

at a minimum, the following information: (1) Title of the standard; (2) any reference number and date; (3) name and address of the national or international standards development organization; (4) a proposed list of devices for which a declaration of conformity to this standard should routinely apply; and (5) a brief identification of the testing or performance or other characteristics of the device(s) that would be addressed by a declaration of conformity.

VI. Electronic Access

You may obtain a copy of "Guidance on the Recognition and Use of Consensus Standards" by using the Internet. CDRH maintains a site on the Internet for easy access to information including text, graphics, and files that you may download to a personal computer with access to the Internet. Updated on a regular basis, the CDRH home page includes the guidance as well as the current list of recognized standards and other standards related documents. After publication in the **Federal Register**, this notice announcing "Modification to the List of Recognized Standards, Recognition List Number: 024" will be available on the CDRH home page. You may access the CDRH home page at <http://www.fda.gov/MedicalDevices>.

You may access "Guidance on the Recognition and Use of Consensus Standards," and the searchable database for "FDA Recognized Consensus Standards" through the hyperlink at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards>.

This **Federal Register** document on modifications in FDA's recognition of consensus standards is available at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm>.

VII. Submission of Comments and Effective Date

Interested persons may submit to the contact person (see **FOR FURTHER INFORMATION CONTACT**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. It is no longer necessary to send two copies of mailed comments. Comments are to be identified with the docket number found in brackets in the heading of this document. FDA will consider any comments received in determining whether to amend the current listing of modifications to the list of recognized standards, Recognition List Number: 024. These modifications to the list or recognized standards are effective upon

publication of this notice in the **Federal Register**.

Dated: June 4, 2010.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2010-13874 Filed 6-9-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276-1243.

Project: Cross-community Evaluation of the Native Aspirations Project—NEW

The Substance Abuse and Mental Health Services Administration's (SAMHSA), Center for Mental Health Services (CMHS) will conduct the Cross-Community Evaluation of the Native Aspirations Project. The cross-community evaluation has two tiers. Community-specific activities (Tier 1) are tied to key components of a community plan developed in each participating community that guides program planning and local evaluation through data-driven frameworks and inquiry. Tier I activities will include process and impact evaluation activities to determine the stage of readiness of communities to implement programs, how accurately community plans reflect the needs and characteristics of each community, how well local resources for American Indian/Alaska Native (AI/AN) youth are mobilized, the experience and impact of the Gathering of Native Americans (GONA), and the impact of the Native Aspirations program on the community. Core cross-community data collection activities (Tier II) are cross-community and include process and impact indicators such as community-level knowledge and awareness of suicide, violence, bullying, and substance abuse; pro-social and help-seeking behaviors among Native youth; and the provision of services specific to Native youth through existing service systems. Tier II activities are directly tied to the primary objectives of the Native Aspirations Project and are

designed to augment data collection through the collection of community- and systems-level change measurement. Activities include the Service Provider Focus Groups and the Community Knowledge, Awareness, and Behavior Survey (C-KABS).

Data will be collected from Native adults and youth involved in the Community Mobilization Plan (CMP) meeting and the Gathering of Native Americans (GONA), key program stakeholders, Native youth service providers (e.g., teachers, mental health providers, case workers, juvenile justice providers), and other community members (Native youth and adults). Data collection will take place in 25 AI/AN communities across three cohorts. Data collection for the Native Aspirations Cross-community Evaluation will occur over a three-year period of funding for each cohort. Clearance is requested for a three-year period of data collection that spans FY2009 through FY2012 during which Cohorts 3 and 4 will receive three years of data collection and Cohort 5 will receive two years of data collection with the final year to be submitted in an OMB renewal package. The following describes the specific data collection activities and the nine data collection instruments to be used, followed by a summary table of respondents and respondent burden.

Community Specific Data Collection Activities—Tier I

- *GONA—Baseline Interviews (1 Version).* Each participating community will have the opportunity to hold a GONA focused on youth violence, bullying, substance abuse, and suicide concerns. Community GONAs follow four themes that correspond to indigenous values and are core resiliency factors for Native people. These values—belonging, mastery, interdependence, and generosity—are the framework for this collaborative community event that focuses on individual and community healing, envisioning community wellness, mapping the assets of the community, and committing action in the community toward prevention efforts centered on youth violence, bullying, substance abuse, and suicide. Baseline GONA interviews will be conducted prior to the GONA in each community and will center on the four values and how respondents view and describe their relationships in and with the community; how people in the community deal with youth violence, bullying, substance abuse, and suicide; community members' willingness to work together to address these issues;

community protective factors; and suggestions for how community members can work together to address these issues. The GONA baseline interviews will be conducted by telephone in year 1 of funding with a maximum of 6 adults per funded community who will attend the GONA in each Cohort. The total number of participants across Cohorts 3, 4, and 5 for 3 years is 150. Items are formatted as open-ended and semi-structured questions. The GONA baseline telephone interviews include 6 items and will take approximately 20 minutes to complete. By using either the GONA Evaluation—Baseline Consent Form, Phone Script or Verbal Consent Form, verbal consent will be received from each respondent prior to administration of the GONA Baseline Interviews.

