SUPPORTING STATEMENT
MATERNAL AND CHILD HEALTH SERVICES BLOCK GRANT
APPLICATION/ANNUAL REPORT GUIDANCE

A. Justification

1. CIRCUMSTANCES MAKING THE COLLECTION OF INFORMATION NECESSARY

This submission is a request for Office of Management and Budget (OMB) approval of the revised Application/Annual Report Guidance that will be used by the 50 States and 9 jurisdictions eligible for State formula grants under the Maternal and Child Health (MCH) Services Block Grant, as authorized by Section 501 of Title V of the Social Security Act (the Act), PL 101-239. All sections of the Title V legislation can be viewed at: http://www.ssa.gov/OP_Home/ssact/title05/0500.htm. The expiration date for the current program Guidance (OMB No. 0915-0172) is January 31, 2015. This revised version contains two documents: 1) Instructions to the States on completing the required Application/Annual Report and Reporting Forms; and 2) Appendix of Supporting Documents, which includes background program information and other technical resources. (Attachment A) The Application and Annual Report fulfill the requirements of Section 505 and Section 506, respectively, of the Title V legislation.

Consistent with previous versions, this Guidance is designed to allow States flexibility in meeting the unique needs of their MCH populations while enabling the Maternal and Child Health Bureau (MCHB) to meet the Title V legislative requirements, to collect and utilize comparative data for addressing National and State MCH priorities, and to demonstrate accountability in the use of the Federal Title V funds. The MCHB, in the Health Resources and Services Administration (HRSA), serves as the Health and Human Services (HHS) Secretary's delegate to collect this information and to review it prior to the award of approximately $540 million annually in State formula grants under the MCH Block Grant program.

The attached Guidance represents a major transformative effort within the HRSA/MCHB, in conjunction with its State partners and other key stakeholders, to restructure the Application and Annual Reporting process. Proposed changes are intended to facilitate the increased alignment of State Title V program efforts with other MCHB investments and to demonstrate the vital leadership role that State Title V programs will play in assuring and advancing public health systems that can readily respond to changing MCH population needs. The aims of the MCH Block Grant to States program transformation are threefold: 1) reduce burden to States; 2) maintain State flexibility; and 3) improve accountability.

The MCH Block Grant is a formula grant under which funds are awarded to 59 States and jurisdictions upon their submission of an acceptable plan that addresses the health services needs within a State for the target population of mothers, infants and children, which includes children with special health care needs (CSHCN). Through this process,

each State and jurisdiction supports and promotes the development and coordination of systems of care for the MCH population, which are family-centered, community-based and culturally appropriate.

History

As one of the largest Federal block grant programs, Title V is a key source of support for promoting and improving the health of the Nation's mothers and children. The purpose of the Title V MCH Services Block Grant Program is to create Federal/State partnerships in all 59 States/jurisdictions that support service systems which address MCH needs, such as:

- Significantly reducing infant mortality;
- Providing comprehensive care for women before, during, and after pregnancy and childbirth;
- Providing preventive and primary care services for infants, children, and adolescents;
- Providing comprehensive care for children and adolescents with special health care needs;
- Immunizing all children;
- Reducing adolescent pregnancy;
- Putting into community practice national standards and guidelines for prenatal care, for healthy and safe child care, and for the health supervision of infants, children, and adolescents;
- Assuring access to care for all mothers and children; and
- Meeting the nutritional and developmental needs of mothers, children, and families.

The State health programs for mothers and children date to 1935, when these programs were first authorized under Title V of the original Social Security Act. In 1981, Title V was amended to create a single block grant program which consolidated seven related categorical health services programs for mothers and children into the MCH Services Block Grant. The Omnibus Budget Reconciliation Act (OBRA) of 1989 tightened accountability of funds expended under the MCH Block Grant program. Congress placed a 10 percent limit on administrative costs and mandated a minimum spending requirement of 30 percent for the following two categories: (1) children's preventive and primary health services and (2) services and service coordination for CSHCN. Special emphasis was placed on the provision of services for low-income individuals and the development of comprehensive plans for State systems of services, in accordance with a State's Five-year Needs Assessment findings. These efforts resulted in State goals and objectives that were consistent with the Nation's Healthy People 2000 objectives.

In 1993, the Government Performance and Results Act (GPRA), Public Law 103-62, was enacted which requires Federal agencies to establish measurable goals that are to be reported as part of the budgetary process. In linking funding decisions with performance, GPRA calls for Federal agencies to develop comprehensive strategic plans, annual performance plans which include measurable goals and objectives, and annual reports that compare actual performance with established performance goals. The Application/

Annual Report became the basis by which MCHB could meet its GPRA Block Grant to States program reporting requirements. Revisions to subsequent versions over the years have been based on changes in MCH priorities, the availability of new National data sources and a continuing effort within the MCHB to refine and streamline the Application/Annual Report preparation and submission process for States and jurisdictions.

