

Justification for Nonmaterial/Nonsubstantive Change

Project Title: National Hypertension Control Initiative

Department of Health and Human Services  
Office of Minority Health  
Rashmita Subedi, Project Officer  
Rashmita.Subedi@hhs.gov  
301-284-2289

JUSTIFICATION FOR NONMATERIAL/NONSUBSTANTIVE CHANGE  
NATIONAL HYPERTENSION CONTROL INITIATIVE

**Purpose of this submission:** This submission is being submitted for a proposed non-substantive change to an existing information collection approval, OMB Control Number 0990-0482, of the National Hypertension Control Initiative (NHCI). This submission seeks to make some non-substantive changes to two data collection instruments aggregating data from community health centers (CHCs) and community-based organizations (CBOs) based on lessons learned from information collected in 2022. Adjustments to some questions/items are intended to clarify the intent of the questions and ease respondent burden.

**Background**

As part of the federal response to COVID-19, the U.S. Department of Health and Human Services (HHS) funded a new initiative involving two cooperative agreements with the American Heart Association (AHA) to improve COVID-19-related health outcomes by addressing hypertension (high blood pressure) among racial and ethnic minority populations. According to the Centers for Disease Control and Prevention, having high blood pressure may increase the risk of severe illness from COVID-19.

The \$32 million project from the HHS Office of Minority Health (OMH) and the Health Resources and Services Administration (HRSA) Bureau of Primary Health Care is implementing a national initiative to improve blood pressure control among the most at-risk populations, including racial and ethnic minorities. The three-year project is supporting 350 participating HRSA-funded community health centers by providing patient and provider education and training for effective hypertension control as well as integration of remote blood pressure monitoring technology into the treatment of hypertension for patients served by participating health centers. The project is also utilizing the American Heart Association's targeted media campaigns and collaborating community-based organizations (CBOs) to help reach Black, Latino, and other impacted communities with i) culturally and linguistically appropriate messages, ii) access to blood pressure screenings, and iii) connection to health centers to encourage proper treatment and management of hypertension of screened individuals. **This initiative serves to increase the number of adult patients with controlled hypertension and reduce the potential risk of COVID-related health outcomes.**

AHA's objective is to identify promising approaches/best practices that combine new blood pressure measurement technology, lifestyle/behavioral modifications, and locally targeted media campaigns to address uncontrolled – including undiagnosed – high blood pressure, especially in racial and ethnic minority, American Indian/Alaska Native and other at-risk populations, given the association of hypertension with worse COVID-19 health outcomes.

**Proposed non-substantive changes for CHC data collection**

**Ongoing data collection from CHCs.** In 2022, the American Heart Association administered an online survey consisting of 34 multiple-choice and numeric entry questions, with skip logic applied to minimize CHC respondent burden. The survey was fielded between July 19 and July 29, 2022. Of the 350 CHCs that were sent the survey, 225 completed the survey.

**Non-substantive change request.** Table 1 outlines the proposed changes to the current CHC data collection instrument. Changes to specific parts of the question are highlighted to accentuate what is being changed. Notably, the proposed changes seek to clarify question verbiage, remove a duplicative question, and include two additional questions to better understand aspects program delivery. Further, the CHC data collection has been changed from a quarterly to a bi-annual cadence. Thus, the proposed nonsubstantive changes results in a net decrease in participant burden by approximately 50% as compared to the original submission. This reduction is reflected in the corresponding burden hours table.

**Table 1: Summary of proposed non-substantive changes to CHC data collection instrument**

	Original Question (2022 data collection)	Reason for change if any	Non-substantive change
#	General Observations/Comments		
	Ensure data collection timeframe is changed from quarterly to bi-annually	Reduce burden for CHCs	Change “between April and June 2022” to respective bi-annual period. Start with “July and December 2022”
	Patient Demographics and Outcomes		
3	How many adult patients did your health center see (via in-person or telehealth visits) for any reason <b>between April and June 2022</b> across all NHCI HRSA-funded sites? (i.e., total number of adult patients seen, according to UDS exclusion criteria) [input number]	Clarify to assess unique patients	How many <b>unique</b> adult patients did your health center see (via in-person or telehealth visits) for any reason <b>between April and June 2022</b> across all NHCI HRSA-funded sites? (i.e., total number of adult patients seen, according to UDS exclusion criteria) [input number]
4	How many adult patients (ages 18-85) had a visit and diagnosis of essential hypertension starting before and continuing into, the measurement period of April to June 2022? [input number]	Clarify to assess unique patients	How many <b>unique</b> adult patients (ages 18-85) had a visit and diagnosis of essential hypertension starting before and continuing into, the measurement period of April to June 2022? [input number]
5	Do you know how many of your adult patients (ages 18-85) had their most recent blood pressure adequately controlled (systolic blood pressure < 140 mmHg and diastolic blood pressure < 90 mmHg) between April and June 2022?  a. Yes b. No c. I don’t know d. No, but I can estimate the percentage	Reorder response options to reduce confusion	“I don’t know” should be last

