Supporting Statement A

Teaching Health Center Graduate Medical Education (THCGME) Program Cost Evaluation

OMB Control No. 0906-XXXX

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Health Resources and Services Administration (HRSA) is requesting OMB approval for a new information collection request for the Teaching Health Center Graduate Program (THCGME) Program Cost Evaluation.

Section 5508 of the Patient Protection and Affordable Care Act of 2010 (ACA) established the THCGME program under Title III, Section 340H of the Public Health Service Act (42 U.S.C. 256h). The purpose of this program is to increase the number of new primary care physicians and dentists, especially in rural and underserved settings. The THCGME program provides Graduate Medical Education (GME) funding to community-based settings to train primary care residents in order to address primary care access issues, particularly in rural and underserved settings. The funding model for the THCGME program differs significantly from traditional Medicare GME, which supports residency training in hospitals, making it difficult for training to occur in ambulatory, community-based settings. Under THCGME, GME funding goes directly to the THCs, enabling these residency programs to train future primary care physicians who are more likely to continue practice in underserved and rural settings. The THCGME program also develops primary care expertise to care for patients in their communities, ultimately increasing the abilities and competencies of primary care physicians and dentists to provide high quality, community-based primary care.

The THCGME program provides GME payments directly to the THCs, at a Per Resident Amount (PRA) rate set at $150,000 per resident per year. An interim PRA was set by HRSA, until such time that the Secretary of HHS defined a direct and indirect payment formula for the program through regulations. The George Washington University (GW) conducted a cost evaluation to identify a PRA that was empirically based on expenses and revenues incurred by THCs who had residents in the 2013-2014 Academic Year. GW collected financial information from THCs using a customized THCGME Costing Instrument. GW's original evaluation (completed in 2016) estimated the PRA at $157,602 in 2017 dollars, based on data from 26 THCs whose data were sufficient for the cost evaluation. Since the time of that estimate, the THCGME program has expanded, with 56 THCs currently running programs with full complements of primary care residents. In September 2019, GW was awarded a three-year contract from HRSA to conduct an updated evaluation of the costs of residency training at THCs, including identifying both direct and indirect expenses and representing the full cohort of THCs currently training residents. This updated cost estimate will provide HRSA with a methodology to determine appropriate THCGME program payments for direct medical expenses (DME) as well as indirect medical expenses (IME).

2. Purpose and Use of Information Collection

The purpose of the current contract is to develop a robust cost estimate of how much residency training costs in THCs. The THCGME Costing Instrument will provide cost information to address the following questions in the HRSA evaluation contract:

- What are the DME and IME costs of training primary care residents in THCs?
- What are the impacts of THC characteristics on direct and indirect costs of residency training?
- What are the ways in which residency training impacts overall operations of THC settings such as FQHCs or other sponsoring organizations?
- What sources of in-kind funding do THCs receive that they would otherwise need to account for in running a residency program?
- How should "opportunity costs" (e.g., time spent teaching vs. patient care by THC providers/faculty members) or other indirect costs be considered in the cost analysis?

The THCGME Costing Instrument (attached in Appendix A) will be administered once to all the THC residency programs. The information gathered in the THCGME Costing Instrument will include, but is not limited to, numbers of precepted visits, faculty and resident salaries and benefits, the costs of medical malpractice insurance, educational programming, administrative support, consortium fees, and patient care. It will also include clinical revenue generated by the residents, financial reports for data validation purposes, as well as general program information to understand the characteristics of THCs and sponsoring institutions that are involved with residency training. The data collected in the THCGME Costing Instrument will provide HRSA with a full methodology to inform efforts to develop direct and indirect payment formulas for the THCGME program.

3. Use of Improved Information Technology and Burden Reduction

The THCGME Costing Instrument has been developed so that it utilizes technology to administer, collect, and analyze the data collected. The THCGME Costing Instrument will be implemented using fillable excel forms. All of the responses (100%) will be collected and submitted electronically.

4. Efforts to Identify Duplication and Use of Similar Information

The THCGME Costing Instrument collects standardized costing information from THC residency programs. Implementation of a standardized THCGME Costing Instrument with all THCs will be critical to establish a reasonable and reliable estimate of the cost per resident for THC residency programs, and to determine the areas and degrees of variation between programs. A previous study conducted by GW provided a methodology to categorize expenses and revenues specific to residency programs; we will use this methodology in the current study with cost data that reflects more recent and accurate THC experience. Since 2015, there has been no other systematic collection of this information in the field. The THCGME Costing Instrument will be made available to the individual THCs to continue collecting relevant costing information and to add to it as needed.

