Supporting Statement A

OAT Telehealth Outcome Measures

OMB Control No. 0915-0311

A.   Justification

1.   Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration's (HRSA) Office of Rural Health Policy (ORHP), Office for the Advancement of Telehealth (OAT) is requesting Office of Management and Budget (OMB) approval for telehealth outcome measures of the telehealth grantees. Specifically we are asking approval to use a performance measurement tool to collect data from grantees receiving funds under the Telehealth Network Grant Program. This performance management tool has been in use since 2002 but program staff were unaware that OMB clearance was required. While working to migrate the performance system into HRSA's Electronic Handbook (EHB), OAT program staff learned that OMB clearance was needed.[1] Upon being informed that this activity required OMB clearance, program staff immediately took steps to bring the forms into compliance as evidenced by the submission of this request. In addition, a revision was made to item 12 in order to capture the number of respondents responding to the tool. The number of respondents includes each individual spoke site(s) within a telehealth network grant project.

The Telehealth Network Grant Program is authorized by Section 330I of the Public Health Service Act. The Health Care Safety Net Amendments of 2002 (Public Law 107-251) amended the Public Health Service Act by adding Section 330I. Under this authority, grants may be awarded to eligible entities to develop telehealth network projects in rural areas, in medically underserved areas, in frontier communities, and for medically underserved populations, to (a) expand access to, coordinate, and improve the quality of health care services; (b) improve and expand the training of health care providers; and (c) expand and improve the quality of health information available to health care providers, and patients and their families. The primary objective of the Telehealth Network Grant Program is to help communities build the human, technical, and financial capacity to develop sustainable telehealth programs and networks. The data collected with the performance measurement tool provides HRSA's OAT with information about outcome measures including the effectiveness of service programs and monitor their progress through the use of performance reporting data. In addition, the data collected from grantees meets the administrative requirement of assessing programs via the Government Performance Review Act of 1993 (GPRA)[2].

---

[1] The EHB allows business processes such as grants management to be broken down into discrete role-based handbooks. The EHB contains electronic forms which can be used in real-time.

[2] GPRA is a law that passed in 1993 which requires that federally funded agencies develop and implement an accountability system based on performance measurement including setting goals and objectives and measuring progress toward achieving them.

The Telehealth Network Grant Program awards demonstration grants to networks that show how telehealth technologies can expand access to quality healthcare; improve and expand training of healthcare providers; and expand and improve the quality of health information available to providers and patients. Because the primary focus of the program has been to fund grantees to build and demonstrate the usefulness and financial viability of telehealth systems in providing health care, this tool provides the needed measures to determine the program's impact on clinical outcomes. As required by GPRA, all federal agencies must develop strategic plans describing their overall goal and objectives. HRSA's OAT has worked with its grantees to develop performance measures to be used to evaluate and monitor the progress of the grantees. Specific categories were designed to be reported through a performance monitoring website.

The HRSA's OAT was established in 1998 with the mission to lead, coordinate and promote the use of telehealth technologies by fostering partnerships within HRSA and other Federal agencies, states and private sector groups to expand the field of telehealth by: administering telehealth grant programs; providing technical assistance; assessing technology investment strategies; developing distance learning and training programs for health care providers; evaluating the use of telehealth technologies; developing telehealth policy initiatives to improve access to quality health services; and promoting knowledge about "best practices." HRSA envisions the use of telehealth technology playing an integral role in facilitating linkages between health care institutions over distance to improve access to quality health care services in this nation and provide educational opportunities or those who would otherwise not have or would have difficulty accessing such opportunities. OAT is the operational focal point within HRSA's Office of Rural Health Policy for advancing the cost-effective use of telehealth technologies throughout the agency. OAT is responsible for allocating and administering funds, evaluating programs and their impact on the population served, and improving the quantity and quality of care. The data collection tool extracts valuable information on services provided that are critical to the mission of HRSA and provides valid and complete information about methods used to measure the impact of the telehealth program on improving access to healthcare services for residents of communities that did not have such services locally before the program. Projects are able to measure the impact of the telehealth program on hospitalization rates and emergency room visit rates per year for patients receiving disease management services for diabetes, congestive heart failure, stroke and other chronic diseases, as well for patients receiving home care/home monitoring services. Projects can measure impact of the telehealth program on controlling blood glucose levels in diabetic patients and can assure the impact of the telehealth program improving efficiency of health care. In addition, projects also measure the impact of the telehealth program on reducing medical errors and collect data to measure other clear outcomes.

