Supporting Statement A

Evaluating the Impact of 1115 Medicaid Waivers on Ryan White HIV/AIDS Program and Its Clients and Providers

Version: June 24, 2013

Health Resources and Services Administration

HIV/AIDS Bureau

OMB Control No. 0915-XXXX

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Terms of Clearance: None.

A. Justification

A1. Circumstances Making the Collection of Information Necessary

In 2010, Congress enacted the Patient Protection and Affordable Care Act (ACA), a groundbreaking effort to assure health care access for all Americans. In response to challenges, the U.S. Supreme Court ruled in June 2012 to uphold the major provisions. However, the Court limited the enforcement mechanism of one critical element of the health care reform strategy, holding that states will not be at risk of losing all federal Medicaid funds if they do not comply with the 2014 expansion of Medicaid to individuals with income up to 133% of federal poverty (around $15,400 per year for an individual). The ACA's national health care reform has the potential to create an AIDS-free generation by dramatically expanding access to medical care, life-saving HIV treatment, and screening. The National HIV/AIDS Strategy, our country's first, sets a new course for an AIDS-free generation, but its success may be in jeopardy without full implementation of the Medicaid expansion.

The expansion of Medicaid will have a profound impact on Ryan White HIV/AIDS Program clients. A large proportion of current AIDS Drug Assistance Program (ADAP) and Ryan White Program clients have incomes of 133% federal poverty level (FPL) or below and are not currently insured. According to the most recent ADAP Monitoring Report, 56% of ADAP clients served in June 2011 had incomes of 133% FPL or below and 60% were uninsured.

Section 1115 of the Social Security Act allows the Secretary of Health and Human Services to waive certain provisions of title XIX of the Social Security Act for experimental, pilot, or demonstration projects. Section 1115 waivers allow states to develop, test, and implement new approaches to providing Medicaid coverage outside of federal program rules, leading up to full implementation of the ACA. Many states have used these waivers to expand Medicaid eligibility to populations beyond those established in federal Medicaid law. A section 1115 Medicaid waiver gives states the flexibility to expand access to PLWH (either through a population specific waiver or a broader waiver that encompasses otherwise ineligible PLWH) and permit eligibility for services without having to be permanently disabled due to an AIDS diagnosis. Provision of these services to PLWH earlier in their HIV disease promotes health and improved health outcomes for this population, while reducing the risk of further transmission of HIV.

The US Department of Health and Human Services, Health Resources and Services Administration (HRSA), HIV/AIDS Bureau has asked John Snow, Inc. (JSI) to study the implementation of 1115 Medicaid waivers that have expanded Medicaid eligibility for PLWH.

The purpose of these discussions will be to learn more about the waivers in place here in a diverse array of states that have implemented these waivers in the past. Discussions are not designed to evaluate individual programs or agencies, but rather to learn more about the waivers in practice. The goal is to understand how Medicaid expansion and the 1115 Medicaid waivers will affect the Ryan White Program as well as PLWH, and how the waivers have prepared states for implementation of the Affordable Care Act. Specifically, discussions will focus on states' experiences with the waiver process, from application to implementation, and practice. JSI will

be holding similar discussion groups with Medicaid and Ryan White Program staff in a total of eight states that have implemented these waivers. Participation in these discussions is completely voluntary.

The collection of this information is authorized under Section 301 of the Public Health Service Act (42 U.S.C.241), included as Attachment A.

A2. Purpose and Use of Information Collection

Leading up to full implementation of the Affordable Care Act, states have begun to use Section 1115 Medicaid demonstration waivers as a ‘‘bridge’’ to 2014. This project will examine 1115 Medicaid waivers that have expanded eligibility to specifically include PLWH who are not otherwise eligible for Medicaid services. Given the important role of the Ryan White Program and Medicaid in meeting the health care needs of PLWH, there is a need to better understand how Medicaid expansion and the 1115 Medicaid waivers will affect the RWHAP and how the waivers have prepared states for implementation of the Affordable Care Act. Analysis of the scope of coverage under the Medicaid waiver and the extent to which essential HIV/AIDS treatment and services are covered will help state policy makers to identify potential gaps and to assess how Ryan White Program services work in conjunction with Medicaid coverage as states prepare for the ACA’s Medicaid expansion. This information will inform Ryan White Program planning and coordination with Medicaid coverage to ensure that even as people move into Medicaid, they are still able to receive the vital enabling services that may not be covered through Medicaid.

