2. *By regular mail.* You may mail written comments to the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development, Attention: Document Identifier/OMB Control Number, Room C4–26–05, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: October 30, 2009.

Michelle Shortt,

Director, Regulations Development Group, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. E9–26829 Filed 11–5–09; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Native Employment Works (NEW) Program Plan Guidance and Report Requirements.

OMB No.: 0970–0174.

Description: The Native Employment Works (NEW) program plan is the application for NEW program funding. As approved by the Department of Health and Human Services (HHS), it documents how the grantee will carry out its NEW program. The NEW program plan guidance provides instructions for preparing a NEW program plan and explains the process for plan submission every third year. The NEW program report provides information on the activities and accomplishments of grantees' NEW programs. The NEW program report and instructions specify the program data that NEW grantees report annually.

Respondents: Federally recognized Indian Tribes and Tribal organizations that are NEW program grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
NEW program plan guidance	26	1	29	754
NEW program report	48	1	15	720

Estimated Total Annual Burden Hours: 1,474.

Additional Information:

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection. E-mail address: *infocollection@acf.hhs.gov*.

OMB Comment:

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Fax: 202–395–7245, Attn: Desk Officer for the Administration for Children and Families.

Dated: November 2, 2009.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. E9–26731 Filed 11–5–09; 8:45 am]

BILLING CODE 4184–01–P

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: Recovery Services for Adolescents and Families—New

The Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Treatment will conduct a data collection on the helpfulness of recovery support services for whether young people and their families after leaving substance abuse treatment. Specifically, the Recovery Services for Adolescents and Families (RSAF) project is evaluating a pilot test of the following recovery support services for whether young people and their families find the following recovery support services helpful: (1) Telephone/text message support; (2) a recovery-oriented social networking site; and (3) a family program. Approximately 200 adolescent respondents will be asked to complete 4 data collection forms (some repeated) during 5 interviews (baseline and 4 follow-ups) over a 12-month period after enrollment or discharge from treatment. Approximately 200 collateral respondents (*i.e.,* a parent/guardian/concerned other) will be asked to complete 7 data collection forms (some repeated) during 5 interviews (baseline and 4 follow-ups) over a 12-month period after their adolescent's enrollment or discharge from treatment. Approximately 15 to 20 project staff respondents, including Project Coordinators, Telephone Support Volunteers, a Social Network Site Moderator, Family Program Clinicians, and a Support Services Supervisor, will be asked to complete between 2 and 5 data collection forms at varying intervals during the delivery of recovery support services. Across all respondents, a total of 28 data collection forms will be used. Depending on the time interval and task, information collections will take anywhere from about 5 minutes to 2 hours to complete. A description of each data collection form follows:

Adolescent Participant

• *Global Appraisal of Individual Needs—Initial (GAIN–I 5.6.0 Full).* The GAIN is an evidence-based assessment used with both adolescents and adults and in outpatient, intensive outpatient, partial hospitalization, methadone, short-term residential, long-term residential, therapeutic community, and correctional programs. There are over 1000 questions in this initial version that are in multiple formats, including

multiple choice, yes/no, and open-ended. Eight content areas are covered: Background, Substance Use, Physical Health, Risk Behaviors and Disease Prevention, Mental and Emotional Health, Environment and Living Situation, Legal, and Vocational. Each section contains questions on the recency of problems, breadth of symptoms, and recent prevalence as well as lifetime service utilization, recency of utilization, and frequency of recent utilization. GPRA data are gathered as part of this instrument in support of performance measurement for SAMHSA programs. It is administered at intake into treatment by clinical staff and used as baseline data for the project.

