

and Availability provides advice to the Secretary and the Assistant Secretary for Health on a range of policy issues that includes (1) definition of public health parameters around safety and availability of the blood supply and blood products, (2) broad public health, ethical and legal issues related to transfusion and transplantation safety, and (3) the implications for safety and the availability of various economic factors affecting product cost and supply.

In keeping with its established mission, the ACBSA will be asked to review and comment on previous ACBSA recommendations including elements of a strategic plan for transfusion and transplantation safety. The review is intended to align the transfusion and transplantation safety initiatives to the Secretary's Strategic Initiatives and Key Inter-Agency Collaborations: (<http://www.hhs.gov/secretary/about/secretarialstrategicinitiatives2010.pdf>).

The Committee will also be asked to comment and make recommendations on prioritizing previous and outstanding recommendations in light of the Assistant Secretary for Health's mission statement: "Mobilizing Leadership in Science and Prevention for a Healthier Nation" and strategic priorities: Creating Better Systems of Prevention; Eliminating Health Disparities and Achieving Health Equity; and Making Healthy People Come Alive for all Americans.

The public will have opportunity to present their views to the Committee on both meeting days. A public comment session has been scheduled for November 5, 2010. Comments will be limited to five minutes per speaker and must be pertinent to the discussion. Pre-registration is required for participation in the public comment session. Any member of the public who would like to participate in this session is encouraged to contact the Executive Secretary at his/her earliest convenience to register for time (limited to 5 minutes) and registration must be prior to close of business on November 3, 2010. It is requested that those who wish to have printed material distributed to the Committee provide thirty (30) copies of the document to the Executive Secretary, ACBSA, prior to close of business on November 3, 2010. If it is not possible to provide 30 copies of the material to be distributed, then individuals are requested to provide at a minimum one (1) copy of the document(s) to be distributed prior to the close of business on November 3, 2010. It also is requested that any member of the public who wishes to

provide comments to the Committee utilizing electronic data projection submit the necessary material to the Executive Secretary prior to close of business on November 3, 2010. Electronic comments must adhere to disability accessibility guidelines (Section 508 compliance).

Dated: September 28, 2010.

Richard A. Henry,

Deputy Executive Secretary, Advisory Committee on Blood Safety and Availability.

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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.

Proposed Project: Evaluation of Pregnant and Postpartum Women (PPW) Program

The Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Substance Abuse Treatment (CSAT), is funding 11 fiscal year (FY) 2009 Services Grants for the Residential Treatment for Pregnant and Postpartum Women (PPW) Program. The purpose of the PPW Program is to provide cost-effective, comprehensive, 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.

CSAT is requesting approval for a total of 8,404 burden hours for this new data collection. CSAT is requesting approval for a total of 23 instruments. Of these 23 instruments, 18 instruments are client-level tools and 5 instruments

are process-level tools. To examine the effectiveness and impact of the PPW program, the current design includes both client-level outcomes and process evaluation components. The purpose of the outcome evaluation component is to examine the extent to which grantees accomplish the five core goals specified by the PPW program request for applications (RFA). These goals include:

- Decrease the use and/or abuse of prescription drugs, alcohol, tobacco, illicit and other harmful drugs (e.g., inhalants) among pregnant and postpartum women;
- Increase safe and healthy pregnancies; improve birth outcomes; and reduce related effects of maternal drug abuse on infants and children;
- Improve the mental and physical health of the women and children;
- Improve family functioning, economic stability, and quality of life; and
- Decrease involvement in and exposure to crime, violence, sexual and physical abuse, and child abuse and neglect.

In order to help interpret client-level outcomes, the process evaluation will explore what grantees are actually doing, how well they are doing it, any challenges encountered, and strategies grantees used to address them.

Data collection instruments will be used to collect outcome and process data for this cross-site accountability evaluation, program and treatment planning, and local evaluations. For clients, data will be collected from women at four time points (intake, 6-months post-intake, discharge, and 6-months post-discharge), consistent with the GPR data collection schedule. The schedule for collecting child data is similar to the mothers, with the addition of a 3-month post-intake time point. The following interview instruments will be used for women, fathers/mother's partner, and children:

Women Focused Tools

- BASIS-24® (psychological symptomology).
- Child Abuse Potential Inventory (overall risk for child physical abuse).
- Ferrans and Powers Quality of Life Index (quality of life measure).
- Family Support Scale (helpfulness of sources of support to parents raising a young child).
- Women's Discharge Tool (services received, length of stay, treatment goals achieved).
- Staff Completed Women's Items (pregnancy status, problems and outcomes).
- Items Administered to Women (children residing with mother in

treatment, tobacco use, physical abuse and sexual abuse in the past year).