The results of these discussions will be used to develop individual case studies for each jurisdiction. Case studies will explore whether and how the 1115 Medicaid waivers have helped states and RWHAP grantees and providers prepare for implementation of the Affordable Care Act, including providing insights into Medicaid expansion. All case studies will then be analyzed as a group. A final report will be prepared for HRSA that identifies key themes across the sites, unique challenges and successes, and any lessons learned that could affect the Affordable Care Act implementation as well as help policymakers understand how Medicaid expansion will affect the Ryan White Program and PLWH in the future.

A3. Use of Improved Information Technology and Burden Reduction

Information technology solutions can often reduce burden and streamline data collection in cases where data are collected more than once. In this case, however, data will be collected only once, and collection time is estimated to be less than two hours per participant.

We will collect only the minimum information necessary for the purposes of the project. In this case, respondent burden will be minimized through a pilot-tested tool that includes on the minimum information necessary, and data will instead be collected through in-person or telephone-based interviews (included as Attachments B, C, D and E).

Data collection has been further minimized through in-depth review of how each state has implemented their waiver, and as such our interviewers will not collect information from participants if it is already publically available.

The purpose of these interviews is to gather data on the variety of ways that states that have implemented 1115 Medicaid waivers, and as such (because experiences are expected to vary widely) the data collection process must be flexible, and we have determined that in-person interviews will be the most effective use of participants' time, and also the most efficient way to capture this information. Finally, information to be gathered will be based on participants' programmatic experience, and as such is not available from existing electronic or other records.

A4. Efforts to Identify Duplication and Use of Similar Information

To date, no other federal research project has analyzed a national sample of 1115 Medicaid waivers to assess impact on Ryan White Program funded services. The research team has conducted an extensive review of existing literature on 1115 Medicaid waivers. Research in this area has focused on how 1115 waivers have been structured and funded; however, there has been very little analysis of the waivers' impact on specific populations or their impact on other safety net programs such as the Ryan White Program. While we are aware of several ongoing projects examining the California 1115 waiver in particular, these projects focus only on California and have not compared the California experience across other states and waiver designs. Further, these projects have also not included informant interviews with the state HIV/AIDS program (i.e., the state's AIDS Director and AIDS Drug Assistance Program Coordinator), which is a key part of our interview plan. We have also been in conversation with a range of additional stakeholders, including the National Alliance of State and Territorial AIDS Directors and state HIV/AIDS advocates to monitor any similar research efforts and will continue to collaborate with these stakeholders moving forward.

A5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

A6. Consequences of Collecting the Information Less Frequently

Failure to collect the data and information described above will hamper our ability to effectively analyze the impact of 1115 waivers on the Ryan White Program. Informant interviews are necessary to assess transition to Medicaid coverage, the extent to which gaps in essential services exist even with Medicaid coverage, and the role that the Ryan White Program plays in coordinating with Medicaid coverage to ensure access to comprehensive HIV/AIDS care and treatment. This information will inform state implementation of the ACA's Medicaid expansion to ensure that Medicaid works in coordination with the Ryan White Program and will inform the future of the Ryan White Program in a post-ACA environment more broadly.

Data will be collected only once per participant.

There are no legal obstacles to reduce the burden.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No other special circumstances apply.

A8. Comments in Response to the Federal Register Notice/Outside Consultation

Section 8A: A 60-day Federal Register Notice was published in the *Federal Register* on April 19, 2013, vol. 78, No. 76; pp. 23570-23571 (included as Attachment F). Two comments were received in support of the project. One correspondent expressed an interest in her organization being involved in the project and requested more information on the project. Information on the project including potential sites for the project was provided. The second correspondent confirmed the need for and potential value of the proposed evaluation. Support for the use of qualitative interviews also was provided. The correspondent's support was acknowledged in a response.

