

MEASURES OF CO-OCCURRING INFRASTRUCTURE (MCI) SUPPORTING STATEMENT

A. JUSTIFICATION

1. *Circumstances of Information Collection*

The Substance Abuse Mental Health Services Administration's (SAMHSA) Center for Mental Health Services (CMHS) and the Center for Substance Abuse Treatment (CSAT) request Office of Management and Budget (OMB) approval to implement Measures of Co-occurring Infrastructure (MCI) for States receiving Co-Occurring State Infrastructure Grants (COSIG). Implementing services for persons with co-occurring mental and substance use disorders is a SAMHSA priority, and a central part of SAMHSA's overall performance measurement efforts is the development of a set of measures specific to this population.

The COSIG program is authorized under Sections 509 and 520 A of the Public Health Services act, as amended.

The Government Performance and Results Act (GPRA) of 1993 required Federal agencies to identify the goals of all funded programs and required reports on the program's success in attaining those goals. Section 1115 of the Act, Performance Plans, states: "In carrying out the provisions of section 1105(a)(29), each agency is required to prepare an annual performance plan covering each program activity. Such a plan shall:

- "Establish performance goals to define the level of performance to be achieved by a program activity;
- "Express such goals in an objective, quantifiable, and measurable form unless authorized to be in an alternative form under subsection (b);
- "Briefly describe the operational processes, skills and technology, and the human, capital, information, or other resources required to meet the performance goals;
- "Establish performance indicators to be used in measuring or assessing the relevant outputs, service levels, and outcomes of each program activity;
- "Provide a basis for comparing actual program results with the established performance goals; and
- "Describe the means to be used to verify and validate measured values."

Furthermore, in its reauthorization of the Substance Abuse and Mental Health Services Administration (SAMHSA) under the Children's Health Act of 2000 (PL 106 310), Congress called on SAMHSA to collaborate with the States and other interested stakeholders to develop a plan "for creating more flexibility for States and accountability

based on outcome and other performance measures.” Performance and outcome measures will reduce State and community reporting requirements while simultaneously presenting useful and reliable information to SAMHSA, Congress, and to other key stakeholders about the effectiveness of SAMHSA’s services and how the services are being applied across the country. Specifically, MCI will include performance measures to assess the extent to which SAMHSA’s COSIG grantees are providing screening, assessment, and treatment services to clients entering substance abuse and mental health facilities.

History of the Proposed Project

Section 3403 of the Public Law 106-310 – Children’s Health Act of 2000 (CHA) contained the requirements that SAMHSA: (1) change the Block Grants into performance-based systems, and (2) submit to Congress within two years a plan for what these performance based programs would look like and how they would operate. This plan would describe how the States would receive greater flexibility, what performance measures would be used to hold States accountable including the requirement that measures be developed for some specific populations including co-occurring populations, definitions for the data elements to be collected, the funds needed to implement this system, where these funds would come from, and needed legislative changes. In partnership with the National Association of State Alcohol and Drug Abuse Directors (NASADAD) and National Association of State Mental Health Program Directors (NASMHPD), SAMHSA began to develop an approach to measuring of co-occurring services infrastructure. In November 2002, a Technical Workgroup comprising representatives from NASMHPD, NASADAD, CSAT, and CMHS developed three performance concepts to support SAMHSA’s emergent activities related to co-occurring mental health and substance abuse disorders. The specific measures proposed for MCI derived from this workgroup and were developed with extensive input from the first cohort of seven COSIG States. The Technical Workgroup’s efforts to develop performance measures occurred in parallel with the development COSIG, a SAMHSA discretionary program that awards grants to States to support activities to reduce barriers to care, and improve treatment services for persons suffering from co-occurring disorders. The COSIG program implemented principles established in SAMHSA’s 2002 Report to Congress on Co-Occurring Disorders, a report required by section 3406 of CHA. In that report, SAMHSA established the following performance measures for services to persons with co-occurring disorders.

- Increase the number of persons with co-occurring disorders served
- Increase the percentage of treatment programs that
 - a) Screen for co-occurring disorders;
 - b) Assess for co-occurring disorders; and
 - c) Treat co-occurring disorders through collaborative, consultative, and integrated models of care.