- *GONA—Follow-up Interviews (1 Version)*. The GONA follow-up interviews will be conducted several weeks after the GONA in each community. Follow-up interviews will center around the four values (belonging, mastery, interdependence, and generosity) and respondents' experience during the GONA; participation in activities; views on community relationships; knowledge of the Native Aspirations Project; knowledge of risk factors for youth violence, bullying, substance abuse, and suicide; community protective factors; willingness of community members to work together and suggestions for working together; and next steps. The GONA follow-up interviews will be conducted in person with a total of 9 adult respondents who attended the GONA from each of the funded communities. Items are formatted as open-ended and semi-structured questions. The GONA follow-up interviews include 11 questions and will take approximately 60 minutes to complete. These follow-up interviews will occur during a site visit in year 1 for Cohorts 3, 4, and 5. The total number of participants across the three cohorts is 225. Each participant will provide written consent prior to the interview through the GONA Evaluation—Follow-up Interview Consent Form.

- *GONA—Youth Follow-up Focus Group Moderator's Guide (1 Version)*. The GONA follow-up focus groups will be conducted several weeks after the GONA with youth who attended the GONA. The focus group moderator's guide follows the same content as the GONA Follow-up Interviews (see above). Cross-community evaluation staff will conduct up to 2 focus groups with youth in each funded community. Focus groups will consist of a maximum of 9 participants per group and will

occur during a site visit in year 1 for Cohorts 3, 4, and 5. Focus group guides contain 11 items and the session will last 2 hours. A total of 450 respondents will participate in GONA focus groups. Caregivers will give consent for youth to participate using the GONA Follow-Up Youth Focus Group Caregiver Consent form and youth will assent to participate using the GONA Follow-Up Youth Focus Group Youth Assent form.

- *Community Plan Focus Group Moderator's Guide (1 Version)*. Respondents participating in the Community Plan Focus Groups include youth and adults who attended the Community Mobilization Plan (CMP) meeting in year 1. The guide consists of questions designed to facilitate group communication around the community mobilization planning process, early implementation of the plan, and organizational and community awareness and involvement. Focus group guides contain 7 items and the session will last 2 hours. The cross-community evaluation team will conduct up to 3 focus groups with a maximum of 9 participants each in year 1 for each funded community in Cohorts 3, 4, and 5. The total number of participants across cohorts is 675. Consent to participate will be obtained from adult participants through the Community Plan Focus Group Consent form and youths' caregivers will use the Community Plan Focus Group Caregiver Consent form to give consent and youth will assent to participate using the Community Plan Focus Group Youth Assent—Attachment B.6).

- *Community Plan In-depth Interviews (2 Versions)*. The Community Plan In-depth Interviews will be conducted in person during year 3. The interviews will be conducted with the same individuals who participated in the CMP focus groups; however, the participants will be divided into two groups with two respective guides. Version 1 will be conducted with participants who remained active in the community mobilization process and Version 2 will be used with respondents who discontinued their involvement with Native Aspirations. The interviews will be used to gather information on the CMP implementation process, organizational and community awareness and involvement with Native Aspirations, and the impact of the Native Aspirations program on the community. The Community Plan In-depth Interview—Version 1 consists of 24 open-ended and semi-structured questions and will take 60 minutes to complete. Version 1 will be conducted with up to 9 participants, including Native youth and adults, in year 3 for

a maximum total of 225 respondents across Cohorts 3, 4, and 5. The Community Plan In-depth Interview—Version 2 consists of 11 open-ended and semi-structured questions and will take 20 minutes to complete. Up to 9 respondents, including Native youth and adults, will be interviewed using Version 2 in year 3. The maximum total of respondents from each funded community across Cohorts 3, 4, and 5 is 225 for Version 2 over the life of the project. Adult participants for both versions will be required to provide written consent prior to participation using the Community Plan In-Depth Interview V.1 Consent form or the Community Plan In-Depth Interview V.2 Consent and youth participants will need written caregiver consent collected on the Community Plan Interview V.1 & V.2 Caregiver Consent forms and youth assent using the Community Plan Interview V.1 & V.2 Youth Assent forms.