5. Impact on Small Businesses or Other Small Entities

The majority of programs fall under the category of small entities. For example, many of the THCs are small community-based non-profits formed to meet the requirements to qualify for THC residency grants and have fewer than 30 employees. In nearly all cases, the entity is "not dominant in its field of operation." Wherever possible, the THCGME Costing Instrument captures information collected as part of the financial management of the organization. We have developed guidance that facilitates completion of the THCGME Costing Instrument and will be providing additional assistance to the programs throughout data collection. The THCGME Costing Instrument focuses on specific costs that measure day-to-day operations and characteristics of the individual programs.

All the organizations have someone who is responsible for financial management and operations, and the THCGME Costing Instrument was designed to be completed by personnel already available within small residency programs.

6. Consequences of Collecting the Information Less Frequently

It is necessary to implement the THCGME Costing Instrument to gather information about the financial framework of the programs. Respondents will complete the data collection tool once. If the data collection is not conducted, HRSA will not be informed with a methodology to appropriately provide payment formulas for DME and IME costs. There are no legal obstacles to reduce the burden.

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

In this request, all guidelines are met and this request fully complies with the regulation. No special circumstances are related to the evaluation.

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

A 60-day Federal Register Notice published in the Federal Register on April 30, 2020, vol. 85, No. 84; pp. 23975-76 (see Appendix B). There was one public comment and recommendations from the GME Expert Panel described below.

Section 8B:

The updated THCGME Costing Instrument was developed from the original THCGME Costing Instrument previously approved by OMB in 2015 for THCs to identify costs and cost off-sets, both explicit and implicit, and to better understand the reasonable cost ranges and factors that contribute to variation.

The GW team consulted with a GME Expert Panel to provide an external informed review of modifications from the original THCGME Costing Instrument and to examine the updated THCGME Costing Instrument for appropriate content, format, and DME and IME costs. The panel was constituted in November 2019 and provides ongoing consultation/expert guidance for a three-year period coinciding with the dates of the project contract (September 2019 – September 2022). The GME Expert Panel convened in November 2019 for a review of the updated THCGME

Costing Instrument. No major problems were identified by the GME Expert Panel. The consensus of the GME Expert Panel was strong support for the updated THCGME Costing Instrument as originally developed. The GME Expert Panel convened again in May 2020 for a review of the most recently updated THCGME Costing Instrument and minor revisions were suggested by the GME Expert Panel and have been made in the updated THCGME Costing Instrument included.

The feedback provided by the public comments and the GME Expert Panel included recommendations to: 1) collect information on telehealth visits in 2018-2019 as a benchmark for telehealth activity post COVID-19 pandemic; 2) change to academic year 2018-2019 for the data collection period; 3) further solidify the IME methodology for the non-THC Federally Qualified Health Center comparison group; and 4) enhance the THCGME Costing Instrument and Instruction Guide. After consideration of the comments, a few line items in the THCGME Costing Instrument and Instruction Guide were further clarified. These line item changes are on the Faculty Salaries and Benefits worksheet and include: defining part time faculty as "other faculty" and separating clinic administrative time into two columns to specify resident-related and non-resident related clinic administrative time.

9. Explanation of any Payment/Gift to Respondents

Respondents will not receive any payments or gifts.

10. Assurance of Confidentiality Provided to Respondents

The THCGME Costing Instrument will be implemented one time with the full cohort of HRSA-funded THCs. As noted above, the THCGME Costing Instrument collects financial and budget data on the residency program and will be implemented as a fillable excel form delivered via e-mail to the THC primary contact person. Completed THCGME Costing Instruments will be exported to a password-protected database. All data will be stored on password-protected secure computers in locked offices. Data reported back to HRSA will be reported on an individual THC basis and as aggregate findings. Any publicly available documents using data from the THCGME Costing Instrument will use aggregate findings only. Publicly available data will include the mean, range and standard deviation of costs to train a resident across all THCs.

The project has been deemed Not Human Subjects Research from IRB, and further review was not required. A copy of the IRB Outcome letter is attached in Appendix C.

11. Justification for Sensitive Questions

The THCGME Costing Instrument asks programs to report their financial information, which may be considered sensitive. The financial information collected in the THCGME Costing Instrument is necessary, as it provides the basis for developing an accurate estimate of the cost of training a resident in a community-based setting. Further, this information is essential in determining if the THCs are funded at the correct amount, and in adjusting the program in future years, as needed. Completion of the THCGME Costing Instrument is voluntary. If financial information is not feasibly collected or reported, programs may choose to leave those fields in the THCGME Costing Instrument blank.

12. Estimates of Annualized Hour and Cost Burden

This section summarizes the total burden hours for this information collection in addition to the cost associated with those hours.

12A. Estimated Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
THC Program Directors and/or Financial Officers	Teaching Health Center Costing Instrument	56	1	56	10	560
Total		56		56		560

12B. Estimated Annualized Burden Costs

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
THC Program Directors and/or Financial Officers	560	$98.02[1]	$54,891.20
Total	560		$54,891.20

[1]Program directors of residency programs are required to be physicians as part of the residency program academic accreditation. Therefore, we used the average hourly wage of physicians provided by the Bureau of Labor and Statistics to calculate the total respondent costs in the table above. The link to the hourly wage information can be found here: http://www.bls.gov/oes/current/oes291069.htm

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

Other than their time, there is no cost to respondents.