The COSIG Request for Applications (RFA), released in 2003, 2004, 2005, and 2006, emphasized these goals and SAMHSA’s focus on appropriate screening, assessment, and coordinated treatment for persons with co-occurring disorders. The measurement

approach developed through the processes described will enable SAMHSA to assess the practices and policies of providers of mental health and substance abuse services for screening and assessing clients for co-occurring disorders, and the providers' approach to service delivery for persons with co-occurring disorders.

2. *Purpose and Use of Information*

A major focus of SAMHSA's COSIG program is increasing the number of substance abuse and mental health treatment programs that screen and assess for co-occurring disorders, and provide appropriate treatment for persons found to have such disorders. The proposed measures will enable SAMHSA to monitor program performance by COSIG grantees. To implement the performance measures, SAMHSA developed a set of instruments to collect data on providers' practices and policy for screening, assessment, and treatment of co-occurring disorders. Data will be collected from participating treatment providers within the 15 current COSIG States (i.e., Alaska, Arizona, Arkansas, Connecticut, the District of Columbia, Hawaii, Louisiana, Maine, Missouri, New México, Oklahoma, Pennsylvania, Texas, Vermont, and Virginia), and in States receiving future COSIG awards. SAMHSA expects to make two new COSIG awards in 2006, and may make additional awards subsequent years.

The measures are *not part of* SAMHSA's National Outcomes Measures (NOMs). As NOMs are adopted by SAMHSA, COSIG grantees will also report client-level outcome data for persons served in COSIG provider sites.

The instruments contain two components:

- Domain 1: Screening, Assessment, and Treatment: Assesses provider practices for screening, assessment, and treatment of clients with co-occurring substance abuse and mental disorders;
- Domain 2: Facility Policy on Screening, Assessment, Referral, and Treatment.

3. *Use of Information Technology*

Data for both Domains 1 and 2 will be collected at the level of the treatment facility. COSIG States are allowed to involve any number of treatment facilities within the State in their COSIG program. Only these facilities will collect and report data for the domains. Identified facilities will report to the State aggregate numbers of screening, assessment, and treatment practices for that facility during the reporting period, and the facilities policies on screening, assessment, and treatment. States will collect the information from the providers and report data to SAMHSA.

Domain 1 (number of persons screened and assessed, and types of treatment perceived by persons with co-occurring disorders) requires a treatment provider to track services for

individual clients. The provider must record whether each client was screened and assessed during a defined period following admission, and the treatment disposition for those clients found to have co-occurring disorders. Some COSIG States, (e.g., Alaska and Texas) are likely to use existing automated State substance abuse and mental health database systems to extract the requested data. Most providers in most States will need to implement tracking procedures to obtain information necessary to complete the MCI questionnaire.

Domain 2 requires only yes/no statements about provider policy and can readily be completed by providers.

The monitoring tools will be available in Word and Excel for respondents who wish to use one of these formats.

4. Efforts to Identify Duplication

The Measures of Co-Occurring Infrastructure are unique in that they constitute SAMHSA's first and only systematic data collection to measure infrastructure for serving persons with co-occurring disorders. Domain 1 counts the number of clients/patients screened, assessed, and treated for co-occurring disorders. No other SAMHSA data collection program is able to identify information about the performance of State and local facilities in screening, assessing, and treating co-occurring disorders or about the number of clients/patients with co-occurring disorders screened, assessed, and treated. Domain 2 obtains information from treatment facilities on their policies on screening, assessment, referral, and treatment.

5. Involvement of Small Entities

The data collection instrument has been designed by consensus among the COSIG States to minimize appropriate response burden. Small businesses are not significantly impacted by the requirements.

6. Consequences If Information Collected Less Frequently

The proposed data have not been collected before and will become a continuing effort. The collected information will provide SAMHSA with data necessary to monitor performance of COSIG States in fulfilling SAMHSA's goal of increasing the number of providers that screen and assess for co-occurring disorders, and that provide appropriate treatment for persons with co-occurring disorders.

Data collection will be ongoing at the provider level, with annual reporting from COSIG States to SAMHSA.

7. *Consistency With the Guidelines in 5 CFR 1320.5(d)(2)*

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2).