Father and Partner Focused Tools

- Ferrans and Powers Quality of Life Index (quality of life measure).

Child Focused Tools

- Brief Infant Toddler Social and Emotional Assessment (children 12–35 months; social and emotional assessment).
- Child Data Collection Tool (all children; descriptive biopsychosocial measure).
- Children's Discharge Tool (all children; services received, length of stay, treatment goals achieved, whether child lived in the facility).
- CRAFFT (children 11–17; adolescent substance use screen).
- Newborn's Medical Record Audit (children birth-3 months; birth outcomes).
- Parenting Relationship Questionnaire (children 2–17 years; parent's relationship with child).
- Parenting Stress Index (children 1 month–12 years; parenting stress).
- Social Skills Improvement System (children 3–17 years; social skills).
- Trauma Symptom Checklist for Young Children (3–12 years; trauma symptoms).
- Staff Completed Child Items (children 0–17; prematurity, child's recent primary residence, whether child will reside in treatment with mother).
- Staff Completed Newborn Items (children 0–3 months; prematurity, length of stay in hospital, neonatal

intensive care unit (NICU), and treatment for neonatal abstinence syndrome).

Note that all child focused tools are records reviews or administered as maternal interviews with the exception of CRAFFT, which is administered to the children directly.

Process Evaluation Tools

- Biannual Project Director Telephone Interview (interview with grantee project directors to clarify information reported in their biannual progress reports);
- Site Visit Protocol—Client Focus Group (focus groups with clients to gather information about their experience in the program);
- Site Visit Protocol—Clinical Director(s)/Supervisor(s) (interviews with both the director of clinical services for women and the director of clinical services for children to gather more specific information about clinical services);
- Site Visit Protocol—Counselor(s) (interviews with counselors to gather information related to daily treatment operations and their experience in providing services); and
- Site Visit Protocol—Program Director (interview with grantee program directors to gather information about overall PPW programmatic issues).

All data will be collected using a combination of observation, records review, questionnaires, and personal interviews. CSAT will use this data for

accountability reporting, and program monitoring 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 total annualized burden to respondents for all components of the PPW program is estimated to be 8,404 hours. Table A–1 presents a detailed breakdown of the annual burden for all data collection instruments for all respondents (*i.e.*, mother, child, project staff, partner/father (family members), medical staff, project director, clinical director, counselor, program director). The number of respondents for all child-focused tools is weighted, based on the percentage of children within the appropriate age bracket in the prior PPW evaluation. With the exception of the CRAFFT, all child-focused tools are completed for the child by the mother or project staff. The burden estimates, also summarized in Table A–2, are based on the reported experience of the 2006 cohort, proprietary instrument developer estimates and experience, pre-testing of the additional items completed by staff and administered to women, and pre-testing of process evaluation measures. There are no direct costs to respondents other than their time to participate.

TABLE A–1—DETAILED ANNUAL BURDEN FOR ALL INTERVIEWS & SURVEYS

Interviews and surveys	Respondent	Number of respondents ¹	Responses per respondent	Total responses	Burden per resp. (hrs.)	Total burden (hrs.)
Child Focused Interviews:						
CRAFFT (11–17 yrs) ²	Child	70	5	350	0.08	28
Brief Infant Toddler Social and Emotional Assessment (12–35 mos) ³	Mother	141	5	705	0.17	120
Child Data Collection Tool (0–17 yrs) ⁴	Mother	440	2	880	0.75	660
Parenting Relationship Questionnaire (2–17 yrs) ⁵	Mother	387	5	1,935	0.25	484
Parenting Stress Index (1 month–12 yrs) ⁶	Mother	418	10	4,180	0.5	2,090
Social Skills Improvement System (3–17 yrs) ⁷	Mother	326	5	1,630	0.42	685
Trauma Symptom Checklist for Young Children (3–12 yrs) ⁸	Mother	290	5	1,450	0.33	479
Women Focused Interviews:						
BASIS–24 [®]	Mother	440	4	1,760	0.25	440
Child Abuse Potential Inventory	Mother	440	4	1,760	0.33	581
Family Support Scale	Mother	440	4	1,760	0.17	299
Ferrans and Powers Quality of Life Index (Women)	Mother	440	4	1,760	0.17	299
Items Administered to Women ...	Mother	440	4	1,760	0.17	299
Partners/Fathers Interview:						