Additionally, the performance measurement tool allows OAT to:
- Fulfill obligations for GPRA requirements and to report to Congress on impact of the OAT telemedicine grant program;
- justify budget requests;
- create a data-reporting tool for grantees to report on their projects' performance relative to the mission of OAT/HRSA as well as individual goals and objectives of the program;
- collect uniform, consistent data which enables OAT to monitor programs;

- provide guidance to grantees on important indicators to track over time for their own internal program management;
- identify topics of interest for future special studies;
- identify changes of healthcare needs to rural communities allowing programs to shift focus in order to meet those needs, thereby improving access to needed services;
- reduce rural practitioner isolation;
- improve health system productivity and efficiency; and
- enhance quality of care.

2.   **Purpose and Use of Information Collection**

In order to evaluate existing programs, data are obtained from the OAT Performance Improvement Measurement System (PIMS), which can be accessed thru HRSA's Electronic Handbook (EHB). The data are used to identify quality improvements, disparities in health care, health status and clinical outcome measures. The tool is also used to address GPRA initiatives. This system provides the government, health centers, patients, general academic and constituent communities with critical information on health care issues that directly affect rural, minority and under-served populations.

There are two data reporting periods each year; during these biannual reporting periods data are reported for the previous six months of activity. Programs have approximately six weeks to enter their data into an interactive website designed by Abt Associates Inc. during each biannual reporting period. The interactive website was successfully migrated into HRSA's EHB in 2008.

The instrument was developed with the following four goals in mind:

   I.   improving access to needed services,
  II.   reducing rural practitioner isolation,
 III.   improving health system productivity and efficiency, and
  IV.   improving patient outcomes.

For each of these categories, specific indicators were designed and data are reported regularly through a performance monitoring website. In addition to providing the required GPRA data, OAT plans to use the reported information to demonstrate the "value-added" that telehealth services contribute to improving health care. OAT has incorporated these performance assessment tools into the routine reporting required as part of the mid-year and annual reports required of their grantees.

All grantees will be asked to address access to telehealth technologies at their respective institutions. Telehealth activities include the practice of telemedicine, delivery of distance education in allied health fields health informatics, health care staff supervision from remote sites, and the provision of consumer health information using telecommunications technologies. Additionally, grantees will be asked to provide network members or satellite site information.

User Level Data

    a. **A unique user identifier:** Each grantee selects a member from the organization to submit data into PIMS. The selected staff member is assigned a unique EHB login and password code to access the system.

    b. **Configuration:** This feature allows participants to establish sites, specialties and settings. Participants can update information when necessary.

Specialties and Services
This allows participants to report the number of encounters by specialty/service, by patient care setting and by the type of telemedicine encounter.

Specialty Areas: This allows users to indicate the medical specialties and services provided through their telehealth system for the current reporting period.

Settings Include:
- Hospital ER
- Hospital In-Patient
- Hospital Outpatient
- Non-Hospital Clinic (e.g., rural clinic, migrant health clinic)
- Private Medical Practice or Physician's Office
- Health Department and Mental Health Agency
- Patient's Home
- Licensed Nursing Home
- Assisted Living Facility
- School
- Prison

Encounter Types:
- Interactive/Real-Time Encounters: Encounters done in an interactive (real-time) video-conferencing format.
- Patient-Present Encounters: Interactive encounters in which the patient is present during the consultation.
- Patient-Not Present Encounters: Interactive encounters in which the patient is not present during the consultation.
- Store-and-Forward: Encounters done in a format where information/images are gathered and sent electronically to be viewed at a later time by a telehealth provider; therefore, encounters are not interactive and not in real-time.
- Biometric Monitoring Interactions: Store-and-forward interactions used for telemetry or patient-monitoring most commonly for home-bound patients. Every 'patient-day' (a day in which a patient received care) should be counted as a separate interaction. Multiple measurements recorded within a single day are counted as one.
- Other: All store-and-forward interactions that do not involve biometric monitoring.
- Patient-Care Encounters/Sessions: This information is obtained with a different form and includes therapy and counseling (including nutritional, group counseling, etc) but not didactic education, community meetings or administrative sessions.