Since its development in 2002, the Title V Information System (TVIS) has contributed to numerous efficiencies in the Application/Annual Report submission process. The TVIS is a Web-based system administered by HRSA's MCHB, which consists of two components: the Title V Block Grant Application/Annual Report Data Entry (used by State/jurisdictional Title V Block grantees to submit their financial, program, and performance data; and the TVIS Reports (a Web-based interface that allows public users to generate reports from Title V data.) Due to the substantial changes in the MCH Block Grant to States Program outlined in this revised Application/Annual Report Guidance, a new electronic data collection and web reports system will need to be designed, developed and deployed. This new TVIS data entry will be operational by April 1, 2015.

2. PURPOSE AND USE OF INFORMATION COLLECTION

The Application/Annual Report Guidance is used annually by the 50 States and nine jurisdictions in applying for Block Grants under Title V of the Social Security Act and in preparing the required Annual Report. Data requested in this revised version of the Application/Annual Report Guidance are necessary to assist States/jurisdictions in telling a more coherent and compelling story about the impact of their Title V programs, both within the State and nationally. These data further help to demonstrate the Title V program's return on investment in ensuring accountability for the ongoing monitoring of health status in women and children, in documenting the progress achieved relative to established National and State performance measure targets and in supporting an effective public health system for the Nation's MCH population.

This version of the MCH Block Grant Application/Annual Report Guidance builds on the performance partnership approach that exists between the MCHB and State Title V agencies. Since May 2013, and in partnership with the State Title V leadership and other national MCH leaders and stakeholders, the MCHB has been engaged in an effort to develop and refine a common vision for transforming the MCH Block Grant to States Program. The changes in the Nation's public health and health care financing systems, MCH population demographics and information technology capabilities provide an opportune time for re-examining the current structure of the MCH Block Grant to States Program and for identifying improvements, new efficiencies and innovations to advance the program in meeting future MCH population needs.

Consistent with the block grant concept, the attached revised Guidance retains the rights of States to determine their own MCH priority needs, to develop tailored strategies for addressing the identified needs and to assume accountability in achieving measurable progress towards their stated program goals. The revised narrative will also allow State

Title V programs to better reflect on their leadership role within a State and to demonstrate the program's contributions to the State's overall public health system in building improved and expanded systems of care for the MCH population.

This Guidance adheres to the specific statutory requirements that are outlined in Sections 501 and 503-509 of the Title V legislation and promotes the use of evidence-based public health practices by States/jurisdictions in developing a Five-year Action Plan that addresses the identified State and National MCH priority needs. The revised Guidance also reaffirms the mission of Title V as "to improve the health and well-being of all of America's mothers, children, and families." For the first time, the Guidance maps the 10 Essential Public Health Services to the three MCH service levels that are included in the revised MCH Pyramid working framework. (Attachment B) This concept is important in conveying Title V's role, first and foremost, as a public health system in the State that works to carry out the core public health functions of assessment, assurance, and policy development, along with the 10 Essential Services of public health.

Uses of Information
The data and attendant information that will be collected by the MCHB from the States through the Application/Annual Report offer utility to both HRSA, MCHB, and to the individual States and jurisdictions.

Federal
The information collected from State Title V agencies in the Application/Annual Report will be used to comply with statutory requirements for MCH Block Grant funds. MCHB will use the information to take two administrative actions:

- Acceptance of Annual Report submitted in accordance with standard format and requirements of Section 506 of the Act; and

- Acceptance of a complete State Application submitted in accordance with the standard format and requirements of the Act.

Additionally, as mandated by Section 506, information provided through the Annual Report and other sources of State data gathered by MCHB will be aggregated and analyzed for inclusion in the TVIS. Such reporting by the States on their performance relative to the National measures is used by MCHB to assess National progress in key MCH priority areas and to facilitate the Bureau's annual GPRA reporting. In addition, the MCHB will use these data to identify current and emerging National MCH priority areas, guide strategic planning efforts and inform the allocation of resources.

State
States will use the National and State-specific data to aid in priority setting for their MCH populations; to respond to other Federal, State, and local performance requirements/requests; and to develop and justify efforts for advancing MCH-related agendas with the legislatures and/or Governor's offices.

Information Collection and Proposed Changes
The combined Application/Annual Report will be completed and submitted to the MCHB on an annual basis. These data offer a consistent way for States to provide tabular information in order to facilitate manipulation of the data and production of reports. The Application/Annual Report will reflect a synthesis of the health status, problems, services, funds and performance that are planned and provided by State Title V programs.