• *Global Appraisal of Individual Needs—Monitoring 90 Days (GAIN–M90 5.6.0 Full).* The GAIN is an evidence-based assessment used with both adolescents and adults and in outpatient, intensive outpatient, partial hospitalization, methadone, short-term residential, long-term residential, therapeutic community, and correctional programs. There are over 500 questions in this follow-up version that are in multiple formats, including multiple choice, yes/no, and open-ended. Eight content areas are covered: Background, Substance Use, Physical Health, Risk Behaviors and Disease Prevention, Mental and Emotional Health, Environment and Living Situation, Legal, and Vocational. Each section contains questions on the recency of problems, breadth of symptoms, and recent prevalence as well as lifetime service utilization, recency of utilization, and frequency of recent utilization. GPRA data are gathered as part of this instrument in support of performance measurement for SAMHSA programs. It is administered by project staff at each of the follow-up timepoints.

• *Supplemental Assessment Form (SAF 0309).* The SAF contains 72 questions that are a combination of multiple choice, yes/no, and open-ended formats. Content areas include: race, happiness with parent or caregiver in several life areas, participation in prosocial activities, receipt of and satisfaction with telephone support services, and usage of and satisfaction with the project's social networking site. It is administered by project staff at each of the follow-up timepoints.

Collateral Participant (parent/guardian)

• *Global Appraisal of Individual Needs—Collateral Monitoring—Initial (GCI).* The GCI contains over 200 items in this initial version that are in multiple formats, including multiple choice, yes/no, and open-ended. The following content areas are covered: relationship to the adolescent respondent, background, and the adolescent's background and substance use, environment and living situation, and vocational information. There are questions on the recency of problems, breadth of symptoms, and recent prevalence as well as lifetime service utilization, recency of utilization, and frequency of recent utilization. It is administered at baseline by project staff.

• *Global Appraisal of Individual Needs—Collateral Monitoring—Monitoring (GCM 5.3.3).* The GCM contains over 200 items in this follow-up version that are in multiple formats, including multiple choice, yes/no, and open-ended. The following content areas are covered: relationship to the adolescent respondent, background, and the adolescent's background and substance use, environment and living situation, and vocational information. There are questions on the recency of problems, breadth of symptoms, and recent prevalence as well as lifetime service utilization, recency of utilization, and frequency of recent utilization. It is administered at each of the follow-up timepoints by project staff

• *Supplemental Assessment Form—Collateral (SAF—Collateral).* The SAF contains 72 questions that are a combination of multiple choice, yes/no, and open-ended formats. Content areas include: knowledge about the adolescent's participation in prosocial activities, receipt of and satisfaction with telephone support services, and usage of and satisfaction with the project's social networking site. It is administered at each of the follow-up timepoints by project staff.

• *Self-Evaluation Questionnaire (SEQ).* The SEQ contains 40 multiple choice items that ask the collateral about feelings and symptoms of anxiety. It is administered at each of the follow-up timepoints by project staff.

• *Family Environment Scale (FES).* The FES contains 18 yes/no items that measure family cohesion and conflict. It is administered at each of the follow-up timepoints by project staff.

• *Relationship Happiness Scale (Caregiver Version).* The Relationship Happiness Scale contains 8 items that ask the collateral about happiness with his/her relationship with the adolescent respondent in various life areas. It is administered at each of the follow-up timepoints by project staff.

Project Coordinator

• *Eligibility Checklist.* The Eligibility Checklist contains 12 yes/no items that are used to determine whether or not an adolescent meets inclusion/exclusion criteria for the project and is eligible to be approached for informed consent. It is completed prior to informed consent by project staff.

• *Telephone Support Volunteer Notification Form.* This form contains a participant's name and contact information. It is completed by project staff and given to volunteers to notify them when someone is assigned to receive telephone support.

• *Family Program Notification Form.* This form contains a participant's name. It is completed by project staff and given to clinicians to notify them when someone is assigned to the family support group.

• *Follow-Up Locator Form—Participant (FLF–P).* The FLF–P contains over 50 items that are a combination of yes/no, multiple choice, and open-ended formats. At the time of informed consent, data are gathered by project staff about an adolescent's contact information, personal contacts, criminal justice contacts, school/job contacts, hang-out information, Internet contacts, and identifying information in order to locate and interview that adolescent over multiple follow-up intervals.