TABLE A-1—DETAILED ANNUAL BURDEN FOR ALL INTERVIEWS & SURVEYS—Continued

Interviews and surveys	Respondent	Number of respondents ¹	Responses per respondent	Total responses	Burden per resp. (hrs.)	Total burden (hrs.)
Ferrans and Powers Quality of Life Index (Partners). Staff Completed Items/Record Reviews at 11 Facilities:	Partner/Father	110	2	220	0.17	37
Children's Discharge Tool (0-17 yrs) ⁹ .	Project Staff	11	80	880	0.58	510
Women's Discharge Tool	Project Staff	11	40	440	0.58	255
Newborn's Medical Record Audit (0-3 mos) ¹⁰ .	Medical Staff	11	25	275	0.08	22
Staff Completed Newborn Items	Medical Staff	11	25	275	0.25	69
Staff Completed Child Items (0-17 yrs) ¹¹ .	Project Staff	11	400	4,400	0.08	352
Staff Completed Women's Items ¹² .	Project Staff	11	160	1,760	0.17	299
Process Evaluation:						
Biannual Project Director Telephone Interview.	Project Director	11	2	22	1	22
Site Visit Protocol—Client Focus Group ¹³ .	Mother	176	1	176	1.5	264
Site Visit Protocol—Clinical Director/Supervisor.	Clinical Director/Supervisor.	22	1	22	2	44
Site Visit Protocol—Counselor(s)	Counselor	33	1	33	1	33
Site Visit Protocol—Program Director.	Program Director	11	1	11	3	33
Total	4,701	28,444	8,404

¹ Data will be collected from women at four time points (intake, 6-months post-intake, discharge, and 6-months post-discharge), consistent with the GPRA data collection schedule. Figures in this table are based on 40 mothers per site with 2 children and 0.25 father/partner per mother. The schedule for collecting child data is similar to the mother's with the addition of a 3-months post-intake time point with selected tools for a total of five time points. All child focused tools are completed by the mother or project staff, with the exception of CRAFFT. For fathers and partners, data will be collected at two points (intake and discharge).

² Based on 8% of 880 minor children ages 11 to 17 at intake, 3 months, 6 months, discharge, and 6-months post-discharge.

³ Based on 16% of 880 minor children ages 12-35 months at intake, 3 months, 6 months, discharge, and 6-months post-discharge.

⁴ Based on 440 mothers having 2 minor children at intake and/or delivery.

⁵ Based on 44% of 880 minor children ages 2 to 17 at intake, 3 months, 6 months, discharge, and 6-months post-discharge.

⁶ Based on 95% of 880 minor children ages 1 month to 12 years (n = 836). For simplicity, this calculation assumes that 95% of mothers have two children in this age group and complete the tool for each child at intake, 3 months, 6 months, discharge, and 6-months post-discharge.

⁷ Based on 37% of 880 minor children ages 3 to 17 at intake, 3 months, 6 months, discharge, and 6-months post-discharge.

⁸ Based on 33% of 880 minor children ages 3 to 12 at intake, 3 months, 6 months, discharge, and 6-months post-discharge.

⁹ Based on 1 staff member at each of the 11 programs completing the tool for 80 children at discharge.

¹⁰ Based on 31% of 880 minor children ages 0-3 months at intake or delivery.

¹¹ Based on 80 minor children per site ages 0 to 17 at intake, 3 months, 6 months, discharge, and 6-months post-discharge.

¹² Based on 1 staff member at each of the 11 programs completing items for 40 women at intake, 6 months, discharge, and 6-months post-discharge.

¹³ Based on 2 focus groups with 8 mothers at each site.

TABLE A-2—SUMMARY TOTAL ANNUAL RESPONDENT BURDEN

Respondent	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
Mothers	440	19,756	6,700
Partners/Fathers	110	220	37
Children (11-17 yrs)	70	350	28
Medical Staff	11	550	91
Project Staff	11	7,480	1,416
Project Director	11	22	22
Clinical Director/Supervisor	22	22	44
Counselor	33	33	33
Program Director	11	11	33
Total	719	28,444	8,404

Note: Total number of respondents represents the number of each type of respondent that will be completing at least one tool across eleven sites over one year of data collection. The number of respondents

(719) reported on this table differs from Table A-1 total number of respondents (4,701) which reflects completion of all tools across eleven sites over one year of data collection.