The transformative effort that MCHB initiated in 2013, in partnership with the State Title V program leadership and other key stakeholders, resulted in revisions to the Title V MCH Block Grant Application/Annual Report Guidance. These revisions are intended to enhance the ability of States to document the impact and value of this investment towards improving MCH outcomes within the State as well as to tell a National story about the impact of Title V funding across the country. One area of focus in revising the program's National Performance Measures (NPMs) is for the Federal MCH program to assume lead responsibility in ensuring that each measure has a National data source, which will allow for more timely, reliable and valid data reporting. In addition to their being more actionable and providing greater accountability, the new performance measure framework is intended to track areas where the State MCH programs can best demonstrate the impact of their Title V investments. Additional information regarding the transformation of the MCH Services Block Grant to States Program is posted on the MCHB website at: http://mchb.hrsa.gov/blockgrant.

Specific changes to this revised version of the Application/Annual Report Guidance include:

1. Narrative reporting will be organized by six population health domains, specifically, Women's/ Maternal Health; Perinatal/Infant's Health; Child Health; CSHCN; Adolescent Health and Cross-cutting or Life Course.

2. Revised performance measure framework will be implemented with States selecting eight of 15 NPMs for their programmatic focus.

3. State-level program data, such as breakdowns of MCH populations by race/ethnicity, health indicator data, and national performance and outcome measure data will be provided by MCHB, as available, from national data sources, thus, reducing the annual reporting burden for States.

4. Given that most MCH issues are multifactorial, evidence-based or -informed strategies will be developed to address each of the NPMs selected by a State, with State being required to report on one or more Evidence-based or -informed Strategy Measures (ESMs) for each of the selected NPMs.

5. Revised instructions and the inclusion of a logic model for the State Title V MCH Block Grant Application/Annual Report process will provide greater emphasis on the need for the State priority needs and national MCH priority areas to drive the State's

reporting on the Five-year (and ongoing) Needs Assessment findings, the selection of eight NPMs which target the State-identified priority needs, the development of ESMs for addressing each of the selected NPMs and the establishment of between three and five State Performance Measures (SPMs) which respond to the State's identified unique needs to the extent that they are not addressed by the NPMs and ESMs.

6. State Application/Annual Report will include a five-year Action Plan for addressing the identified MCH priority areas.

7. An Executive Summary will be included with each submitted Application/Annual Report.

8. A Five-year Needs Assessment Summary will be integrated into the State's MCH Block Grant Application/Annual Report and will replace the more comprehensive, stand-alone Five-year Needs Assessment document that the State previously submitted.

9. Health System Capacity Indicators will be eliminated.

10. Federal and State Title V program budget and expenditures will be reported separately by the State.

The following additional changes were also made to promote consistency across States in meeting the reporting requirements and to enhance the ability of States to clearly convey their Title V program efforts.

11. A Glossary of MCH terms relative to the Title V program was updated and revised (Section H of the Supporting Documents).

12. In consultation with a working group that consisted of the Association of Maternal and Child Health Programs (AMCHP) leadership, Dr. Donna Peterson and MCHB program staff, the MCH service framework was revised and the MCH service levels redefined (Attachment B).

13. The AMCHP convened a working group, which consisted of family leaders, to develop revised language for the revised Application/Annual Report Guidance that emphasized the importance of family/consumer partnership and accurately defined it.

This revised version of the Guidance contains data collection and reporting requirements that are consistent with GPRA and the established Federal/State Title V MCH administrative partnership. Through such reporting, MCHB and the States demonstrate accountability in the use of Federal Title V funds and the required State matching funds for meeting the legislative intent.

3. USE OF IMPROVED INFORMATION TECHNOLOGY AND BURDEN REDUCTION

HRSA has made efforts to improve the use of information technology in data collection. Following the approval of the 1997 revisions, HRSA developed and instituted an automated electronic data collection process and implemented the TVIS. This information system captures the performance data and other key program and financial information submitted by States in their yearly Applications/ Annual Reports. Examples of the data that are collected include information on populations served; budget and expenditure breakdowns by source of funding, service and program; program data, such as individuals served and breakdowns of MCH populations by race/ethnicity; and performance and outcome measure data for the National and State measures.

Electronic Data Reporting

Electronic data reporting has increasingly reduced the burden on States and jurisdictions first introduced in 2002, as it provides for automatic calculations of ratios, rates, and percentages; captures past years' data; and assures that the data presented in multiple tables are entered only once. Further reductions in burden are expected with the modernization and introduction of a new electronic system in 2015.