• *Follow-Up Locator Form—Collateral (FLF–C).* The FLF–C contains over 50 items that are a combination of yes/no, multiple choice, and open-ended formats. Data are gathered about a collateral's contact information, personal contacts, and job contacts in order to locate and interview that collateral over multiple follow-up intervals. It is administered at the time of informed consent by project staff.

• *Follow-Up Contact Log.* The Follow-Up Contact Log is open-ended and provides space for all data collected during attempted and completed follow-up contacts, over the phone and in-person, to be recorded. It is completed throughout the follow-up timeperiod.

• *Volunteer/Staff Survey.* The Volunteer/Staff Survey contains 10 items in fill-in-the-blank, yes/no, and multiple choice formats. Items ask about background, demographic information, and role in the project. It is completed once by all volunteers and staff at the start of the project.

Telephone Support Volunteer

• *Telephone Support Case Review Form.* The Telephone Support Case Review Form contains multiple rows that allow a volunteer to record 5 pieces of data about adolescents that they make phone calls to: initials, treatment discharge status/date, weeks since treatment discharge, date of last telephone session, and number of

completed telephone sessions since discharge. This allows the volunteer and supervisor to monitor the progress of active cases. The form is completed by the volunteers every week.

• *Telephone Support Call Log.* The Telephone Support Call Log is open-ended and provides space for all data collected during attempted and completed support contacts to be recorded. The form is completed by the volunteer throughout the period of telephone support.

• *Adolescent Telephone Support Documentation Form.* The Adolescent Telephone Support Documentation Form contains 22 items that are asked of an adolescent during a telephone support contact by a volunteer. The form is used to record yes/no and open-ended responses to questions asking about substance use and recovery-related activities. The volunteers complete the form every time there is a telephone support session with an adolescent.

• *Telephone Support Discharge Form.* The Telephone Support Discharge Form contains 10 fields to record the following information at the end of an adolescent's participation in telephone support: adolescent name, today's date, volunteer name, notification date, telephone support intake date, telephone support discharge date, reason for discharge, number of completed sessions, referral for more intervention, and successful contact for more intervention. This form is completed by volunteers when telephone support ends for each adolescent.

• *Volunteer/Staff Survey (Telephone Support Volunteer)—See Volunteer/Staff Survey (Project Coordinator)* above.

Social Network Site Moderator

• *Social Networking Moderator Log.* The Social Networking Moderator Log contains 11 fields for the moderator to record usage data for the project's social networking site. The moderator tracks number of visits to the site, number of unique visitors, messages posted, chat room attendance, and problems with users. This form is completed weekly by project staff.

• *Volunteer/Staff Survey—See Volunteer/Staff Survey (Project Coordinator)* above.

Family Program Clinician

• *Family Program Progress Notes.* The Family Program Progress Notes form is open-ended and provides space for all data collected during attempted and completed family program contacts to be recorded. This form is completed by the clinician throughout the time family members are active in the family support program.

• *Family Program Attendance Log.* The Family Program Attendance Log is used to record 6 pieces of information about each attempted session: session number, scheduled date, was the session rescheduled (yes/no), was the family member a no-show (yes/no), did the family member attend the session (yes/no), and comments. This form is completed by the clinician throughout the time family members are active in the family support program.

• *Family Program Case Review Report.* The Family Program Case Review Report contains multiple rows that allow a clinician to record information that allows the clinician and supervisor to monitor the progress of active cases. Areas asked about include: family program procedures delivered, date of last session, and weeks in family program. This form is completed by the clinician weekly throughout the time family members are active in the family support program.

• *Family Program Discharge Form.* The Family Program Discharge Form contains 9 fields to record the following information at the end of participation in the family program: caregiver name, today's date, adolescent name, notification date, clinician name, family program intake date, family program discharge date, reason for discharge, and number of completed sessions. This form is completed by the clinician each time family members of a given participant end involvement in the family support program.

• *Volunteer/Staff Survey—See Volunteer/Staff Survey (Project Coordinator)* above.

