for further discussion, development, and validation. Breakout sessions following the didactic portion of the workshop will allow for more in-depth group discussions of potential approaches to address these challenges.

The workshop seeks to involve industry and academia in addressing the challenges in the development of novel

endpoints for premium IOLs. By bringing together all of the relevant stakeholders, which include clinicians, researchers, industry representatives, and regulators, to this workshop, we hope to facilitate the improvement of regulatory science in this rapidly evolving product area.

FDA and AAO recognize the unique opportunity this workshop provides for all stakeholders of the ophthalmic device community and that the knowledge and education provided from this workshop will further strengthen our mission of protecting the public health.

II. Topics for Discussion at the Public Workshop

Topics to be discussed at the public workshop include, but are not limited to:

- Safety assessments for premium IOLs and how they could differ from those for monofocal IOLs.
- Patient-reported outcome measures and the need to develop and validate them for assessing the safety and effectiveness of premium IOLs.
- Objective assessments of accommodation and their challenges.
- Subjective assessments of accommodation and extended depth of focus and their challenges.

These topics will be presented by experts in the associated area, and the afternoon will allow for more in-depth discussions of the given topics in small breakout sessions.

Dated: September 3, 2013.

Leslie Kux,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Proposed Collection; Comment Request

In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 concerning opportunity for public comment on proposed collections of information, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish periodic summaries of proposed projects. To request more information on the proposed projects or to obtain a copy of the information collection plans, call the SAMHSA

Reports Clearance Officer on (240) 276-1243.

Comments are invited on: (a) Whether the proposed collections of information are 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 collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Proposed Project: National Mental Health Services Survey (N-MHSS) (OMB No. 0930-0119)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Behavioral Health Statistics and Quality (CBHSQ), is requesting a revision to the National Mental Health Services Survey (N-MHSS) (OMB No. 0930-0119), which expires on June 30, 2015. The N-MHSS provides national and state-level data on the number and characteristics of mental health treatment facilities in the United States, annually, and national and state-level data on the number and characteristics of persons treated in these facilities, biennially.

An immediate need under N-MHSS is to update the information about facilities on SAMHSA's online Behavioral Health Treatment Services Locator (see: <http://findtreatment.samhsa.gov>), which was last updated with information from the abbreviated N-MHSS (N-MHSS-Locator Survey) in 2012. A full-scale N-MHSS will be conducted in 2014 and 2016 to collect (1) the information about facilities needed to update the online Locator, such as the facility name and address, specific services offered, and special client groups served, and (2) additional information including client counts and the demographics of persons treated in these facilities. An abbreviated N-MHSS (N-MHSS-Locator Survey) will be conducted in 2015 to update the information about facilities on the online Locator. A data collection in conjunction with adding new facilities to the online Locator as they become known to SAMHSA is also being requested. Both the 2015 N-MHSS-Locator Survey and the addition of new facilities to the online Locator will use the same N-MHSS-Locator Survey instrument.

This requested revision seeks to change the content of the currently

approved abbreviated N–MHSS (i.e., N–MHSS-Locator) survey instrument, and the previously approved 2010 full-scale N–MHSS (OMB No. 0930–0119) to accommodate two related N–MHSS activities:

- (1) collection of information from the total N–MHSS universe of mental health treatment facilities during 2014, 2015, and 2016; and
- (2) collection of information on newly identified facilities throughout the year, as they are identified, so that new facilities can quickly be added to the online Locator.

The survey mode for both data collection activities will be web with telephone follow-up.

The database resulting from the N–MHSS will be used to update SAMHSA’s online Behavioral Health Treatment Services Locator and to produce a national directory of mental health facilities on compact disk (CD), both for use by the general public, behavioral health professionals, and treatment service providers. In addition, a data file derived from the survey will be used to produce a summary report providing national and state-level data.

The report and a public-use data file will be used by researchers, mental health professionals, State governments, the U.S. Congress, and the general public.

The request for OMB approval will include a request to conduct the full-scale N–MHSS in 2014 and 2016 and an abbreviated N–MHSS-Locator survey in 2015.

The following table summarizes the estimated annual response burden for the N–MHSS:

ESTIMATED ANNUAL RESPONSE BURDEN FOR THE N–MHSS

Type of respondent	Number of respondents	Responses per respondent	Average hours per response	Total burden hours
Facilities in full-scale N–MHSS universe in 2014 and 2016	17,000	1	0.75	12,750
Newly identified facilities in Between-Survey Update in 2014, 2015, and 2016 ¹	1,700	1	0.42	714
Facilities in N–MHSS-Locator Survey universe in 2015	17,000	1	0.42	7,140
Average Annual Total	18,700	1	0.62	11,594

¹ Collection of information on newly identified facilities throughout the year, as they are identified, so that new facilities can quickly be added to the Locator.

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 2–1057, One Choke Cherry Road, Rockville, MD 20857 or email her a copy at summer.king@samhsa.hhs.gov. Written comments should be received by November 5, 2013.

Summer King,
Statistician.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of 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 certified laboratories and IITF 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 (NLCPP) 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://www.workplace.samhsa.gov>.

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 Instrumented Initial Testing Facilities (IITF) 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 IITF in the applicant stage of certification are not to be considered as meeting the minimum requirements described in the HHS Mandatory Guidelines. A 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 Laboratories and Instrumented Initial Testing Facilities (IITF) meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

Instrumented Initial Testing Facilities (IITF): None.

Laboratories:
ACL Laboratories, 8901 W. Lincoln Ave., West Allis, WI 53227, 414–328–7840/800–877–7016 (Formerly: Bayshore Clinical Laboratory).