	Original Question (2022 data collection)	Reason for change if any	Non-substantive change
8	<p>Between April and June 2022, what populations have you reached with materials on the importance of blood pressure screenings, self-measured blood pressure, and blood pressure management? (Select all that apply.)</p> <ul style="list-style-type: none"> <li>a. Hispanic, Latino, or Spanish-speaking populations</li> <li>b. Asian</li> <li>c. Native Hawaiian Other Pacific Islander</li> <li>d. Black/African American</li> <li>e. Indian or Alaska Native</li> <li>f. White</li> <li>g. More than one race</li> <li>h. Unreported or Unknown</li> <li>i. None of these</li> </ul>	Clarify “populations” and make specific to patients.	Between April and June 2022, what <b>patient</b> populations have you reached with materials on the importance of blood pressure screenings, ...
9	<p>What is the minimum number of patients that you are trying to reach with SMBP support?          [Input numerical number]</p>	Clarify question to ensure respondents respond with the number of patients HRSA requires them to reach – 51% of their patient data	<p>HRSA requires grantees to set a goal to provide SMBP to at least 51% of all hypertensive patients.</p> <p>What is the minimum number of patients you are required to reach with SMBP support?</p> <ul style="list-style-type: none"> <li>a.</li> </ul>
10	<p>Please indicate the percentage of patients who received the following types of care at your health center between April and June 2022. [Response choices: Don’t Know; None; Open Ended]</p> <ul style="list-style-type: none"> <li>a. Offered an SMBP device?</li> <li>b. Accepted an SMBP device or participation in an SMBP program?</li> <li>c. Trained in how to use an SMBP device?</li> <li>d. Transmitted readings from the SMBP device (via an App, portal, or platform)</li> <li>e. Had SMBP data reviewed by the care team</li> <li>f. Had a treatment change based upon the SMBP data (such as adding a medication)</li> <li>g. Experienced a change in their BP as a result of a medication change</li> <li>h. Achieved BP control</li> <li>i. Were discharged from an SMBP program?</li> </ul>	<p>The percentage ranges offered for this question are too wide to detect change over time. (0-25; 26-50;51-75; 76-100%).</p> <p>Drop option “i” as it carries multiple meanings – dropping out due to end of program or could be due to other clinical health trigger.</p>	<p>Change response options to:</p> <ul style="list-style-type: none"> <li>a. [enter percentage]</li> <li>b. None</li> <li>c. Don’t know</li> </ul> <p>IF “Don’t know”</p> <p>Can you estimate the percentage of patients?</p> <ul style="list-style-type: none"> <li>a. 0-20 %</li> <li>b. 21-40%</li> <li>c. 41-60%</li> <li>d. 61-80%</li> <li>e. 81-100%</li> </ul>

	Original Question (2022 data collection)	Reason for change if any	Non-substantive change
			f. Don't know
<b>Measure Accurately</b>			
11	Does your health center have a documented protocol or process for blood pressure measurement for adults aged 18 or older with hypertension? a. Yes b. No (skip next question) c. I don't know (skip next question)	Clarify meaning/intent of question	Does your health center have a documented protocol process or a Policy & Procedure for blood pressure measurement for adults aged 18 or older with hypertension?
12	Does your health center monitor staff compliance with this protocol or process for blood pressure measurement as part of quality improvement activities? a. Yes b. No c. I don't know	Clarify meaning/intent of question	Does your health center monitor staff compliance with this protocol or process for blood pressure measurement as part of quality improvement activities through chart review or performance observation?
New Question		New question to mirror similar concept with "Act Rapidly" question 17	Does your BP measurement protocol include any of the following? (Select all that apply) a. avoid caffeine b. avoid tobacco c. avoid exercise d. empty bladder e. assess available cuff sizes f. sit in chair, bare arm, g. engage in 5 min rest, no talking h. repeat measurement i. documentation j. notification of patient and provider
<b>Partner with Patients</b>			
21	Which of the following does your health center consistently use when educating patients on the importance of blood pressure screenings, self-measured blood pressure, and blood pressure management? (Select all that apply.)	Add additional response option	Add the following response option; "Return demonstration technique"