8. *Consultation Outside the Agency*

In addition, the following individuals developed or reviewed and commented on the development of the measures:

Ron Kessler, Ph.D.	Professor of Healthcare Policy Harvard Medical School, Boston, MA	617 432-3587
Fred Osher, M.D	Center for Behavioral Health, Justice, and Public Policy, University of Maryland Medical School, Baltimore, MD	410 646-3511
Stanley Sacks, Ph.D.	Director, Center for Integration of Research and Practice, National Development & Research Institutes, New York, NY	212 845-4429
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Yoku Shaw-Taylor, Ph.D.	Research Scientist, NORC	202 429-1954

A Federal Register notice was published on May 4, 2006 (vol. 71 no. 86, p. 26382) soliciting public comments on the information collection. Four comments were received in response to the Notice. The entire responses are presented in Attachment B.

1. *Sterling Deal*, the Virginia COSIG Project Director's, main point is that "the data to be collected are not consistent with either assessing the State's actual infrastructure development, does not acknowledge the need to collect the information through counties or community service boards, and requests information at the program level that is beyond the core universal developmental activities that COSIG is designated to promote in State infrastructure."

SAMHSA Response: Screening, assessment, and appropriate treatment *are* core universal developmental activities under COSIG. Measures were developed with input from the first cohort of seven COSIG States. States will be required to collect information only from those provider agencies they have chosen to be part of their COSIG program.

2. *Jeffrey Shelton*, Mental Health/Substance Abuse Administrator, Chesapeake Community Services Board, Chesapeake, Virginia, asks several technical questions about the MCI questionnaire, the most substantive of which is whether screenings will be done in clients homes.

SAMHSA Response: The proposed data collection protocol is an approach to collecting information about provider practice. It does not prescribe practice. The location at which screening or assessment may occur is irrelevant so long as the services are provided as part of the facility's client services.

3. *Robert Primrose*, COSIG Project Director in the Commonwealth of Pennsylvania, has several questions: (1) is the data request for all clients who enter treatment or only those with co-occurring disorders? SAMHSA Response: The data to be collected is for all clients seen, not only those who enter a treatment regimen. (2) The State has integrated mental health and substance abuse and it is not clear which choice should be selected on the form. SAMHSA Response: The category "integrated mental health and substance abuse co-occurring program will clarify the instructions if necessary. (3) These data are not currently collected and will create a burden. SAMHSA Response: Eleven States were involved in the development of the instrument. SAMHSA believes that it has struck a appropriate balance between the Federal government's need for data to monitor and manage its programs and the need to control the response burden. (4) The purpose of the requirement is unclear. SAMHSA Response: As stated in the *Federal Register* of May 4, SAMHSA's goals for the COSIG program are to: (a) increase percentage of treatment programs that screen for co-occurring disorders; (b) increase percentage of treatment programs that assess for co-occurring disorders; (c) increase percentage of treatment programs that treat co-occurring disorders through collaborative, consultative, and integrated models of care; (d) increase the number of persons with co-occurring disorders served. The proposed measures are intended to provide data about these goals.

4. *Christine Cline and Kenneth Minkoff*, the President and Senior Systems Consultant, of ZiaLogic make several points: (1) the process of State data collection is defined outside of SAMHSA's partnership with the States and intermediary entities (e.g., counties, community service boards). SAMHSA Response: Only those provider sites that are part of a State's COSIG program are required to provide the proposed data. (2) The authors' goal is universality of "co-occurring disorder capability;" the authors do not agree with the data form's separation into mental health, substance abuse, and integrated mental health and substance abuse disorders. They also prefer process questions such as "how does the State communicate with its intermediaries or programs the following question, and how does it retrieve the information that is responsive to the question?" SAMHSA Response: The proposed measures, developed in consultation with NASADAD, NASMHPD, and the first cohort of COSIG grantees, specifically address SAMHSA's goals for screening and assessing for co-occurring disorders, and for providing appropriate services to persons with co-occurring disorders. These goals are explicitly stated in the COSIG RFA. (3) The definitions are not fully consistent with what is happening in the field, and not fully aligned with definitions that have been already developed and articulated by COCE." SAMHSA Response: The definitions

used are the same ones used by SAMHSA’s Co-Occurring Center of Excellence (COCE), In fact, definitions in the recent COCE publication, “Overview Paper Number 1: Definitions and Terms Related to Co-Occurring Disorders” (available at www.coce.samhsa.gov) contain language developed specifically for the proposed measures. (4) The authors suggest that the States be asked another set of questions with detailed questions to substitute for the ones in the proposed questionnaire. SAMHSA Response: The posed questions are interesting, and several ask for the same information but at a county and program level, not the facility level. However, because the purpose of the proposed measures is to obtain information useful to SAMHSA in monitoring progress toward COSIG goals, it is fully appropriate and necessary to collect data from those providers participating in a State’s COSIG program.