The Title V Block Grant Application and Annual Report software, which allows grantees to enter data into Web-based forms and report sections, is derived from the *Guidance and Forms for the Title V Application and Annual Report, Maternal and Child Health Services Title V Block Grant Program*. State users electronically enter data and upload information as appropriate. The interface provides the "forms" of the Application that can be completed online, and those forms in turn submit data to a relational database that is developed to HRSA standards (e.g., SQL Server Relational Database) and is integrated with the larger and related agency system known as the HRSA's Electronic Handbooks (EHB). This system provides significant benefits, as users are permitted to complete their Application/Annual Report forms via the Web and to submit Application/Annual Report forms directly to the database. In addition to data entry, the electronic system displays the State-submitted data on publicly accessible Web Reports. It should be noted that States are required to provide data only for the Application/Annual Reporting year, as other data cells are pre-populated from previous years' submissions.

TVIS is a database that allows users to search and sort data on the health status of the Nation's mothers and children. This database assures that Title V program data on maternal and child health are uniformly available from all 50 States and 9 jurisdictions. Access to the data enables States, communities, policymakers, and health care professionals to make better-informed decisions about meeting the health care needs of women and children in the United States. Since TVIS makes all information publicly accessible on the Web, States have strong incentive to ensure the quality and accuracy of the data they submit. The data reported annually by the States are available to the public at: https://mchdata.hrsa.gov/TVISReports.

The transformative changes outlined in this version of the Title V MCH Block Grant Application/Annual Report Guidance mandate the development of a new data collection and Web report system. This modernization and redesign reflect an ongoing commitment by MCHB to improve and assure continued programmatic efficiency, transparency and quality. A contract is currently in place to support the development and implementation of this new information system.

4. EFFORTS TO IDENTIFY DUPLICATION AND USE OF SIMILAR INFORMATION

In establishing State reporting requirements, MCHB considers the availability of National data from other Federal agencies. As required by Section 509(a)(5) of the Act, every effort is made to not duplicate data collection efforts. Considerations for determining the required data reporting elements, as specified in the MCH Block Grant Application/ Annual Report Guidance, include:

- Data are unique to the Title V program at both the State and National levels;
- Data are required by statute;
- Data are needed to address Departmental Needs; and/or
- Data are not available from other sources.

The data requirements specified in Sections 505 and 506 have been discussed extensively with States in public meetings. Addressing them is part of the shared responsibility that exists through the program's administrative structure of a Federal/State partnership.

Reduced duplication is one of the triple aims of the MCH Block Grant to States transformation process. The burden associated with the State data collection and reporting efforts in this version of the Application/Annual Report Guidance is estimated to be half the number of hours that were needed to fulfill the data requirements contained in previous program Guidances. In the revised performance measure framework, the focus is on the establishment of a set of population-based measures (i.e., NPMs) which utilize State-level data derived from National data sources and for which State Title V programs will aim to demonstrate impact. Effective with this Guidance, available National outcome and performance measure data will be collected and made available to States by MCHB. States will no longer be responsible for its annual collection and reporting.

In addition to reduced reporting burden through the pre-population of National data for each State, the total number of reporting forms has been reduced from 21 to 11. Other efficiencies that have been incorporated into the revised Application/Annual Report Guidance include:

- Incorporation of a Needs Assessment Summary into the yearly Application to eliminate duplication in States having to report similar information and data across two separate documents;
- Simplification and streamlining of the narrative format for the State Application/Annual Report to allow for more focused reporting of Title V-led and

supported activities for each of the six specified population health domains (i.e., Women's/Maternal Health; Perinatal/Infant's Health; Child Health; CSHCN; Adolescent Health; and Cross-cutting or Life Course for issues that span across multiple life stages);
- Incorporation of a logic model and Five-year State Action Plan to enable States to more clearly and accurately tell the Title V story; and
- Clarification of reporting form instructions and inclusion of an updated Glossary to better capture areas of focus in today's Federal and State MCH programs (e.g., priorities, targeted health outcomes, evidence-based practices and quality improvement efforts) and to allow for more consistent reporting across States relative to their budget/expenditure data and types of services provided.

5. IMPACT ON SMALL BUSINESSES OR OTHER SMALL ENTITIES

No small business or other small entities are involved.

6. CONSEQUENCES OF COLLECTING THE INFORMATION/LESS FREQUENT COLLECTION

Annual submission of an Application is required by law to entitle a State to receive MCH Block Grant funds (Sec.505). An Annual Report on the expenditure of the previous year's funds is also required by Section 506 of Title V. Section 505(a) requires a State to conduct a State-wide Needs Assessment every 5 years. The next Needs Assessment reporting is due to be submitted in FY 2015.

7. SPECIAL CIRCUMSTANCES RELATING TO THE GUIDELINES OF 5 CFR 1320.5

This data collection is consistent with the guidelines in 5 CRF 1320.5.