	Original Question (2022 data collection)	Reason for change if any	Non-substantive change
	a. Verbal instruction by any care team member in the patient’s primary language b. Printed materials in the patient’s primary language c. Printed materials designed for patients with low literacy levels d. Printed materials with images that reflect the racial or ethnic diversity of the patient receiving the materials e. Video instructions in the patient’s primary language f. I don’t know g. Other [entry box]		
22	When providing patients with materials on the importance of blood pressure screenings, self- measured blood pressure, and blood pressure management, does your health center provide population-specific materials (such as culturally competent materials for recent immigrants or refugees)? a. Yes b. No c. I don’t know	Delete the question as it’s duplicative of Q21	Delete the question as it’s duplicative of Q21
24	Between April and June 2022, which of the following lifestyle changes did any care team member in your clinic recommend to patients? (Select all that apply.) a. Avoid tobacco use b. Drink alcohol in moderation c. Follow the DASH eating plan d. Lose weight (if overweight) e. Decrease sodium intake f. Consume recommended amount of dietary potassium g. Participate in physical activity regularly h. Create stress strategies i. None of these lifestyle changes j. Other [entry box]	Add response to response options	c. Follow the DASH eating plan or Mediterranean diet a. Get adequate sleep
26	Does your health center assess the following social determinants of health? [Check all that apply] a. Participant’s housing situation b. Whether participants are facing challenges meeting household utility bills c. Participant’s refugee status d. Whether lack of transportation kept a participant from medical appointments, meetings, work, or from getting things	Add new response options to be more inclusive and revise language for clarity.	a. Housing Security b. Transportation c. Racism and discrimination d. Physical Insecurity (crime)

	Original Question (2022 data collection)	Reason for change if any	Non-substantive change
	<p>needed for daily living</p> <p>e. Whether a participant was experiencing symptoms of depression or other mental health issues</p> <p>f. Whether a participant is facing challenges with access to food to every day</p> <p>g. Whether a participant is facing challenges obtaining healthy/nutritious foods such as fruits and vegetables</p> <p>h. Other social determinants of health</p>		<p>violence)</p> <p>e. Education status</p> <p>f. Employment Status / Income</p> <p>g. Access to technology (e.g. internet, mobile phone)</p> <p>h. Access to nutritious foods such as fruits and vegetables</p> <p>i. Physical activity opportunities</p> <p>j. Social Support / Social Network</p> <p>k. Language and Literacy skills</p>
<b>Self-measured blood pressure (SMBP)</b>			
29	<p>What percent of patients with hypertension at your health center are currently participating in an SMBP program?</p> <p>a. 0% (None)</p> <p>b. 1% to 25%</p> <p>c. 26% to 50%</p> <p>d. 51% to 75%</p> <p>e. 76% to 100%</p> <p>f. I don't know</p>	Clarify place of participation and denominator	What percent of <b>all your</b> patients with hypertension at your health center are currently participating in an SMBP program <b>at your health center</b> ?
32	<p>Which competencies are included in the training on SMBP techniques? (Select all that apply.)</p> <p>a. Correct positioning</p> <p>b. Correct cuff size for arm size</p> <p>c. Use of clinically validated devices for upper arm</p> <p>d. How to record SMBP measurements</p> <p>e. How to track and relay blood pressure readings to the health center (via manual or electronic means)</p> <p>f. When to record SMBP measurement (2x in the am +</p>	Add new response option	Add "Use of a demonstration video for initial training and future reference"

	Original Question (2022 data collection)	Reason for change if any	Non-substantive change
	2x in the pm x 3-7 days g. Return demonstration or 'teach back' approach h. None of these i. Other [entry box]		
New Question		New question to assess patients rejecting SMBP program	How many patients with hypertension at your health center decline participating in an SMBP program when it is introduced to them? [insert number, I don't know]  IF "I don't know"  What percent of patients with hypertension at your health center decline participating in an SMBP program when it is introduced to them? a. 0% (None) b. 1% to 25% c. 26% to 50% d. 51% to 75% e. 76% to 100% f. I don't know



### **Proposed non-substantive changes for CBO data collection**

**Ongoing data collection from CBOs.** The NHCI is currently engaging CBOs in the EmPOWERED to Serve (ETS) Health Lessons, a curriculum offering a way to engage communities and motivate community members to take steps towards creating a culture of health. Participants are completing four training modules:

1. Control your Blood Pressure
2. Get Active
3. Know Diabetes by Heart
4. Salt and Cardiovascular Risk

At the beginning and conclusion of each module, participants are directed to an online pre/post quiz to assess their i) knowledge and ii) confidence related to blood pressure and lifestyle changes related to blood pressure control, and iii) obtain participant feedback related to ETS modules. CBOs are required to report the number of participants that completed each module, the number that completed each quiz, and the number of referrals to clinical care

**Non-substantive change request.** The current pre-post survey modules do not collect specific information on the name of the CBO each participant is engaging with. The study team intended to rely on IP addresses where surveys are completed along with identifiers submitted by respondents. The study team would like to include one additional question to specifically identify each respondent's CBO. Notably, to minimize participant burden, this question provides a drop-down menu of CBO names who are participating in NHCI activities; as such, there are no additional burden hours associated with inclusion of this question. See below:

“What organization are you affiliated with?”

Further, burden hours for the CBO ETS activities have been significantly reduced due to programmatic delays in delivery of ETS health lessons. As such, our burden hours have been recomputed to reflect these changes.

### **Estimates of Annualized Burden Hours and Cost**

#### **Burden Hours**

The total annual estimated burden imposed by this collection of information is 3,450 hours per year for the CHCs and CBOs anticipated to participate in the study, an annual decrease of 1,770 hours as outlined in the initial application for these activities. NHCI plans to implement certain strategies to ensure participant burden is as minimal as possible. CHC data collection is being shifted from quarterly to bi-annually. Overall, the CHC data collection burden is being reduced by 50% (2,100 hours in 2022 to 1,050 hours in 2023). Similarly, the CBO data collection burden is being reduced from its initial annualized estimated of 3,120 hours to a new estimate of 2,400 hours, an annual reduction of 720 hours.

While data entry for CHCs will be via an online data platform, CHCs will additionally be emailed a printable version containing all possible survey questions. This will allow participants to efficiently review all questions and confirm corresponding answers prior to accessing the

online survey, which due to its online display, would present one to two survey questions at a time. The estimated burden time per response for CHC bi-annual data collection includes any time to research question responses, as well as the time associated with accessing and entering these responses into the online data platform.

AHA will continue to engage and expand the number of CBO partners facilitating educational health lessons and providing related data as the project progresses. However, due to programmatic delays, no data were collected in year 1. As such, for the purposes of estimating CBO-related burden hours, the maximum number of CBO respondents (n=16/3, or approximately 6) for this activity is an average of the predicted number of CBO partners we should have during the entire project (i.e., 0 in year 1; 6 in year 2; 10 in year 3).

Similar logic was used to estimate the burden hours for individuals receiving ETS health lessons and completing corresponding questionnaires at CBOs; questionnaires should take an individual no longer than 10 minutes to complete. We anticipate each of our collaborating CBOs to deliver quarterly health lessons, with up to a maximum of 500 individuals receiving each lesson. Further, CBOs will work to collect questionnaire submissions from approximately 30 percent of attendees. Thus, burden hours for this component would be estimated as 6 CBO partners per year x 4 health lessons x 2 times per year x 500 participants per lesson X 0.30 participant surveys = 7,200 individuals completing pre and post surveys each year.

Type of Respondent	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
CHC health care professionals (bi-annual data entry in DREaM)	350	2	1.5	1,050
Consumers (ETS health lesson learning questionnaires)	7,200	2	10/60	2,400
Total				3,450

A. Burden Cost (average hourly rate)

Type of Respondent	Total Burden Hours	Hourly Wage Rate Respondent	Respondent Cost
Health care professionals (bi-annual entry)	1,050	\$41.30	\$43,365.00
Consumers (ETS health lesson learning questionnaires)	2,400	\$27.07	\$64,968.00
Total	3,450		\$108,333.00

The \$41.30 hourly wage rate for health care professionals is based on the U.S. Department of Labor, Bureau of Labor Statistics May 2020 report “National Occupational Employment and Wage Estimates United States” for Healthcare Practitioners and Technical Occupations.

The number of respondents and length of response was determined on the basis of survey length estimates from Qualtrics and other survey instruments. The actual numbers will vary depending upon the topic of interest.

The total estimated cost for the proposed changes to information collection corresponding to 3,450 hours of reporting time is **\$108,333.00; an overall reduction of 720 hours and \$19,501.50** from the estimates in our initial submission.