9. *Payment to Respondents*

Respondents will receive no payment or gifts.

10. *Assurance of Confidentiality*

Data collection will be at the treatment facility level, and addresses provider-level policy and practice. Domain 2 applies only to provider policy. Domain one addresses provider services delivered to clients. No information will be collected from clients or about clients other than services received. Information will be aggregated at the provider level and forwarded to States with no client-identifying information, and no client-identifying information will be sent to SAMHSA.

Legal Protections:

The data collection will conform to all requirements of the Privacy Act of 1974, under the System of Records: Alcohol, Drug Abuse and Mental Health Epidemiologic and Biometric Research Data, HHS/ADAMHA/OA, #09-30-0036.

The 42 Code of Federal Regulations, Part 2, applies to all drug and alcohol treatment programs. It makes all records and data confidential. Such data cannot be released except:

- With patient consent
- To medical personnel in a medical emergency
- To a court in compliance with a court order
- For research or audit

It is pursuant to these regulations that interviewers become subject to fines up to \$500 for the first violation of confidentiality and fines of up to \$5,000 for each subsequent offence (2.1 Sec 408(f), 2.2 Sec 33(f)).

11. Questions of a Sensitive Nature

The collection of information about provider service practices is essential to the implementation of an effective monitoring system for COSIG grants. *There are no questions about sensitive individual behavior*, only questions about the process and structure of treatment. Procedures described above will ensure protection of all data and of individual rights.

12. Estimates of Annualized Hour Burden

SAMHSA will collect information from 242 current providers participating in their States' COSIG programs. Additional COSIG States and providers will be added in future years.

Data collection instruments are included in Attachment A.

The instruments were designed to collect the necessary information with as minimal burden to States and respondents as possible. An estimate of the annual collection burden on participants is presented in the table below. SAMHSA bases this estimate partially on information provided by potential respondents.

Estimate of Annual Cost Burden to Respondents

Data Collection	Number of Respondents	Hours Per Response	Total Burden Hours	Hour Wage	Total Hour Cost
Capacity to Screen, Assess and Treat	242	4.5 hours	1,089	\$14.32	\$15,594
Measure 2: Policy on Screening, Assessment, Referral, and Treatment	242	3 minutes	12	\$14.32	\$172
Total	242		1,101		\$15,766

Total Annual Burden Hours: 1,101

13. Estimates of Annualized Cost Burden to Respondents

There are no capital and/or maintenance costs to respondents.

14. *Estimates of Annualized Cost to the Government*

The total cost to the government for activities directly related to this data collection is estimated to be \$17,000.

15. *Changes in Burden*

This is a new collection of information.

16. *Time Schedule, Publication and Analysis Plans*

This section contains plans for the study, including the time schedule, discussion of reports, and analysis planned

Time Schedule

The following schedule is expected:

TASKS	APPROXIMATE COMPLETION
OMB clearance anticipated	October, 2006
Pre-collection meeting with COSIG representatives	One month after OMB approval
Start data collection	Two months after OMB approval
States submit data to SAMHSA	12 months after OMB approval
SAMHSA compiles State data	13 months after OMB approval
SAMHSA prepares report	14 months after OMB approval

Reports

Within 2 months of State data submission, SAMHSA will compile and analyze data submitted by States, and will produce an annual report addressing each of the key issues.

Analysis

SAMHSA will analyze the utility and completeness of the data collected and then will prepare a final report summarizing the results. SAMHSA will also analyze the data collected to develop a baseline to assess changes over time. The essential analysis will enable reporting on the following.

1. Percentage of clients screened for co-occurring disorders;
2. Percentage screened who were 'positive;'
3. Percentage clients with positive screens who were assessed;
4. Percentage assessed determined to have co-occurring disorders; and
5. Treatment model for persons with co-occurring disorders.