Service Availability in Remote Communities

Participants are asked to report information about the availability of services in the community. Specifically, they are asked to report whether a specialty/service is available in the community, whether a visiting specialist provides the service regularly, whether their OAT telemedicine program offers the services to the site, and whether another telemedicine program offers the service/specialty. Participants indicate how far one would have to drive from the community to see a specialist in-person.

Patient Travel

Users measure patient travel that is 'saved' or avoided through the use of telemedicine. Distance is measured between the hub site and the remote site (patients' physical location). The number of sessions is also obtained in this area.

Number of Practitioner Referrals

This area focuses on the reliance of referring practitioners on telemedicine. Users track the number and type of patients each practitioner refers for telemedicine. The data are aggregated to show the percentage of referring rural practitioners who had 0-10 referrals, 11-20 referrals, etc. The data will also be aggregated to show the percentage of referring practitioners who referred patients for care in 0-5 specialties, 6-10 specialties, etc.

Emphasis is on 3 types of referrals:
- Clinicians referring from remote site- These are referrals made by a clinician at the patient/patient data location, usually a rural site.
- Specialists using telemedicine to see their own patients-   These are referrals made by a specialist at the consulting location. This is common for post-discharge follow-up encounters between specialist and patients.
- Patient 'self-referrals'- This type of referral addresses the situation in which a patient presents at a remote/rural site requesting a telemedicine consult with a specialist but does not have a referral from any practitioner.

The performance measurement tool also collects outcomes measures for chronic conditions. The form gathers data on patients with chronic conditions for whom the program provided care other than home-health care, i.e. care provided in other settings or through other means not including tele-home health care. The form specifically addresses the five chronic conditions that are the most commonly served by telehealth programs (congestive heart failure, diabetes, asthma, chronic obstructive pulmonary disease, mental health, and other chronic conditions). Grantees now report on the number of (unduplicated) patients served during the six month reporting period, the number of unduplicated diabetic patients served for at least three months during the six month reporting period and the number of diabetics in good glucose control, served for at least three months during the six month reporting period. These measures were included to meet specific PART requirements of the long-term outcome measures of the Telehealth Network Grant Program involvement with chronic disease management.

3. **Use of Improved Information Technology and Burden Reduction**

The OAT PIMS tool is fully electronic within HRSA's Electronic Handbook. The system design provides pre-formatted and interactive data entry that helps assure standardized data across the Telehealth Network Grant Programs and greatly simplifies the data entry process. The grantee provides sites and services information and the system only generates forms based on this data. Patient travel, chronic disease, dermatology and homecare information will be in spreadsheet format. The worksheets collect specific information about each service provided. Calculations in the spreadsheets are fully automated. Drop down menus are also used to simplify selections. Instructions are attached to each individual worksheet.

4. **Efforts to Identify Duplication and Use of Similar Information**

Data of the type required to evaluate or monitor the Telemedicine program are not available elsewhere. The information is not intended to reflect all telemedicine activity nationwide; it reflects only the activity of the telemedicine programs funded by HRSA's OAT. As such, this gives an indication of telemedicine programs and services, but not the total volume of this activity nationwide. The OAT PIMS tool is necessary for the program to monitor the objectives that the funding initiative is designed to meet.

5. **Impact on Small Businesses or Other Small Entities**

This project does not significantly impact small business or small entities.