Cross Community Data Collection Activities—Tier II

- *Service Provider Focus Group Moderator's Guide (2 Versions)*. The Service Provider Focus Groups are designed to facilitate conversation and information sharing with youth service providers across communities to acquire a broader understanding of provider and service availability for Native youth. Version 1 participants will include agency staff such as teachers, mental health professionals, justice providers, and welfare providers. Version 2 participants will include non-agency staff such as paraprofessional providers or "natural helpers." However, specific provider types will be identified for each participating community as a function of their existence and number. Version 1 of the focus group guides consists of 9 items and Version 2 consists of 7 items, each with additional sub-questions/probes covering the availability of wellness and mental health services, how agencies work together, awareness of violence/suicide prevention activities, and areas for improvement. Focus groups will include a maximum of 9 participants per group, with up to 3 focus groups in each community in each of years 1 (baseline) and 3 (follow up). Two focus groups will be conducted with agency staff using Version 1, for a maximum total of 900 respondents across the life of the project. One focus group will be conducted with non-agency staff using Version 2 for a maximum number of 450 participants for each Cohort. Focus groups will last approximately 2 hours. Written consent will be obtained prior to focus group participation using the Service Provider Focus Group V.1

Consent form and Service Provider Focus Group V.2 Consent form.

- *Community Knowledge, Awareness, and Behavior Survey (C-KABS)—Adult Version.* The C-KABS—Adult Version is designed to gather knowledge and awareness information from adult community members related to suicide, substance abuse, violence, and bullying. In addition, respondents will report on their exposure to Native Aspirations Project activities regarding the prevention of suicide, substance abuse, violence, and bullying. Other constructs include the availability of services, knowledge of youth risk factors, and stigma around and attitude toward seeking services for wellness. The C-KABS—Adult Version will be administered annually, for all three years of the project, to 100 Native adults from each funded community. The survey consists of 36 open and closed-ended questions that include Likert-type agreement scales, prevalence scales and questions, behavior scales and questions, true/false items, and demographic questions. The survey takes approximately 45 minutes to complete. A total of 7,500 respondents will participate from Cohorts 3, 4, and 5. Written consent will be obtained using the C-KABS Adult Consent form.

- *Community Knowledge, Awareness, and Behavior Survey (C-KABS)—Youth Version.* The C-KABS Youth Version will be administered to youth participants (age 11 and older) to gather information about existing social norms around help-seeking behavior, pro-social behavior (e.g., traditional Indian activities) among youth, and the extent to which respondent youth have been exposed to risky behaviors (suicide, violence, substance abuse, and/or bullying), as well as their exposure to prevention efforts for risky behaviors related to the Native Aspirations Project. The survey will also contain items about youths' access to pathways to risky behaviors (e.g., how hard/easy is it to get drugs/alcohol), access to and awareness of/willingness to seek help for these behaviors for themselves or others, and youths' engagement in risky and protective behaviors. The C-KABS Youth Version will be administered annually, for all three years of the project, to 100 Native youth from each funded community. The survey consists of 38 open and closed-ended questions that include Likert-type agreement scales, prevalence scales and questions,

behavior scales and questions, true/false items, and demographic questions. A total of 7,500 youth will participate from Cohorts 3, 4 and 5. Youths' caregivers will provide consent for youth to participate using the C-KABS Youth Caregiver Consent form and youth will assent to participate using the C-KABS Youth Assent form.

- *Community Readiness Assessment (1 Version).* The CRA addresses six readiness dimensions focused on identified social concern (i.e., youth violence, bullying, and suicide). These dimensions include (a) community prevention efforts, (b) community knowledge of prevention efforts, (c) leadership, (d) community climate, (e) knowledge about the problem, and (f) resources for prevention efforts. In addition, there are nine developmental levels of readiness within which a community must progress through. CRAs include 26 interview questions which address each of the six community readiness dimensions; most items are formatted as open-ended questions with three items scored on a scale of 1 to 10. During years 1 and 3, CRAs will be conducted with each funded community in Cohorts 3, 4, and 5 to address youth violence, bullying, and suicide from a multi-faceted perspective. Telephone interviews will be conducted with up to six key informants in the community. Interviews will last 60 minutes and a maximum of 300 respondents will be interviewed. Overall readiness scores will be determined based on key informants' responses and will indicate the community's status with respect to each of these dimensions. Consent will be obtained using either the Community Readiness Assessment Verbal Consent form or the Community Readiness Assessment Written Consent form.