These figures will be available at the facility level, at the State level, and at the COSIG program level. Because primary data will be submitted at the facility level, the data will enable SAMHSA to identify the number of treatment programs that screen, assess, and provide appropriate treatment for persons with co-occurring disorders. Because each provider will report the number of persons identified as having co-occurring disorders and their treatment dispositions, SAMHSA will be able to identify the number of persons with such disorders that receive treatment. And because identical data will be obtained annually, SAMHSA will be able to track changes in all of these measures over time.

Useful additional comparisons include mental health facilities, substance abuse facilities, and facilities that provide both mental health and substance abuse services.

One manner to test data validation is to compare results, as feasible, to other existing data sets. One comparison of the performance measures with other treatment data will be conducted. The National Survey of Substance Abuse Treatment Services (N-SSATS) does allow comparison of the results of the study with the percentage of facilities that report the provision of assessment services. The analysis will be supplemented by a test of the utility of the monitoring tools by speaking with appropriate State and Federal staff to ensure that they meet the policy needs of the States, CSAT, and SAMHSA. Finally, SAMHSA can select a sample of reporting facilities and conduct an onsite test of external validity through an audit of cases.

17. Display of Expiration Date

The expiration date will be displayed.

18. Exceptions to Certification Statement

These activities will comply with requirements in 5 CFR 1320.9. Certificates are included in this package.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

1. Respondent Universe and Sampling Methods

To minimize response burden, SAMHSA will allow COSIG states to employ sampling procedures for both providers within a state and clients within a provider.

The current COSIG program consists of 15 States: Alaska, Arizona, Arkansas, Connecticut, the District of Columbia, Hawaii, Louisiana, Maine, Missouri, New Mexico, Oklahoma, Pennsylvania, Texas, Vermont, and Virginia. The States have included 269 providers in their COSIG program, and these providers serve, in the aggregate, over 211,000 clients annually. SAMHSA anticipates that new COSIG States will be added in future years, increasing the size of provider and client universes. Table 1 presents information about facilities and clients within the 15 current COSIG states.

Table 1: Providers and Clients within the 15 COSIG States.

State	Number of COSIG-affiliated facilities	Number of facilities with more than 30 clients in year	Number of facilities with more than 20 clients in year	Number of facilities with more than 20 clients admitted in last 30 days	Total clients per year
Alaska	74	49*	52*	N/A	8,764
Arizona	1	0	1	0	^N/A
Arkansas	33	33	33	26	79,253
Connecticut	2	2	2	2	2,814
District of Columbia	61§	26§	30§	N/A	6,248
Hawaii	3	3	3	2	1,118
Louisiana	20	20	20	20	16,916
Maine	3	3	3	3	11,018
Missouri	10	8	9	7	7,227
New Mexico	3	3	3	3	1,679
Oklahoma	15	15	15	12	16,542
Pennsylvania	14	5	10	2	552
Texas	9	9	9	6	6,225
Virginia	11	11‡	11‡	7	37,206
Vermont	10	10	10	8	15,502
TOTAL	269	197	211	98	211,064
* Alaska provided data for 57 of the 74 COSIG-affiliated facilities					
§ DC provided data for 50 of the 61 COSIG-affiliated facilities					
‡ Virginia provided data for 8 of the 11 COSIG-affiliated facilities					
^ Arizona's provider is a new program; no historical data					

The sampling strategy for both providers and for clients is the same. SAMHSA will randomly select a sample large enough to produce a 95% confidence interval with a margin of error of +/- 5%. Table 2 presents the sample size required for various size universes to achieve this criterion.

Table 2: Sample Size Table (Assuming a proportion=50% and desired 95% Confidence Interval of +/- 5%)¹

Universe	Sample	Universe	Sample	Universe	Sample
10	10	125	94	1,250	294
20	19	150	108	1,500	306
25	23	200	132	2,000	322
30	28	250	151	3,000	340
40	36	300	168	4,000	350
50	44	400	196	5,000	357
60	52	500	217	7,500	365
70	59	600	234	10,000	370
80	66	800	259	50,000	381
100	79	1,000	277	100,000	383

For instance, for a universe of 100, a random sample of 79 is sufficient for a 95% confidence interval +/- 5%.