6. **Consequences of Collecting the Information Less Frequently**

Without semi-annual reporting on the use of Telehealth Network Grant Program funds, HRSA's OAT would not be able to carry out its responsibility to oversee compliance with the intent of congressional appropriations in a timely manner. Because Telehealth is a critical component of health care, specifically in rural areas, semi-annual reporting of the characteristics of the Public Health Service Act, Section 330I - Telehealth Network Grants is necessary to determine whether the administration of the funds is responding to the changes in the affected population(s).
If the information is not collected at all, HRSA's OAT will not be able to provide critical data that are needed to justify the GPRA, as mandated by OMB. The information being reported supports the following:

- whether program funds are being spent for their intended purposes;
- what types of and how many individuals are receiving services;
- whether there is an increase in the number of communities that have access to pediatric and adolescent, and adult mental health services where access did not exist in the community prior to the Telehealth Network Grant Program;

- helps determine if there is an increase in the number of diabetic patients enrolled in a telehealth diabetes case management program with ideal glycolic control; and
- whether there is an increase in the number of services and/or sites that provide access to health care as a result of the Telehealth Network Grant Program per federal program dollar expended.

7.   Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The data is being collected in a manner fully consistent with the guidelines in 5 CFR 1320.5.

8.   Consultation Outside the Agency

The notice required in 5 CFR 1320.8(d) was published in the *Federal Register* on December 19, 2006 (Volume 71, No. 243, pages 75968-75969).

A 60-day Federal Register Notice was published in the Federal Register on September 5, 2013, vol. 78, No. 172; pp. 54660 – 54661. No public comments were received.

The OAT Advisory Committee held conference call meetings weekly to identify measures for the monitoring system. All of the advisory committee members were current grantees providing telemedicine services to the community. Their expertise was crucial in identifying key performance measures/indicators to be used to evaluate and monitor the progress of the program. The committee gave additional advice/input at the January 2002 Grantee Meeting. Once the committee finalized the measures, a pilot test was conducted using nine grantees. The Advisory Committee Members are listed in the table below.

Name	Location	Address/Phone Number
Anne Bynum, Ed.D.	UAMS Regional Programs Little Rock, Arkansas	Univ of Arkansas for Medical Sciences (UAMS) 1123 South University Suite 400 Little Rock, AR 72201 Phone: (501) 686-2595
Michael Hillman, M.D.	Marshfield Clinic Marshfield, Wisconsin	Marshfield Clinic 1000 North Oak Avenue Marshfield, WI 54449 Phone: (715) 387-5773
Sam Burgiss, Ph.D.	University of Tennessee Medical Center Knoxville, Tennessee	University of Tennessee Graduate School of Medicine 1924 Alcoa Highway Knoxville, TN 37920 (865) 544-8059
Susan L. Dimmick, Ph.D.	University of Tennessee Medical Center	University of Tennessee, Knoxville

Name	Location	Address/Phone Number
	Knoxville, Tennessee	College of Communications 271 Comm Building Knoxville, TN 37996 Phone: (865) 974-8155
Jana Katz-Bell	UC Davis Health System Sacramento California	UC Davis Health System 2315 Stockton Boulevard Sacramento, CA 95817 Phone: (916) 734-1361
Stuart M. Speedie, Ph.D.	Medical School, University of Minnesota Minneapolis, Minnesota	University of Minnesota Medical School Box 293 Mayo 420 Delaware Street, SE Phone: (612) 624-4657
Susan Gustke, M.D.	North Carolina Institute for Health and Safety Greenville, North Carolina	East Carolina University 1157 UOA Site Road Greenville, N.C. 27834 Phone: (252) 744-1000
Nancy Brown-Connolly	Ventura, California	65 Shamrock Drive Ventura, CA 93003 Phone: (805) 642-5049
David J. Cook, Ph.D.	Kansas University Medical Center Kansas City, Kansas	KU Medical Center Mail Stop 3013 3901 Rainbow Boulevard Kansas City, KS 66160 Phone: (913) 588-0435
Thelma McClosky-Armstrong	Eastern Montana Telemedicine Network Billings, Montana	Eastern Montana Telemedicine Network Deaconess Billings Clinic Foundation P.O. Box 37000 Billings, MT 59107 Phone: (406) 657-4057
Barry Kling	University of Missouri Health Care Billings, Montana	3808 Berrywood Drive Columbia MO 65201 Phone: (573) 474-1997
Pam Whitten, Ph.D.	Michigan State University East Lansing, Michigan	Department of Telecommunications 409 Communication Arts Building Michigan State University East Lansing, MI 48824-1212 Phone: (517) 432-1332