Support Services Supervisor

• *Adolescent Telephone Support Quality Assurance Checklist.* This checklist contains 43 items that ask the supervisor to rate how well a telephone support volunteer delivered required service components to adolescents. Volunteers are rated on a scale of 1 through 5 in the following areas: substance use since last call (no use), substance use since last call (use), substance use since last call (still using), substance use since last call (stopped using), attendance at 12-step meetings, recovery-related activities, activities related to global health, follow-up since last call, closing the call, overall, general clinical skills, and overall difficulty of session. This form is completed for each reviewed recording of a telephone session by a supervisor.

• *Social Networking Quality Assurance Checklist.* This checklist contains 17 items that ask the supervisor to rate how well a social networking site moderator delivered required service components to adolescents. The moderator is rated on a scale of 1 through 5 in the following areas: group discussions, administrative tasks, overall, and general skills. This form is completed for each review of the social networking site by a supervisor.

• *Family Program QA Checklist.* This checklist contains 72 items that ask the supervisor to rate how well a family program clinician delivered required service components to family members. The clinician is rated on a scale of 1 through 5 in the following areas: initial meeting motivational strategies, domestic violence precautions, functional analysis of substance use, positive communication skills, use of positive reinforcement, time out from positive reinforcement, allowing the identified patient to experience the natural consequences of substance use, helping concerned significant others' enrich their own lives, maintaining the identified patient in recovery-oriented systems of care, and general. This form is completed for each reviewed recording of a family session by a supervisor.

• *Volunteer/Staff Survey—See Volunteer/Staff Survey (Project Coordinator)* above.

The following table is a list of the hour burden of the information collection by form and by respondent:

DETAILED INFORMATION ON FORMS GROUPED BY RESPONDENT

Instrument/form	Number of respondents	Responses per respondent	Total responses	Hours per response	Total annualized hour burden per respondent*
Adolescent Participant					
GAIN–I 5.6.0 Full	200	1	200	2	2
GAIN–M90 5.6.0 Full	200	4	800	1	4
SAF	200	5	1000	.25	1.25
Subtotal	200		2000		7.25
Collateral (parent/guardian/concerned other) Participant					
Collateral–I	200	1	200	.25	.25
Collateral–M	200	4	800	.25	1
Collateral SAF	200	5	1000	.25	1.25
Self-Evaluation Questionnaire	200	5	1000	.16	.8
Family Environment Scale (Cohesion and Conflict Scales)	200	5	1000	.08	.4
Relationship Happiness Scale (Caregiver)	200	5	1000	.08	.4
Subtotal	200		5000		4.1
Project Coordinator:					
Eligibility Checklist	4	50	200	.25	12.5
Locator—Participant	4	50	200	.32	16
Locator—Collateral	4	50	200	.25	12.5
Follow-Up Contact Log	4	50	200	.16	8
Telephone Support Volunteer Notification Form	4	50	200	.16	8
Family Program Notification Form	4	50	200	.16	8
Volunteer/Staff Survey	4	1	4	.25	.25
Subtotal	4		1204		65.25
Telephone Support Volunteer:					
Telephone Support Case Review Form	8	450	3600	.25	112.5
Telephone Support Call Log	8	25	200	.16	4
Telephone Support Documentation Form	8	450	3600	.5	225
Telephone Support Discharge Form	8	25	200	.16	4
Volunteer/Staff Survey	8	1	8	.25	.25
Subtotal	8		7608		345.75
Social Network Site Moderator:					
Social Networking Moderator Log	1	52	52	.5	26
Volunteer/Staff Survey	1	1	1	.25	.25
Subtotal	1		53		26.25
Family Program Clinician:					
Family Program Progress Notes	4	650	2600	.16	104
Family Program Attendance Log	4	50	200	.08	4
Family Program Case Review Form	4	650	2600	.25	162.5
Family Program Discharge Form	4	50	200	.16	8
Volunteer/Staff Survey	4	1	4	.25	.25
Subtotal	4		5604		278.75
Support Services Supervisor:					
Telephone Support QA Checklist	1	12	12	1	12
Social Networking QA Checklist	1	12	12	.5	6
Family Program QA Checklist	1	12	12	1	12
Volunteer/Staff Survey	1	1	1	.25	.25
Subtotal	1		37		30.25
Total	418		21,506		757.6