Sampling Facilities. Step one of sampling will be selection of facilities. As seen in Table 1, the current universe of COSIG-affiliated programs is 269 distributed among 15 States. Twelve of the 15 States have fewer than 30 treatment facilities. As shown in Table 2, few facilities would be randomly deselected in states with 30 or fewer facilities, so in those states, all facilities will participate in data collection. In states with more than 30 facilities, SAMHSA will determine the exact number of facilities that must participate to reach the 95% confidence criterion, and randomly select from all facilities within the state those that must participate. This procedure will yield a total sample of 242 providers across the current 15 COSIG states, which is the number used in the burden table. States have the option of requiring all providers to participate. [Six percent of providers in the current COSIG States serve fewer than 20 clients annually, in the aggregate serving less than 0.3% of all clients. To avoid unstable counts at the facility level, SAMHSA may choose to exclude these small facilities from sampling.]

¹ The formula for determining sample can be presented as:
 $n^* = z^2 * p(1-p) / d^2$ and $n = n^* / (1 + N/n^*)$ with finite population correction, where:
 n^* = sample size when population size is large,
 n = sample size adjusted for small population size,
 N = population size,
 p = target proportion to be estimated,
 z = Normal distribution cutoff for a 95% confidence interval
 d = desired half-width of 95% confidence interval

Sampling Clients. Based on historical data, providers will estimate the number of clients to be served during the 12-month reporting period. Using Table 2, SAMHSA will provide to each provider the minimum number of clients that must be tracked for reporting purposes. Providers must collect appropriate data until the minimum number is reached. States may set higher requirements.

2. *Information Collection Procedures*

There are two domains:

- Domain 1: Screening, Assessment, and Treatment: Assesses provider practices for screening, assessment, and treatment of clients with co-occurring substance abuse and mental disorders;
- Domain 2: Facility Policy on Screening, Assessment, Referral, and Treatment.

Domain 1 requires a treatment provider to track services for individual clients. The provider must record whether each client was screened and assessed following admission, and the treatment disposition for those clients found to have co-occurring disorders. Some COSIG States, (e.g., Alaska and Texas) are likely to use existing automated State substance abuse and mental health database systems to extract the requested data. Most providers in most States will need to implement tracking procedures to obtain information necessary to complete the MCI questionnaire. Please note that the monitoring tools attached to this document are not client tracking forms, but a format for reporting aggregate information about screening, assessment, and treatment practices within a provider during a defined time period.

Domain 2 requires only yes/no statements about provider policy and can be readily completed by providers.

Each participating State will be asked to compile specific information regarding the two co-occurring measurement domains. Collection is expected to begin in the first quarter of 2007 and will continue through the duration of the COSIG program.

The data collection forms for this study have been designed via consensus by 7 participating COSIG States, four other States, and SAMHSA.

3. *Methods to Maximize Response Rates*

The data collection instruments have been developed to minimize the response burden and to increase the likelihood of response by the treatment facilities. Sampling procedures will further reduce burden on respondent providers. The State governments are required to provide this information as a term of the COSIG grant program, and will be responsible for requiring their participating COSIG providers to engage in the collection and reporting of data.

4. *Tests of Procedures*

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The original instrument was developed by a Task Force comprised comprising the Center for Mental Health Services (CMHS), the Center for Substance Abuse Treatment (CSAT), the National Association of State Alcohol and Drug Abuse Directors (NASADAD), and the National Association of State Mental Health Program Directors (NASMHPD). A workgroup with representatives from 11 States helped develop the data collection instruments and the procedures.

5. *Statistical Consultants*

The material has been reviewed by:

Sadeq Chowdhury, Ph.D.	Senior Statistician National Opinion Research Center at the University of Chicago (NORC)	202 223-1637
James M. Herrell, Ph.D., M.P.H.	Social Science Analyst Center for Substance Abuse Treatment (CSAT)	240 276-2789
Susan Hayashi, Ph.D.	Vice President JBS International	240 645-4588
Charlene Le Fauve, Ph.D.	Chief, Co-Occurring and Homeless Activities Branch, CSAT	240 276-2787
Lawrence Rickards, Ph.D.	Chief, Homeless Programs Branch, CMHS	240-276-1985
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Yoku Shaw-Taylor, Ph.D.	Research Scientist, NORC	202 429-1954

LIST OF ATTACHMENTS

- A. Instrument for OMB Review
- B. Comments received in response to FRN