8. COMMENTS IN RESPONSE TO THE FEDERAL REGISTER NOTICE/OUTSIDE CONSULTATION

Section 8A:

The 60-day notice required in 5 CFR 1320.8(d) was published in the *Federal Register* on June 27, 2014 (Vol. 79, No. 124, pages 36537-36539). Public comments received during the 60-day public comment period (June 27-August 26, 2014) informed the development of the revised *Title V Maternal and Child Health Services Block Grant to States Program Guidance and Forms* and the Appendix of Supporting Documents.

In an effort to derive a realistic burden estimate for the reporting requirements outlined in the revised MCH Block Grant Application/Annual Report, the MCHB contacted the MCH leadership in three States. Their names and contact information are provided below.

NAME	CONTACT INFORMATION
Sam Cooper, LMSW (AMCHP President-Elect) Director, Specialized Health Services Section Director, Office of Title V & Family Health Texas Department of State Health	Telephone: 512-776-2002 Email: sam.cooper@dshs.state.tx.us
Millie Jones, PA (AMCHP President) Clinical Consultant, Bureau of Community Health Promotion Wisconsin Department of Health & Family Services	Telephone: (608) 266-2684 Email: Millie.Jones@dhs.wisconsin.gov
Danette Wong Tomiyasu Chief, Family Health Services Division Hawaii Department of Health	Telephone: (808) 586-4121 Email: danette.tomiyasu@doh.hawaii.gov

In addition to soliciting input from the three MCH leaders cited above, the draft Application/Annual Report Guidance was discussed with the State MCH and CSHCN Directors at the face-to-face Application/Annual Report review in August. Feedback received indicated the difficulty for States in estimating the amount of burden that will be incurred with the new reporting requirements. The State MCH Director in Arkansas commented that the changes will require some retooling of the State systems as well as the Federal system.

Public comments were received from a total of 50 respondents including the MCH and/or CSHCN leadership in 31 States and five (5) counties, eight (8) commenters who represented a National association/organization, four (4) commenters who offered the family perspective or were representatives of a family support organization and two (2) commenters that represented an organization which served CSHCN. Many of the respondents included multiple comments in their responses. A log of the public comments received is provided in Attachment C.

All of the comments received were given serious consideration by MCHB prior to finalizing this version of the Application/Annual Report Guidance. Of the numerous public comments that were received by MCHB, many respondents addressed similar topic areas or issues. The following discussion points capture the most commonly expressed themes and the MCHB's response.

1) **Burden Estimates** – Of the 59 States and jurisdictions, five States (California, New York, North Dakota, Oregon and Utah) expressed concerns that the proposed burden hours were an underestimate. One State (Tennessee) commented that the burden estimates were "potentially reasonable," and one other State (Minnesota) noted the difficulty in providing estimates for the potential burden hours at this time.
   MCHB Response: Revisions to the Application/Annual Report Guidance are intended to reduce reporting burden for the States; however, the MCHB acknowledges that it is difficult to estimate the level of burden given the changes in reporting framework and data requirements that are contained in this revised Application/Annual Report Guidance. It is recognized that the full extent of the anticipated burden reduction will be realized over time as States become more

familiar with the new instructions and reporting requirements. Once implemented, the MCHB plans to solicit additional burden information from States and will conduct a burden reassessment to obtain more accurate estimates. It should also be noted that these estimates reflect the average level of burden necessary to meet the specified reporting requirements. States often report a range of burden hours due to the differences in their population size, program resources and the extensiveness of the processes they use to conduct their Five-Year Needs Assessment and to prepare the yearly MCH Block Grant Applications/Annual Reports.

2) **Family/Consumer Engagement** – The Application/Annual Report Guidance includes added language that highlights the importance of family/consumer partnerships in driving change and transformation in State MCH and CSHCN programs and assuring cultural and linguistic competence and health equity. Nine respondents commented on the program's reporting requirements and definition for family/consumer partnership presented in the program Guidance.
MCHB Response: As part of the transformation process, the AMCHP convened, at the request of the MCHB, an expert group to provide recommendations on key discussion points and potential language for describing family/consumer partnership. The language developed by the expert group was used in writing the revised Guidance. This collaborative work will be ongoing as the MCHB moves forward in operationalizing the new narrative and performance requirements.

