document number 1558 to identify the guidance you are requesting.

CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved submissions, approved applications, and manufacturers' addresses), small manufacturer's assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH Web site may be accessed at *http://www.fda.gov/cdrh*. A search capability for all CDRH guidance documents is available at *http://www.fda.gov/cdrh/guidance.html*. Guidance documents are also available on the Division of Dockets Management Internet site at *http://www.fda.gov/ohrms/dockets*.

IV. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to the review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (the PRA) (44 U.S.C. 3501–3520). The collections of information addressed in the draft guidance document have been approved by OMB in accordance with the PRA under the regulations governing premarket notification submissions (21 CFR part 807, subpart E, OMB control number 0910–0120). The labeling provisions addressed in the guidance have been approved by OMB under OMB control number 0910–0485.

V. 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 comments 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.

Dated: October 19, 2006.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. E6–18318 Filed 10–30–06; 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: 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 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: Cross-Site Assessment of the Residential Treatment for Pregnant and Postpartum Women (PPW) and Their Children Program—(OMB No. 0930–0269)—Revision

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), is funding additional Services Grants for Residential Treatment for Pregnant and Postpartum Women (PPW). The purpose of the PPW is to expand the availability of comprehensive, high quality residential treatment services for pregnant and postpartum women who suffer from alcohol and other drug use problems, and for their infants and children impacted by the perinatal and environmental effects of maternal substance use and abuse.

Section 508 [290bb–1] of the Public Health Service Act mandates the evaluation and dissemination of findings of residential treatment programs for pregnant and postpartum women. This cross-site accountability assessment will assess project activities implemented for these services.

The grantees were brought to consensus surrounding an evaluation design and methods of data collection with accompanying instruments, via the work of the project officer and consultant experts in the field. The data collection instruments will be used for program and treatment planning, local evaluations, and for this cross-site accountability evaluation. For mothers, administration of data collection instruments will occur at intake, 6 months post-intake, discharge, and 4 months post-discharge.[1] The following four different interview instruments will be used for mothers:

1. Child Data Collection Tool, Part 1 (child's personal background) and Part 2 (child's medical background);
2. Ferrans and Powers Quality of Life Index© Generic Version—III;
3. BASIS–24® (pilot study used BASIS–32®)—behavioral health assessment; and
4. Allen Barriers to Treatment Instrument.

For all children under 18 years, program staff will collect information from observation, interview, and records review. For infants and children, data collection will occur at a time within 30 days of the mother's intake or the child's birth, 3 months post-intake/birth, 6 months post-intake/birth, discharge, and 4 months post-discharge.[1] Children's data collection tools include the following:

1. Child Well-Being Scales (staff observation and records review for all children);
2. Denver Developmental Screening Inventory II (ages 0 to 6 years, 0 days);
3. Middle Childhood Developmental Assessment Guide (ages 6 to 10);
4. Adolescent Childhood Development Assessment Guide (ages 11 to 17); and
5. CRAFFT substance abuse screening instrument (ages 11–17).

In addition, records review will be conducted by program staff on all program participants. First, at each data collection period except for 4 months post-discharge, staff will complete the Women's Medical Record Audit and the Child's Medical Record Audit (or the Newborn's Medical Record Audit at delivery.) Second, staff will complete the Women's Discharge Tool and the Children's Discharge Tool at discharge.

[1] The 4 month post-discharge administration replaces the 12-month post-admission administration approved by OMB for the pilot study. This modification was made because it is believed that post-discharge followup information will be more informative and will have more cases than 12 months post-admission.

All data will be collected using a combination of observation, records review, self-administered paper-and-pencil questionnaires, and personal interviews. CSAT will use this data for this evaluation to inform public policy, research, and programming as they relate to the provision of women's services. Data produced by this study will provide direction to the type of technical assistance that will be required by service providers of women's programming. In addition, the data will be used by individual grantees to support progress report efforts.

The following table shows the estimated annual response burden for this collection.

ESTIMATES OF BURDEN HOURS

Form name/type of administration	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
Women Interviews					
Child Data Collection Tool (Personal Interview)	963	4	3,852	0.75	2,889
Allen Barriers to Treatment Instrument (Self-administered paper & pencil).	963	4	3,852	0.28	1,091
Quality of Life Inventory (Self-administered paper & pencil).	963	4	3,852	0.25	963
BASIS–24 (Personal Interview)	963	4	3,852	0.17	642
Total for Women	963		15,408		5,585
Child Interviews/Observations					
Denver Developmental Screening Inventory II (ages 0m to 6y, 0m) (Personal Interview & Observation).	1,926	5	9,630	0.50	4,815
CRAFFT (ages 11–17) (Personal Interview)	1,225	5	6,125	0.17	1,021
Middle Childhood Developmental Guide (ages 6 to 10) (Personal Interview).	657	5	3,285	0.33	1,095
Adolescent Development Guide (ages 11 to 17) (Personal Interview).	1,225	5	6,125	0.33	2,042
Total for Children	3,852		25,165		8,973
Observation/Records Review by Staff at 8 Facilities					
Child Well-Being Scales (age 0–17) (Observation & Records Review).	8	3,852 X 5	19,260	0.33	6,420
Women's Medical Record Audit (Records Review)	8	963 X 3	2,889	0.25	722
Children's Medical Record Audit (Records Review)	8	2,812 X 1 (intake) 3,852 X 3 (follow-up)	14,368	0.25	3,592
Newborns' Medical Record Audit (Records Review)	8	1,040 X 1	1,040	0.08	87
Women's Discharge Tool (Records Review)	8	963 X 1	963	0.58	562
Children's Discharge Tool (Records Review)	8	3,852 X 1	3,852	0.58	2,247
Total for Staff:	8		42,372	2.08	13,630
3-Year Total	4,823		82,945		28,188
Average Annual	1,608		27,648		9,396

Note: For mothers, administration of data collection instruments will occur at: (1) Intake, (2) 6 months post-intake, (3) discharge, and (4) 4 months post-discharge. For the Child Data Collection Tool, each mother will respond for each of her estimated 4 children at intake only. For infants and children, data collection will occur at: (1) a time within 30 days of the mother's intake or the child's birth, (2) 3 months post-intake/birth, (3) 6 months post-intake/birth, (4) discharge, and (5) 4 months post-discharge. It is estimated that 27 percent (1,040) of the children (3,852) will be delivered while the woman is in the treatment facility. For these infants, the Newborn's Medical Record Audit will be completed at delivery, and the Children's Medical Record Audit will be completed at 3 months post-admission, 6 months post-admission, and at discharge.

Send comments to Summer King, SAMHSA Reports Clearance Officer, Room 7–1044, 1 Choke Cherry Road, Rockville, MD 20850. Written comments should be received by January 2, 2007.

Dated: October 4, 2006.

Elaine Parry,

Acting Director, Office of Program Services.

[FR Doc. E6–18266 Filed 10–30–06; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[USCG–2006–26114]

National Boating Safety Activities: Funding for National Nonprofit Public Service Organizations

AGENCY: Coast Guard, DHS.

ACTION: Notice of funds availability.

SUMMARY: The Coast Guard seeks applications for fiscal year 2007 grants and cooperative agreements from national, nongovernmental, nonprofit public service organizations. The Boating Safety Financial Assistance Program is listed in section 97.012 of the Catalog of Federal Domestic