14. Annualized Cost to Federal Government

The systems used to collect the data will be at GWU and the cost to the government for this contract is $645,949 annually. It is estimated that the amount of staff time needed for the contract representative and review and approval of reports is 2 FTEs at the GS-13; Step level 5—for a total of $232,706. Collectively the estimated annualized cost to the government in staff time is estimated to be $878,655.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

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

Data collected through the THCGME Costing Instrument serve a number of important purposes including strengthening program performance, responding to federal reporting requirements, and responding to congressional inquiries. Since programs are publicly- funded, data collected may be showcased in peer-reviewed articles, conferences, and/or reports published through and/or sponsored by HRSA. In the case of publication, all THC identifiable information will be aggregated and de-identified.

The time schedule for the project is as follows:

Distribution of the THCGME Costing Instrument: The GW team anticipates distributing the THCGME Costing Instrument 1-2 weeks following OMB approval. They will use the organization's 2018-2019 academic year data for the analysis.

Data collection: Data collection will begin 2 weeks after OMB approval and end 32 weeks after OMB approval. Data collection and cleaning will go through a multi-stage process to ensure that the information collected from the THCs is accurate and consistent and conforms to the purposes of the costing evaluation to identify all relevant expenses and revenues associated with residency training in THC settings.

1. GW will hold technical assistance webinars to explain the THCGME Costing Instrument and data collection process to Program Directors, Chief Financial Officers, and other THC staff who will be responsible for submitting program responses for the THCGME Costing Instrument.
2. Like the previous study, the GW team will ask THCs to complete the THCGME Costing Instrument to the best of their ability and submit it to GW.
3. The GW team will conduct a virtual site visit with each THC to jointly review the THCGME Costing Instrument and make changes in real time, based on discussions with the THC staff, as determined by GW and the THC Program Director.
4. The GW team will supplement the THCGME Costing Instrument data with other secondary sources to support or enhance direct data collection, and to inform their understanding of the THC data. These secondary data sources include the Uniform Data System data, Medicare Cost Reports, and findings from peer-reviewed and grey

literature. These secondary data sources may identify additional common cost elements among THC FQHCs and non-THC FQHCs as well as unique features of THCGME programs.

The GW team anticipates having additional communications via telephone or email with the THCs throughout the data collection process to follow-up, verify, and assist with ongoing questions in relation to the THCGME Costing Instrument.

The analysis plan for cleaning, analyzing, and reporting data will consist of the following steps:

Step 1: Data cleaning: Data cleaning will begin 12 weeks after OMB approval and end 50 weeks after OMB approval. Data will be cleaned using a series of predetermined analytic rules within 30 days of receipt at GW. Errors or discrepancies in the data will be flagged and resolved with individual THCs where appropriate. GW may request documentation as part of the validation process. These requests would take place on an ad-hoc basis. This documentation may include: general ledgers and trial balances used in the THCGME Costing Instrument, audited financial statements for the periods covering the academic year, source documentation as needed, and supporting schedules to develop a cross-walk between the general ledger and the THCGME Costing Instrument. They expect that THCs will have these documents readily available since they will need the documents to complete the THCGME Costing Instrument. These document requests do not present an additional burden to the THCs.

Following the GW study team's internal review and quality checks, data will be reviewed and validated by two external GME auditing experts. A final review will be conducted by the GW study team. Because they fielded the original THCGME Costing Instrument, they are familiar with the types of responses they are likely to get from programs, including inaccuracies or incomplete answers before data went through an extensive cleaning process. The study team can anticipate some of the challenges that THCs will have completing the updated THCGME Costing Instrument. They will develop a list of data elements, assumptions, examples, hypothetical scenarios, or other information to facilitate an efficient and high-quality data reporting process.

Step 2: Analysis. Data analysis will begin 48 weeks after OMB approval and will end 92 weeks after OMB approval. Analysis of all data will be conducted under the THC Evaluation contract. In this second step, the GW study team will first identify the descriptive statistics of the THCs in the full data sample. Then, GW will begin construction of the data set through conducting an analysis of THCs by major categories of expenses and revenues. The GW study team will identify cost estimate formulas for DME and IME costs for residency training in THCs. To the extent possible, GW will develop adjustments to the formulas based on various THC characteristics, such as size, geographical location, specialty, and governance model.

Step 3: Reporting. Data reporting will begin 53 weeks after OMB approval and will conclude no later than 90 weeks after OMB approval (6 weeks prior to the end of the contract). GW will provide HRSA with data on all THCs individually identified. However, in the case of publication, all specific THC identifiable information will be aggregated and de-identified.

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

The OMB number and Expiration date will be displayed on every page of every form/instrument.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.