ANNUALIZED SUMMARY TABLE

Respondents	Number of respondents	Total responses	Total annualized hour burden per respondent *
Adolescent	200	2000	7.25
Collateral	200	5000	4.1
Project Coordinator	4	1204	65.25
Telephone Support Volunteer	8	7608	345.75
Social Network Site Moderator	1	53	26.25
Family Program Clinician	4	5604	278.75
Support Services Supervisor	1	37	30.25
Total	418	21,506	757.6

* Total Annualized Hour Burden per Respondent = Responses per Respondent × Hours per.

Written comments and recommendations concerning the proposed information collection should be sent by December 7, 2009 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: October 30, 2009.

Elaine Parry,

Director, Office of Program Services.

[FR Doc. E9–26803 Filed 11–5–09; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0319]

Guidance for Industry and Food and Drug Administration Staff; In Vitro Diagnostic 2009 H1N1 Tests for Use in the 2009 H1N1 Emergency; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance entitled ''In Vitro Diagnostic 2009 H1N1 Tests for Use in the 2009 H1N1 Emergency.'' FDA is issuing this guidance to inform industry and agency staff of its recommendations for the type of information and data FDA believes needs to be included in an Emergency Use Authorization Request (EUA) for in vitro diagnostic (IVD) devices intended for use in diagnosing 2009 H1N1 Influenza virus infections during the emergency involving Swine Influenza A[1]. The Secretary of the Department of Health and Human Services (HHS) declared the emergency on April 26, 2009, in accordance with the Federal Food, Drug, and Cosmetics Act (the Act).

DATES: Submit written or electronic comments on this guidance at any time. General comments on agency guidelines are welcome at any time.

ADDRESSES: Submit written requests for single copies of the guidance document entitled ''In Vitro Diagnostic 2009 H1N1 Tests for Use in the 2009 H1N1 Emergency'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 4613, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your request, or fax your request to 301–847–8149. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments concerning this guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.regulations.gov*. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Sally Hojvat, Center for Devices and Radiological Health WO/66, rm. 5552, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–5455.

SUPPLEMENTARY INFORMATION:

I. Background

This guidance document provides recommendations on the types of information and data that FDA believes needs to be included in an Emergency Use Authorization Request (EUA) for in vitro diagnostic (IVD) devices intended for use in diagnosing 2009 H1N1 Influenza virus infections during the emergency involving Swine Influenza A. While FDA encourages the submission of premarket notifications (510(k)s) for all 2009 H1N1 tests, the agency is aware that during a declared emergency, it may not be possible for manufacturers of 2009 H1N1 tests to submit a 510(k) prior to distributing or offering a test. For example, during the initial phase of the emergency, positive clinical specimens may not be readily available for use in device evaluations. The identification of acute test capacity need may limit the ability to test the usual number of specimens needed for a 510(k). Additionally, appropriate validation specimens may not be available in certain areas at the time the test is needed. If manufacturers of 2009 H1N1 tests are unable to submit a premarket notification and there is a continued public health need for 2009 H1N1 tests during this declared emergency, manufacturers should submit an EUA request to FDA. Public participation is not feasible or appropriate since the agency must act immediately to protect the public health during the declared emergency concerning 2009 H1N1 Influenza. This guidance applies to 2009 H1N1 tests during the time that the declaration of emergency concerning 2009 H1N1 Influenza is in effect.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on *in vitro diagnostic 2009 H1N1 tests for use in the 2009 H1N1 emergency*. It does not create or confer any rights for or on any person and does not operate to bind FDA or the

[1] Swine Influenza A is now known as 2009 H1N1 Influenza (2009 H1N1).