Name	Location	Address/Phone Number
Elizabeth Krupinski, Ph.D.	University of Arizona Health Sciences Center Tucson, Arizona	Arizona Telemedicine Program P. O. Box 245067 Tucson, AZ 85724-5067 Phone: (520) 626-4758
Arvind Patel, M.D.	Regional Medical Center Lubec, Maine	8 Mountainview Drive Orono, Maine 04473 Phone: (207) 866-3660
Holly Russo	El Paso, Texas	Texas Tech University Health Sciences Center 6458 La Posta Drive El Paso, TX 79912 Phone: (915) 842-0728
Andrea Hassol	Abt Associates, Inc. Cambridge, Massachusetts	ABT Associates, Inc. 55 Wheeler Street Cambridge, MA 02138 Phone: (617) 349-2488
David Ault	Abt Associates, Inc. Cambridge, Massachusetts	ABT Associates, Inc. 55 Wheeler Street Cambridge, MA 02138 Phone: (617) -349-2669

9. Explanation of any Payment/Gift to Respondents

Respondents will not be remunerated.

10. Assurance of Confidentiality Provided to Respondents

The OAT PIMS does not require any information that could identify individual clients. Names and personal identifiers will not be included in an aggregate data report. All reports and tabulated data that will be released to the general public will be summaries of information across grantees.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature collected through the OAT PIMS. No patient or client-level identifying data will be reported. Identification of the grantees as recipients of telemedicine funds is a matter of public record, as these recipients receive funds directly from HRSA.

12A. Estimated Annualized Burden Hours

The average annual burden hours of 9,800 are displayed in the table below. The estimate is based on trials regarding the amount of time it would take to review and complete data entry.

Form	Number of Respondents	Responses per Respondent	Total Responses	Hour Burden	Total Burden Hours
OAT Performance Measurement Tool	700	2	1,400	7	9,800

12B.   Estimated Annualized Burden Costs

Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Nursing, Psychiatric and Home Health Aides	4900	$11.69	$57,281
Medical Records and Health Information Technicians	4900	$17.68	$86,632
Total	9800	$29.37	$143,913

13.   Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

There are no capital or start up costs for respondents related to this effort.

14.   Annualized Cost to Federal Government

The cost of the contract to collect the information is $50,000. A Grade 13 Federal employee with a salary of $103,872 will work on this project 20% of the time. Therefore, the total annual cost to the Federal Government is $70,774.40.

15.   Explanation for Program Changes or Adjustments

This is an on-going collection of information. The Telehealth Network Grant Program supports established and/or existing telehealth networks with extensive experience in providing major clinical services to rural communities throughout the U.S. Many of these telehealth networks

have several network member partners (i.e. spoke sites) that are committed to the grant project. As a result, each spoke site is required to report as a respondent. The number of active spoke sites committed to the grant project fluctuates from year to year and, therefore, in the "Estimates of Annualized Hour and Cost Burden", the "Number of Respondents" was increased from "667" to "700" to better reflect this fluctuation.

16. Plans for Tabulation, Publication, and Project Time Schedule

The OAT data web application that grantees access was migrated into HRSA's EHB immediately following OMB's initial approval.

Since the development of the Web application, grantees have submitted their raw data that supports responses to the GPRA measures, twice each year. The first data submission occurred in 2002. Beginning in April 1, 2007, grantees submitted the data collection component that includes service and outcome data for diabetes and other chronic disease conditions. A HRSA contractor currently provides support both for the Web application system and technical assistance to grantees as they complete and submit their OAT data reporting requirements.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The expiration date will be displayed.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.