3) **Page Limits for the Executive Summary and Needs Assessment Summary** – Concern was expressed by approximately eight States (California, Massachusetts, North Dakota, Ohio, Tennessee, Texas, Virginia and Wisconsin) that the specified page limits of three (3) pages for the Executive Summary or 20 pages for the Needs Assessment Summary might be insufficient to address the reporting requirements specified in the Guidance. The comments were largely focused (five of eight States) on the established three-page limit for the Executive Summary. At least four States (Iowa, Kansas, New York and Utah) expressed their support for the Executive Summary or the Needs Assessment Summary, as proposed.
MCHB Response: While only a small number of the 59 States/jurisdictions expressed concern about the page limit for the Executive Summary, the MCHB increased the page limit from three (3) pages to "up to five (5) pages." In addition, the MCHB revised the narrative instructions in the Application/Annual Report Guidance on preparing the Executive Summary to be less inclusive and more suitable to what could be reasonably included in a "summary" overview. As the MCHB is strongly committed to reducing burden and only two States (Massachusetts and North Dakota) commented on the proposed page limit for the Needs Assessment Summary, the limit of 20 pages was retained in the revised program Guidance. The instructions in the Application/Annual Report Guidance were also revised to better clarify the required content for both summaries. Some of the concerns around the incorporation of charts and graphs are expected to be addressed through added functionality in the new TVIS.

4) **Terminology and Glossary** – Approximately five commenters (three from Washington State) noted inconsistencies in the Application/Annual Report Guidance when referencing children with special health care needs (CSHCN). In concert with the families they serve, some State Title V programs generally reference this population as children "and youth" with special health care needs (CYSHCN.) Numerous commenters also expressed support for having a Glossary of terms included in the Guidance. Interest in the Glossary primarily focused on a need to have definitions for the three service levels of the updated MCH Pyramid.
MCHB Response: As the legislation references CSHCN, this terminology was adopted in the Guidance. However, States are not precluded from using CYSHCN in their programs. The draft Application/Annual Report Guidance that was released in June 2014 did not include a Glossary of terms. While it was always intended that the final Guidance would include a Glossary, the MCHB sought to involve its State partners, the AMCHP and other MCH leaders in the development of new definitions for the three service levels of the MCH Pyramid and in the inclusion of other relevant MCH terms. An updated Glossary has been added to the revised Application/Annual Report Guidance. (See Appendix H of the Supporting Documents, which accompanies the Application/Annual Report Guidance.)

5) **Title V's Role as "Safety Net**" – Concern was expressed by three States and the AMCHP that the reference to the State Title V programs as a "safety net" program might be misinterpreted to mean the delivery of "direct health care services." Many State Title V programs do not provide direct health care services.
MCHB Response: State Title V programs play an important role in serving as a safety net for the Nation's MCH population. In partnership with the AMCHP, the MCHB developed more specific and clearer definitions for the levels of MCH services that are depicted in the MCH Pyramid (Attachment B). These definitions serve to clarify that Title V's role as a safety net for the MCH population goes beyond its legislatively-defined role as the "payer of last resort" in assuring the provision of direct health care services.

6) **State Reporting on Newborn Screening** – Approximately three comments were received which questioned the data elements on Form #4 and their relevance and utility for State Title V programs.
MCHB Response: The MCHB reviewed Form 4 and consulted with the leadership in the Federal Newborn Screening program. The form was revised based on their recommendations. Revisions include: 1) change in the reporting requirement for Column D from those individuals (i.e., infants, older children and women) who "need treatment and received it" to the number and percentage of individuals who were "referred for treatment"; 2) the drop list for the Recommended Uniform Screening Panel (RUSP) that was incorrectly included on Form 4 in the draft Application/ Annual Report Guidance for Older Children and Women was deleted with States instructed to enter (as in previous Guidances) the screening programs they provide for these populations; 3) reporting field was added to allow States to provide a brief narrative description of their long-term follow-up activities; and 4) instructions for completing the form were revised and clarified.

7) **Performance Measure Framework** – Numerous comments were received on the linkage between the NOMs and NPMs, how specific NPMs were defined, the categorization of the NOMs and NPMs into one of six population health domains, the pre-population of National data for States and MCHB's expectations for the development of State-specific Structural/Process Measures and SPMs.
MCHB Response: The new Performance Measure Framework represents the core of the transformational changes to the MCH Block Grant to States program. Developed by an expert committee (which consisted of a team of MCHB Senior Epidemiologists and Title V MCH and CSHCN program staff as well as Dr. Christie Bethel, Researcher and Visiting Professor, at Johns Hopkins University,) the proposed measures were widely vetted prior to release of the draft Application/Annual Report Guidance in June 2014. Comments received during the 60-day comment period were reviewed and given serious consideration by the expert committee. These comments provided insight into needed clarifications in the draft Application/Annual Report Guidance relative to the performance measure framework, the definition of NOMs and NPMs and how they are linked, how States select measures in the population domains and how States define their Evidence-based or –informed Strategy Measures (ESMs.) Also, the comments informed a review of the legislatively required data elements. The clarifications and modifications to the NOMS and NPMs, as presented in the attached Application/Annual Report Guidance, reflect the recommendations of the expert committee and an attempt by MCHB to add clarity to the reporting instructions and to better describe the new performance measure framework.