Section 8B: The individuals below were directly consulted on the interview tools, and participated in a pilot test of the instruments. All consultations occurred in May and June 2013, and no major problems were identified. Other than the public comments noted in Section 8A above and the individuals consulted below, no additional public contacts or opportunities for comment were conducted.

- Michael Goldrosen, Director, HIV/AIDS Services Division, Infectious Disease Bureau, Boston Public Health Commission, mgoldrosen@bphc.org, 617.534.2370.
- Craig Wells, Deputy Executive Director and HIV Drug Assistance Program Director, Community Research Initiative of New England, cwells@crine.org, 617.502.1734.
- Kathleen Clanon, MD, Interim Chief Medical Officer, Alameda County Health Care Services Agency, Kathleen.Clanon@acgov.org, 510.618.3452.
- Sophy Wong, Medical Director, Alameda Health Consortium, sophy.wong@gmail.com, 510.297.0233.
- Karen Mark, Interim Chief, Office of AIDS, California Department of Health, karen.mark@cdph.ca.gov, 916.449.5905

A9. Explanation of any Payment/Gift to Respondents

No payments or gifts will be provided to respondents.

A10. Assurance of Confidentiality Provided to Respondents

At the beginning of each interview, the participant will be informed that information collected during interviews will not attributed to any individual by name, but that the final report will include the names of all individuals who participated in the study, and may include examples of the waivers' impact in specific locations.

The project has been reviewed by the JSI IRB and is exempt from human subjects protection oversight as permitted in CFR 46.101 (b) 2. With the current methodology, no further IRB involvement or approval is required (included as Attachment G: IRB Waiver Letter).

A11. Justification for Sensitive Questions

None of the interview questions are of a personal, sensitive or private nature. Participants will be asked only about their programmatic experience of implementing the 1115 Medicaid waiver in their jurisdiction or at their organization. Information collected during interviews will not attributed to any individual by name. However, the final report will include the names of all individuals who participated in the study, and may include examples of the waivers' impact in specific locations.

A12. Estimates of Annualized Hour and Cost Burden

12A.

Exhibit 12-A: Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
State Medicaid agency representatives	Qualitative Interview Data Collection Tool for State Medicaid Agency Groups	40	1	2	**80**
Ryan White Part A administrators	Qualitative Interview Data Collection Tool for Ryan White Part A Administrators and Members of Planning Councils	64	1	2	**128**
Ryan White Part A planning council members*	Qualitative Interview Data Collection Tool for Ryan White Part A Administrators and Members of Planning Councils	16	1	2	**32**
Ryan White Part B and ADAP directors	Qualitative Interview Data Collection Tool for Ryan White Part B and ADAP (AIDS Directors, Part B Coordinators and ADAP Coordinators)	80	1	2	**160**
Ryan White Part C grantees and similar clinical providers	Qualitative Interview Data Collection Tool for Ryan White Clinical Providers (RW Part C Grantees	80	1	2	**160**

	in clinical settings or Similar Clinical Care Providers)				
Total		**280**			**560**

* We will interview 10 individuals for each state's Part A program. Of these, we estimate that two will be planning council members.

12B.

Exhibit 12-B: Estimated Annualized Burden Costs

Type of Respondent	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Costs**
State Medicaid agency representatives	**80**	**$36.42**	**$2,913.60**
Ryan White Part A administrators	**128**	**$39.86**	**$5,102.08**
Ryan White Part A planning council members	**32**	**$0 (volunteer)**	**$0.00**
Ryan White Part B and ADAP directors	**160**	**$36.42**	**$5,827.20**
RW Part C grantees and clinical providers	**160**	**$45.54**	**$7,286.40**
Total			**$21,129.28**

A13. Estimates of other Total Annual Cost Burden to Respondents or Recordkeepers/Capital Costs

There are no direct costs to respondents other than their time to participate in the study.

A14. Annualized Cost to Federal Government

The total project budget is $496,450. The estimated total cost of the data collection-related tasks of this activity to the government are estimated to be 72% of overall project costs, or $357,444.