Written comments and recommendations concerning the proposed information collection should be sent by November 3, 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: 202-395-7285.

Dated: September 28, 2010.

Elaine Parry,

Director, Office of Management, Technology and Operations.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

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

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Project: Assessment of the Underage Drinking Prevention Education Initiatives State Videos Project—New

The Substance Abuse and Mental Health Services Administration's Center for Substance Abuse Prevention (CSAP) is requesting Office of Management and Budget (OMB) approval of three new data collection instruments—

- State Video Contacts Form.
- Video Viewers Form.
- Dissemination Update Online Form.

This new information collection is for the assessment of the 2010-2013 Underage Drinking Prevention Education Initiatives State Videos project. In 2007, four States participated in a pilot study to produce videos on the topic of underage drinking prevention. Based upon the success of those videos, 10 additional States and 1 Territory were provided funds to produce videos in 2009. Contingent on available funds, CSAP hopes to invite approximately 10 States/Territories per year to produce their own videos.

Over the next 4 years, CSAP will conduct a process and outcome assessment of this project. The process assessment will focus on the experiences associated with planning and producing the State videos. The

outcome assessment will examine the effectiveness of the State Videos project in meeting the core project objectives and will capture the State's dissemination efforts. The process and outcome assessments will encompass State videos that will be produced in 2010-2013 and those that were produced in 2007 and 2009. State contacts will be asked to update their dissemination information online if there have been changes in these figures during the previous 6 months, up through 2013. Additionally, data will be collected from viewers of the State videos using an online survey.

The information will be collected from the primary contact employee designated by the States that have agreed to participate in the production of a video for the State Videos project. The viewers' information will be collected from those who voluntarily decide to complete a short survey after seeing the video.

SAMHSA/CSAP intends to support annual videos on State underage drinking prevention videos. The information collected will be used by CSAP to help plan for these annual video productions and provide technical assistance to the participating States. The collected information will also provide a descriptive picture of the initiative, indicate how the videos have been received, and highlight some factors that may be associated with successful dissemination outcomes.

The information needs to be obtained using a combination of initial telephone interviews to collect process data, followed by online forms to collect outcome and dissemination data. A survey of viewers, collected online, will also be used to assess the effectiveness of the State videos in increasing awareness of the underage drinking prevention activities in these States. This information collection is being implemented under authority of Section 501(d)(4) of the Public Health Service Act (42 U.S.C. 290aa).

State staff members will be contacted once the video has been finalized. These State staff members will be asked to complete a short telephone interview that asks questions about the process of producing the State video. The State Video Contacts Form includes nine items about the State video, including:

- State's objectives for the video on underage drinking prevention.
- Targeted audiences.
- Satisfaction with technical assistance (TA) received.
- Usefulness of preplanning materials.
- Helpfulness of TA during different phases of production.

- Recommendations for improving the process.
- Recommendations for improving the content of the video.
- Advice to other States interested in producing a video.

If the State has disseminated the video at the time of the initial telephone interview, then they will also be asked to complete the second part of the State Video Contacts Form, which collects information on dissemination outcomes. The State Video Contacts Form includes 19 items about the dissemination activities of the State's video, including:

- Time when they disseminated the video.
- Methods of dissemination.
- Number of people who viewed the video.
- Number of DVDs and videotapes requested.
- Effectiveness of the dissemination methods.
- Factors that contributed to the effectiveness of dissemination.
- Effect of TA received.
- Effect of the video in raising awareness about underage drinking prevention successes in the State.
- Effect of the video in raising awareness about underage drinking prevention challenges in the State.
- Effectiveness of the video in presenting State's/Territory's prevention activities.
- Feedback received.
- Unintended positive outcomes.
- Effect of TA in improving the capacity to provide effective prevention services.

After the State points of contact have completed the State Video Contacts Form online, they will be requested to update dissemination activities online if there have been any changes during the past 6 months. This form includes seven items, including:

- If there have been changes in dissemination during the past 6 months.
- Most recent dissemination numbers by method.
- Facilitation factors.
- Additional feedback.
- Additional unintended positive outcomes.

Data will also be collected from viewers of the State videos. Each State video will include instructions to viewers on how to access the Video Viewers Form. The instructions may be a unique URL, or they may consist of instructions on each State's Web site on underage drinking prevention. This information will allow the CSAP to provide feedback to the States on their video and to measure the effectiveness of their video. The Video Viewers Form includes 24 items about the video, including: