DEPARTMENT OF HEALTH & HUMAN SERVICES

Health Resources and Services Administration

Healthcare Systems Bureau
Rockville, MD 20857

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TO: Josh Brammer, OMB Desk Officer

FROM: Lisa Wright-Solomon, HRSA Information Collection Clearance Officer

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Request: The Health Resources and Services Administration (HRSA) Bureau of Primary Health Care requests approval for changes to the Health Center Patient Survey relating to COVID-19 (OMB 0915-0368 expiration date 03/31/2023).

Purpose: The purpose of this request is to make changes to the survey screening instrument, main survey instrument, and showcard booklet to expand response options due to COVID-19 and to provide clarification to questions due to the increase in telehealth services provided by health centers. Collection of this information will provide more accurate data reporting on several key measures, allowing HRSA to better track the impact of the COVID-19 pandemic on health center patients and gain a better understanding training and technical assistance, funding, and other resource needs for this and future public health emergencies . In addition to changes to the survey instruments, changes in survey design, sampling methods, and survey materials are also needed due to the onset of the COVID-19 pandemic.

This memo explains the changes and supporting rationale.

Changes: **Instruments:**

Table A includes the type of instrument that received the change, the variable name which was altered/added, a description of the change, and the rationale for the change. Attached are the patient screening instrument (Attachment 1), main survey instrument (Attachment 2), and showcard booklet (Attachment 3) with the changes tracked, for reference. The overall scope of change to the screening and main survey instrument is minimal, representing an update of existing content, except for the addition of four new questions. All edits are to address concerns and experiences related to the COVID-19 pandemic.

Survey Design, Patient Sampling and Recruitment, and Survey Materials

Because the COVID-19 pandemic has limited our ability to conduct interviews in-person, we are expanding the current survey design to a mixed-mode design (in-person and phone/video). We will start data collection with a few heath centers in 2020 with phone/video interviews only, and shift to a combination of in-person (where feasible) and virtual interviewing in 2021.

CURRENT SURVEY DESIGN AND SAMPLING PROTOCOL

The currently approved survey design is an in-person, face-to-face computer-assisted personal interview (CAPI). Interviewers visit the health center on agreed upon days with the health center. Each morning before the start of data collection, the interviewer trains the receptionist on how to recruit and sample patients. Recruitment starts when a patient walks into the health center to receive services. The receptionist will pre-screen the patient for eligibility (i.e., the patient received services from the health center the past 12 months) and provide the patient with a study brochure that has information about the study. The receptionist will keep track of the patient's age, race/ethnicity, veteran status, the total number of patients who enter the site, the number of patients who are eligible, and the number of patients who are referred to the interviewer. The counts will be used for analysis weights for the survey.

If a patient belongs to one of the oversampling groups (Asian, American Indian/Alaska Native, Native Hawaiian/Pacific Islander, 65 years and older, veteran), the receptionist will always refer the patient to the interviewer. If the interviewer is busy or unavailable, the receptionist will hand the selected patient a study material and instruct him/her to wait in a designated area. When the interviewer is available and ready, he/she will look for a patient holding the study material. If a patient belongs to a group that will not be oversampled, the receptionist will refer the first eligible patient registered after the interviewer has informed the receptionist that he/she is ready for the next interview. When the patients approach the interviewer, the interviewer will determine eligibility and population type (i.e., homeless, migrant/seasonal farmworker, public housing, or general community) with the use of the patient screener. Eligible and interested patients will be taken to a private location at the health center and administered the appropriate informed consent procedures and survey. The interviewer will read the entire consent form

from their laptop and obtain verbal consent which is recoded in the CAPI. The patient will receive $25 in cash or a cash equivalent.

PROPOSED SURVEY DESIGN AND SAMPLING PROTOCOL

The proposed alternate design will start with an all virtual (phone/video) survey mode, with the addition of in-person, face to face interviews when it is feasible to do so. Phone/Video interviews will be decentralized with interviewers conducting interviews from their homes. The initial recruitment of patients will happen at the sites on agreed upon data collection days. Each morning before recruitment begins, the interviewer trains the receptionist virtually on recruiting and sampling patients.

Specifically, we will provide two options for patient sampling and recruitment. The first, which is the preferred option, is comparable to the original sampling and recruitment procedures, except that the interviewer will not be at the site. As each patient enters the site during the sample selection period, the receptionist(s) will register him/her to receive health services and record a tally mark on the patient tally sheet. The receptionist will determine whether each arriving patient meets the initial eligibility criteria to be considered for the Patient Survey (i.e., has received services at least once in the past year and is not an unaccompanied 13–17-year-old). The receptionist will also ask eligible patients questions about their race/ethnicity, veteran status, and age to determine whether they belong to the oversampling groups. The receptionist will introduce the study to the patient and encourage them to participate. The receptionist will also hand out a study brochure (Attachment 4) and a flyer (Attachment 5). The study brochure has been slightly modified to make them appropriate for virtual interviews. The flyer is a newly created patient-facing recruitment material developed specifically for phone interviews. The flyer will have the Field Supervisor's (FS') phone number patients will need to call into in order to participate. To ensure legitimacy of the respondent, the flyer will have a unique identifier that the FS will ask for when the patient calls.
In addition to patients who walk-in to the site on the sample selection period, there are also patients who receive services through telehealth on these days. We want to include these patients in our sampling frame. We will ask health centers to inform patients who received services through telehealth about the study. These patients will also be provided with electronic copies of the brochure and flyer with the FS' contact information that will be sent via email.

When a patient calls, the FS first asks for the unique ID printed on the flyer. If the patient is able to provide the number, the FS will screen the patient for eligibility (i.e., the patient received services at least once in the past year). If deemed eligible, the FS will schedule an appointment for an interview with the interviewer.

The interviewer will call the patient at the scheduled appointment time and attempt to complete the interview. The interviewer will obtain verbal consent from the respondent and record this in the CAPI, which is the same consent protocol we established for in-person interviews. If the interview is conducted via video, the interviewer will show the showcard booklet with response categories on the screen. If the interview is done over the phone, the interviewer will send a PDF of the showcards via email if available or read the response options to the respondent.
When the interview is completed, respondents will receive a $25 gift card or a check as an incentive for participating.

If the first sampling and recruitment option does not work for the site, we will propose a second option of asking for a list of patients who visit the health center on agreed upon sampling dates. The list will contain the patient's first name, age, race, phone number and email address, if available. RTI's statisticians will randomly select patients from the list based on the currently established sampling protocols. The statisticians will provide the list of sampled patients to the FSs. FSs will then assign the sampled patients to the interviewers. The interviewer will contact the patient, introduce the study, and gain their cooperation. As with the first option, respondents will receive a $25 gift card or check as an incentive for participating.

We anticipate that not all patients will be able to complete the interview by phone or through a videocall. For example, homeless or migrant workers may have limited or no access to a telephone or a computer. One option we have considered is to interview these patients in-person at a later time, when it is feasible to do so. Another option would be to secure an interviewing room (like we would if we were interviewing in-person) at the health center and have either a phone or tablet/computer in the room where the patient can complete the interview with an interviewer interviewing virtually. Setting up a room at the health center will provide electronic access to patients who otherwise will not be able to participate in the study.

In addition to survey materials mentioned above, minor modifications were also made to the consent forms (Attachments 6 to 9) and recruitment scripts (Attachments 10 and 11) to make them appropriate for phone interviewing.

Given the unprecedented nature of the pandemic and the response of health centers to address this crisis, we feel the changes mentioned above are necessary.

Time Sensitivity: The data collection changes must be completed in a timely manner to ensure that the survey data collection schedule will not experience significant delay. Approval of these changes is needed by December 29, 2020 to implement the changes in the data collection instruments and to prepare for the timely collection of data critical to HRSA researchers.

Burden: These changes included herein do not substantially change the estimated reporting burden for health centers. Making these changes will allow HRSA researchers to accurately capture patient data in the midst of the COVID-19 pandemic response.

PROPOSED CLARIFICATIONS AND NON-SUBSTANTIVE CHANGES:

Table A

Instrument	Variable	Change implemented	Rationale
Patient Screener	S1b	Language added to clarify "in-person or telehealth" services received and a definition of "telehealth".	This is the main screening question to determine survey eligibility. It is important for patients to include telehealth services as there is an expected increase due to COVID-19.
Patient Screener	S1c	New question added to determine if the patient's most recent visit was due to COVID-19 infection.	Data on reason for visit is important and COVID-19 is likely to be an important reason for their health center visit.
Main Survey	MED2a	Response options added to include COVID-19 reasons that the patient was unable to get care.	Important to capture the various reasons and it is anticipated that COVID-19 may be one of the reasons.
Main Survey	MED5a	Response options added to include COVID-19 reasons that the patient was delayed in receiving care.	Important to capture the various reasons and it is anticipated that COVID-19 may be one of the

			reasons.
Main Survey	ROU_TELE	New question added to determine how often patient received telehealth services in the past 12 months.	The COVID-19 pandemic may result in an increase in telehealth services. This information will be helpful to complement data collected on in-person visits.
Main Survey	ROU13a	Response options added to include COVID-19 reasons that the patient did not have a well-child check-up.	Important to capture the various reasons and it is anticipated that COVID-19 may be one of the reasons.
Main Survey	CON15_COV1 CON15_COV2	Two new questions added about COVID-19 testing and test results.	Collecting data on COVID-19 testing and test results is an important component of the patient's health center experience.
Main Survey	HEA1	Wording added to question to include "telehealth visits" as an example of what the patient should not include when answering the question.	For this question, it is important to exclude "telehealth visits" and should be included in the question due to the expected increase in telehealth.
Main Survey	HEA2	Wording added to question to not include "telehealth visits" when answering the question.	For this question, it is important to exclude "telehealth visits" and should be included in the question due to the expected increase in telehealth.
Main Survey	PRS2a	Response options added to include COVID-19 reasons that the patient was unable to get prescription medicines.	Important to capture the various reasons and it is anticipated that COVID-19 may be one of the reasons.
Main Survey	PRS3a	Response options added to include COVID-19 reasons that the patient was delayed in getting prescription medicines.	Important to capture the various reasons and it is anticipated that COVID-19 may be one of the reasons.
Main Survey	DEN4	Response options added to include COVID-19 reasons that the patient was unable to get dental care.	Important to capture the various reasons and it is anticipated that COVID-19 may be one of the reasons.
Main Survey	DEN6	Expanded response options to determine whether the delay in getting dental care was due to COVID-19 or not due to COVID-19.	Important to capture whether the delay was due to COVID-19.

Main Survey	DEN8	Response options added to include COVID-19 reasons that the patient was delayed in getting dental care.	Important to capture the various reasons and it is anticipated that COVID-19 may be one of the reasons.

As a result of the expanded response categories in the main survey instrument (MED2a, MED5a, ROU13a, PRS2a, PRS3a, DEN4 and DEN8), corresponding edits were made to the showcard booklet used during the conduct of the interview to display the response options to the patient.

Attachments:

1. Health Center Patient Screening Instrument (All changes and additions are tracked in the attached document)
2. Health Center Patient Survey Instrument (All changes and additions are tracked in the attached document)
3. Patient Showcard Booklet (All changes and additions are tracked in the attached document)
4. Study Brochure (Changes are highlighted in yellow.)
5. Recruitment Flyer (This is a new form.)
6. Informed Consent Form for Adult Survey Participation – Phone version (All changes are tracked.)
7. Informed Consent Form for Parent or Guardian Proxy - Phone version (All changes are tracked.)
8. Parent or Guardian Permission Form for Accompanied Adolescent - Phone version (All changes are tracked.)
9. Assent Form for Accompanied Adolescent - Phone version (All changes are tracked.)
10. Field Interviewer Recruitment Script (All changes are tracked.)
11. Receptionist Recruitment Script (All changes are tracked.)