The estimated annual and total costs listed in the table below correspond to the cost of the primary data collection component of this project. All data collection activities will occur within nine months following OMB clearance; therefore the estimated annual cost will also be $357,444. The annualized contractual cost as well as the annualized federal cost to support the

HRSA Contracts Officer Representative (COR) and Health Scientist is provided in the table below.

Exhibit A-14: Estimated Annual and Total Cost

Task/Activity	Federal Salary Grade	Percent Effort	Annualized Cost
Data collection and data entry			$294,124
Data analysis and reporting			$63,320
HRSA COR	GS-15-9	7%	$10,885
HRSA Health Scientist	GS-14-10	7%	$9,574
Total Annualized Cost			$377,903

A15. Explanation for Program Changes or Adjustments

This is a new data collection.

A16. Plans for Tabulation, Publication, and Project Time Schedule

Qualitative data gathered from state Medicaid programs and RWHAP participants will be the foundation for the case studies JSI will develop for HAB. These data will be collected during discussions with individuals and groups in each state.

All discussions will be audio recorded, and notes will be taken by a member of the JSI research team. A final set of notes for each discussion will be prepared in Word® format, using the audio recordings for confirmation and verification. These notes will then be compiled into a single document for each state, representing the raw qualitative data. Using the compiled data for a state, the JSI research team members who participated in the discussions in that state will develop a case study that summarizes the Medicaid expansion and its impact on the RWHAP.

The state-specific case studies will be developed using standard qualitative techniques. First, the team will review the compiled notes document, and during a facilitated group process, develop a list of preliminary themes and subthemes. These will be derived primarily through analysis of concept repetition (meaning, how often similar ideas were expressed across the different experts) and through investigator triangulation (meaning that themes were identified and confirmed independently by more than two members of the team). Concept repetition will be facilitated using standard manual or digital coding and search functions within Word/Adobe software platforms. It is not anticipated that qualitative data analysis software will be needed. However, if the team feels that its analysis and case studies will be enhanced by such software, the identified themes will be used as the basis for coding the compiled notes in NVivo® (Version 9.0, QSR International; Cambridge, MA).

In addition to individual case studies, JSI will prepare a final report that synthesizes across the case studies to identify common themes, unique findings, best practices, lessons learned,

missteps, successes, and challenges. This final report will be developed similarly to the individual case studies. The case study documents will be reviewed by the entire team, and common and unique themes will be identified using a facilitated group process.

Information collection will not use statistical methods such as sampling, imputation, or other statistical estimation techniques. As such, Supporting Statement B is not included with this submission.

Our scope of work does not entail dissemination of results, other than presentation within HRSA. Data collection will be completed within six months after OMB approval is granted. Data collection, data analysis, and report of findings will be completed within nine months after approval.

Exhibit A-16: Project Time Schedule

Activity	Time Schedule
Data collection and data entry	Beginning 1 month post OMB approval, ending 6 months post OMB approval
Data analysis, drafting of case study reports	Beginning 2 months post OMB approval, ending 6 months post OMB approval
Submit case study reports to HRSA for review and comment, finalize case study reports	Beginning 7 months post OMB approval, ending 8 months post OMB approval
Prepare draft of the final project report, submit to HRSA for feedback, finalize final project report	8 months post OMB approval
Present findings to HRSA	9 months post OMB approval

A17. Reason(s) Display of OMB Expiration Date is Inappropriate

HRSA does not seek this exemption.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

Attachments

Attachment A: 42 U.S.C.241

Attachment B: Qualitative Interview Data Collection Tool for State Medicaid Agency Groups

Attachment C: Qualitative Interview Data Collection Tool for Ryan White Part A Administrators and Members of Planning Councils

Attachment D: Qualitative Interview Data Collection Tool for Ryan White Part B and ADAP (AIDS Directors, Part B Coordinators and ADAP Coordinators)

Attachment E: Qualitative Interview Data Collection Tool for Ryan White Clinical Providers (RW Part C Grantees in clinical settings or Similar Clinical Care Providers)

Attachment F: 60 Day Federal Register Notice

Attachment G: IRB waiver letter