8) **Budget Forms and State Action Plan** – Some States commented on the need for clearer instructions, timeline and definitions/examples relative to budget/expenditure reporting by Class of individuals and Types of Services and in the development of a Five-year State Action Plan.
MCHB Response: In partnership with the AMCHP and other MCH leaders, the MCHB developed new definitions for the three service levels of the MCH Pyramid to assist States in reporting on the legislatively-required budget/expenditure data elements. (Attachment B) The MCHB also clarified the instructions for completing the budget/expenditure reporting forms and the required content and structure of the Five-year State Action Plan. As part of clarifying the reporting elements on Form 3b, "Types of Individuals Served," the three legislatively-defined MCH population groups were added to assist States in their reporting on the use of Federal and non-Federal Title V funds for direct services. In addition, a drop-down box was added to assist States in listing the types of direct services they support through their Federal and non-Federal MCH Block Grant funds. Form 5a was also revised to enable States to better capture the "reach" of their Title V programs in serving the broader MCH population through population-based services. In response to the comments received, the MCHB revised Appendix G of the Supporting Documents to include a timeline and checklist of required Application/Annual Report components.

9) **Legislatively-Required Data Elements Not Addressed in Draft Guidance** – One State noted in its comments that the draft Application/Annual Report Guidance did

not address the requirements in the Federal law on the proportion of infants born with fetal alcohol syndrome, the proportion of infants born with drug dependency and the proportion of women who deliver and do not receive prenatal care during the first trimester of pregnancy.

MCHB Response: Three new NOMs were added to address the reporting requirements that were noted in the respondent's comments. Detail sheets to define the added NOMs were also developed. The MCHB further conducted an internal review to confirm that the legislatively-required reporting elements were addressed in the revised Application/Annual Report Guidance. Through this process, MCHB noted that the rates of infant mortality and low birth weight by race and ethnicity and by county were not included. The required reporting elements on workforce category were also not included. Based on the findings of the internal review, a new Form 11 was developed. It was further determined that the State demographic data (SDD) included on the original Form 11 of the draft Application/Annual Report Guidance were not required by legislation. As such, these data elements were removed from the revised program Guidance.

Section 8B:

There was an extensive collaboration process in the development of this version of the MCH Block Grant Application/Annual Report Guidance, a wide range of State and National MCH leaders and key stakeholders. The visioning process for transforming the Block Grant began in May 2013 with a three-pronged approach that involved the convening of an internal MCHB workgroup, an AMCHP workgroup that consisted of its State Title V Board members and an external group, chaired by Dr. Donna Petersen, Dean of the College of Public Health at the University of South Florida, which included National (non-State Title V) MCH leaders. This process called for a re-examination of the Title V program and its mission/vision, performance measurement and program Guidance to States for writing an Application/Annual Report, which included reporting on the Five-year Needs Assessment and the annual grant review process. Based on the recommendations of the three workgroups, the MCHB developed a framework for transformation of the Title V MCH Block Grant to States program. Input was solicited from the broader community of State Title V programs and MCH stakeholders through a Web-based drop box, a series of Web-based "listening sessions" and a town hall session at AMCHP's annual conference in February 2014. The drop box alone yielded hundreds of comments from the MCH field. In an effort to ensure that the voice of families helped to drive the transformation process, the MCHB reached out to family representatives and organizations. All of this input helped to inform the development of the draft Application/Annual Report Guidance, which was released for a 60-day public comment period at the end of June 2014. The public comments received further guided the development of the attached revised Application/Annual Report Guidance.

9. EXPLANATION OF ANY PAYMENT/GIFT TO RESPONDENTS

Respondents will not be remunerated.

10. ASSURANCE OF CONFIDENTIALITY PROVIDED TO RESPONDENTS

The Privacy Act does not apply in this data gathering effort because the information to be collected will not identify any individuals by name or collect any individual information.

All Annual Reports, Applications, and associated information submitted under Title V are public documents and available to the public on demand. Section 505 requires each State to have public disclosure for a period of time through the MCH Block Grant Application process to facilitate public review and comment by interested persons or organizations during its development or transmittal.

11. JUSTIFICATION FOR SENSITIVE QUESTIONS

There are no questions of a sensitive nature associated with this data collection effort.