Data Abstraction and Submission. In addition to the above described data collection activities, data from existing sources abstracted using the Data Abstraction and Submission Form (i.e., management information systems (MIS), administrative records, case files, etc.) will be analyzed across communities to support the impact stage of Tier I of the cross-community evaluation. To minimize data collection burden on community members, this activity will be tailored to key components identified in the community plan and will be developed around existing data systems and related infrastructures. Cross-

community technical assistance providers will assist in the identification of existing data sources and their relevance to locally planned Native Aspirations activities. Data elements may be requested from educational systems, juvenile justice/law enforcement sources, mental health agencies, child welfare, Medicaid, and community organizations (e.g., YMCA, Boys and Girls Clubs, etc.). A maximum of 10 data elements each will be requested from education and juvenile justice/law enforcement sources and a maximum of 5 data elements each will be requested from mental health, child welfare, Medicaid, and community organizations. These data will be aggregated from existing data sources, some of which are attendance sheets, management information systems, etc. Communities are responsible for aggregating these data and submitting them to the Native Aspirations Cross-community Evaluation team by mail, electronic mail, or by uploading the data. The burden associated with accessing, aggregating, and submitting existing data is approximately 6 hours per activity per year. Data abstraction and submission will occur two times per year in each funded community in Cohorts 3, 4 and 5. Seven respondents (one each representing education, juvenile justice, law enforcement, mental health, child welfare, Medicaid, and community organizations) in each community will perform data abstraction and submission for a total of 175 respondents and 2,100 hours across three years of data collection for Cohorts 3, 4, and 5.

Given the expected variation in available technology (e.g., Internet) and geographic spread of the target populations, flexible implementation options for surveys include local distribution or administration of surveys, in-person group, and Internet options and will be determined with each participating community and used when relevant and viable.

The average annual respondent burden is estimated below. The estimate reflects the average annual number of respondents, the average annual number of responses, the time it will take for each response, and the average annual burden across three years of OMB clearance, which includes three years of data collection for Cohorts 3 and 4 and two years of data collection for Cohort 5.

ANNUALIZED AVERAGES: RESPONDENTS, RESPONSES AND HOURS

Measure name	Number of respondents	Number of responses per respondent	Hours/response	Response burden*
Community Specific Data Collection Activities—Tier I				
GONA Baseline Interviews	50	1	0.33	17
GONA Follow-up Interviews	75	1	1.0	75
GONA Youth Follow-up Focus Groups	150	1	2.0	300
Community Plan Focus Groups	225	1	2.0	450
Community Plan In-depth Interviews—V. 1	51	1	1.0	51
Community Plan In-depth Interviews—V. 2	51	1	0.33	17
Service Provider Focus Groups—V. 1	252	1	2.0	504
Service Provider Focus Groups—V. 2	126	1	2.0	252
Cross Community Data Collection Activities—Tier II				
C—KABS Adult Version	2,234	1	0.75	1,676
C—KABS Youth Version	2,234	1	0.75	1,676
Community Readiness Assessment	84	1	1.0	84
Data Abstraction and Submission Form	156	2.0	6.0	1,872
Total	5,688			6,974

*Rounded to the nearest whole number.

Written comments and recommendations concerning the proposed information collection should be sent July 12, 2010 to: SAMHSA Desk Officer, Human Resources and Housing Branch, Office of Management and Budget, New Executive Office Building, Room 10235, Washington, DC 20503; due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, respondents are encouraged to submit comments by fax to: 202-395-5806.

Dated: June 3, 2010.

Elaine Parry,

Director, Office of Program Services.

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BILLING CODE 4162-20-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Current List of Laboratories 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 currently certified to meet the standards of Subpart C 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), on September 30, 1997 (62 FR 51118), and on April 13, 2004 (69 FR 19644).

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

If any laboratory 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://www.workplace.samhsa.gov> and <http://www.drugfreeworkplace.gov>.

FOR FURTHER INFORMATION CONTACT: Mrs. Giselle Hersch, Division of Workplace Programs, SAMHSA/CSAP, Room 2-1042, One Choke Cherry Road, Rockville, Maryland 20857; 240-276-2600 (voice), 240-276-2610 (fax).

SUPPLEMENTARY INFORMATION: The Mandatory Guidelines were developed in accordance with Executive Order 12564 and section 503 of Public Law 100-71. Subpart C of the Mandatory Guidelines, "Certification of Laboratories Engaged in Urine Drug Testing for Federal Agencies," sets strict standards that laboratories must meet in order to conduct drug and specimen validity tests on urine specimens for Federal agencies. To become certified, an applicant laboratory must undergo three rounds of performance testing plus an on-site inspection. To maintain that

certification, a laboratory must participate in a quarterly performance testing program plus undergo periodic, on-site inspections.

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

In accordance with Subpart C of the Mandatory Guidelines dated April 13, 2004 (69 FR 19644), the following laboratories meet the minimum standards to conduct drug and specimen validity tests on urine specimens:

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

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

Advanced Toxicology Network, 3560 Air Center Cove, Suite 101, Memphis, TN 38118. 901-794-5770/888-290-1150.

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

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.;