12. ESTIMATES OF ANNUALIZED HOUR AND COST BURDEN

The annual burden estimate for this activity is based on burden estimates and consultations with a few States on the proposed changes. It is recognized that the full extent of the anticipated burden reduction will be realized over time as States become more familiar with the new instructions and reporting requirements. The estimated average annual burden is as follows:

Section 12A:

Estimated Annualized Burden Hours

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Burden per Response (in hours)	Total Burden Hours
Application and Annual Report without 5-Year Needs Assessment	59	1	59	123	7,257
Application and Annual Report with 5-Year Needs Assessment	59	1	59	189.3	11,169
Average Total Annual Burden	59	1	59	156.15	9,213

Section 12B:

Estimated Annualized Burden Costs

As a Block Grant, States do not collect and report salary information or the working hour distribution of staff who are involved in administering the Title V program. In addition, the salary of staff supported under Title V will vary significantly across States. Organizational capacity also varies, with the larger States typically utilizing more program staff than do smaller States. Each State Title V program has a unique organizational structure. Given its public health leadership role and the breadth of the services that are supported, the administration of a State Title V program requires multiple partners and health department units (e.g., MCH Director and staff, CSHCN Director and staff, Epidemiologist(s) and other supportive staff in Vital Statistics and Laboratory Services.)

Based on the Bureau of Labor Statistics, Occupational Employment and Wages for May 2013, the national mean wage estimate for Medical and Health Services Managers in organizations that include public health agencies is $48.72 http://www.bls.gov/oes/current/oes119111.htm. The preparation and yearly submission of the Application/Annual Report and Five-Year Needs Assessment requires multiple levels of staff. As the Health Services Manager likely has one of the higher salaries, this rate was used to calculate the following annualized cost to the State Title V programs.

Type of Respondent	**Average Total Annual Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
Health Services Manager	9,213	$48.72	$448,857
Total	9,213	$48.72	$448, 857

13. ESTIMATES OF OTHER TOTAL ANNUAL COST BURDEN TO RESPONDENTS OR RECORDKEEPERS/CAPITAL COSTS

There is no capital, start-up costs, or operation and maintenance costs associated with this data collection.

14. ANNUALIZED COST TO THE FEDERAL GOVERNMENT

Given this period of transition to a new performance measure framework and a more streamlined Application/Annual Report Guidance for States, the level of effort associated with this activity is approximately 0.7 full-time equivalent (FTE) of one Federal staff (GS-15/10). The estimated annual salary cost of this level of effort is $109,970. Subsequent versions will require less policy development and oversight. Using the

transformed framework, development of future Application/Annual Report Guidances will likely require one Federal FTE at the GS-13/10 level. In addition to Federal program staff salary, approximately $120,000 is needed annually to support operational costs associated with the annual review of each of the 59 State MCH Block Grant Applications/Annual Reports. Contract costs for the operations and maintenance of the TVIS for FY 2012 and 2013 were $575,207 and $586,774, respectively. Due to the development of a new TVIS, the contract amount for the operations and maintenance of the existing TVIS for FY 2014 was reduced from $598,503 to $297,503. A contract was awarded on Sept. 30, 2014 for the development of a new TVIS at a cost of $1,122,987 in the Base Year and $1,045,727 for the First Option Year. This cost will be reduced to approximately $700,000 for support of operations and maintenance in Option Year 03.

On this basis, the estimated annual cost to the Federal government for the development of this transformed MCH Block Grant to States Application/Annual Report Guidance, review of the first year State Applications/Annual Reports and development of a redesigned TVIS that aligns with the new reporting requirements is $1,352,957.

15. EXPLANATION FOR PROGRAM CHANGES OR ADJUSTMENTS

The current inventory for this activity in a year in which States do not report on the findings of a Five-year Needs Assessment is 14,514 hours. Given the transformative changes contained in this version of the MCH Block Grant to States Application/Annual Report Guidance, burden to the States is expected to be reduced by 50% (7,257 hours). For a year in which States report on the Five-year Needs Assessment, burden is expected to decrease from 22,332 hours to 11,169 hours. It is recognized that the full extent of the anticipated burden reduction will be realized over time, as States become more familiar with the new instructions and reporting requirements and with the development and implementation of a new electronic Web-based data entry and Web-reports system.

16. PLANS FOR TABULATION AND PUBLICATION AND PROJECT TIME SCHEDULE

The State/jurisdictional MCH Block Grant Application/Annual Report document is submitted each year on July 15th, with review of each submitted document completed by early September. Announcements of funding decisions are usually made by October or as soon as possible in the fiscal year after MCHB receives the appropriation.

Aggregation of data from the Annual Reports will begin each year in early Fall after receipt of the reports from States. Web-based display of the States' annual submission of their Title V Block Grant Needs Assessment, Applications and Annual Reports generally occur in early November. Given the design of a new TVIS in 2015, the Web Reports for the FY 2016 Applications and FY 2014 Annual Reports are expected to be operational by January 15, 2016.

17. REASON(S) DISPLAY OF OMB EXEMPTION DATE IS INAPPROPRIATE

The expiration date will be displayed.

18. EXCEPTIONS TO CERTIFICATION FOR PAPERWORK REDUCTION ACT SUBMISSIONS

This project meets all of the requirements in 5 CFR 1320.9. The certifications are included in the package.