Request for Approval for a Nonsubstantive Change:

NATIONAL HOSPITAL AMBULATORY MEDICAL CARE SURVEY

OMB No. 0920-0278 (Exp. Date 09/30/2023)

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National Center for Health Statistics

NATIONAL HOSPITAL AMBULATORY MEDICAL CARE SURVEY Nonsubstantive Change Request

The National Center for Health Statistics (NCHS) requests a non-substantive change to the approved data collection for the National Hospital Ambulatory Medical Care Survey (NHAMCS) (OMB No. 0920-0278, Exp. Date: 09/30/2023). We are requesting changes to the 2022 NHAMCS Hospital Induction Questionnaire (**Attachment A**) and the NHAMCS Ambulatory Unit Induction Questionnaire (**Attachment B**) and the Patient Record Form (PRF) (**Attachment C**). This change is to allow the addition and modification of survey questions that will collect data which can be used to provide understanding and nationally representative estimates on experiences of the provision of COVID-19 vaccines by hospital emergency departments (EDs) as the ongoing novel coronavirus disease (COVID-19) pandemic in the United States continues to evolve; and assess the prevalence and impact of telehealth utilization in EDs. On September 4, 2020, NHAMCS was approved to collect data for three years – 2021, 2022, and 2023 – from emergency departments (EDs) of non-federal, short-stay hospitals. The current approved supporting statement included approval to modify selected sections of the 2021-2023 surveys when needed.

For the <u>Hospital Induction Questionnaire</u>, we propose the following changes:

The addition of 11 new questions:

- Three new questions will ask about the facility's conglomerate status.
- Four new questions will be related to the burgeoning field of telemedicine and its impact in the EDs (which has become increasingly more prevalent since March 2020).
- One new question will ask whether a hospital respondent can separate their hospital medical records, in the instance that a merger or separation event has been identified for that hospital.
- Three new questions related to COVID-19 vaccination efforts among health care personnel.

Two modifications:

 One existing COVID-19 introductory statement will be modified to include language about telemedicine; one existing COVID-19 question will be modified to update terminology used to refer to a suspected COVID-19 case.

The removal of 8 COVID-19 questions:

• The removal of eight of nine COVID-19 questions involving PPE shortages, the availability of COVID-19 screening areas outside the ED entrance, and clinical care providers testing positive for COVID-19 infection.

For the Ambulatory Unit Induction Questionnaire, we propose the following changes:

The addition of 5 new questions:

New Revenue, Ownership, Operation, Federal Tax ID, and Staff (ROOFS) questions (see
 Attachment B, #1) that will formally validate and/or confirm the eligibility of an ED's
 Emergency Service Area (ESA) to determine that it meets the survey's inclusion criteria for
 participation.

For the Patient Record Form (PRF), we propose the following:

The addition of two new questions:

• COVID-19 test options to the diagnostic section of the ED PRF instrument.

Finally, this submission proposes the modification of the assurance of confidentiality language given to respondents to incorporate NCHS's compliance with the Federal Cybersecurity Act of 2015 (6 U.S.C. §§ 151 & 151 note) for both induction questionnaire components.

Changes to the content in both the Hospital Induction Questionnaire (**Attachment A**) and the Ambulatory Unit Induction Questionnaire (**Attachment B**), as well as the PRF (**Attachment C**) are presented in the included attachments and are described in more detail in sections A1 and A2. The new 2022 induction interviews for both the Hospital Induction and the Ambulatory Unit Induction are presented in **Attachments D** (Hospital Induction) and **E** (Ambulatory Unit Induction).

Given that interviewers have gained efficiency in entering response options for the other non-COVID-19 and telehealth questions; and that the questions will not apply to all respondents, the relative change in the number of amended survey questions between the overall addition of 18 new questions and the removal of 8 questions from the existing survey will be absorbed by the current estimated burden calculations. Therefore, no change in burden is expected.

A1. Circumstances Making the Collection of Information Necessary

Hospital and Ambulatory Induction Questionnaires

Telehealth Justification

The COVID-19 pandemic has propelled the utilization of telehealth in health care. Due to factors such as the implementation of public health guidance and policy changes related to telehealth in health care during COVID-19, there has been a substantial increase in telehealth visits since the pandemic. According to an article in CDC's *Morbidity and Mortality Weekly Report* that analyzed telehealth use during the emergence of the COVID-19 pandemic from four large national telehealth providers, there was a 154% increase in telehealth visits in March 2020, compared to the same time in the previous year¹.

¹ Demeke HB, Merali S, Marks S, et al. Trends in Use of Telehealth Among Health Centers During the COVID-19 Pandemic — United States, June 26–November 6, 2020. MMWR Morb Mortal Wkly Rep 2021;70:240–244. DOI: http://dx.doi.org/10.15585/mmwr.mm7007a3

With this drastic increase in telehealth, it is important for NHAMCS to capture how it is used in the ED setting. Therefore, these new questions related to telehealth are designed to provide further insight into the utilization of telehealth by assessing its impact and innovation in emergency care delivery in the United States. Four questions will be used to assess telehealth: (1) the use of telemedicine technology for ED patient visits; (2) the type(s) of telemedicine tool(s) that are used during ED patient visits; (3) what proportion of ED patient visits are through telemedicine technology; (4) and the longevity of telehealth services by asking whether EDs plan to discontinue telehealth services within the next year.

The telemedicine questions being added to NHAMCS are modified from the National Electronic Health Records Survey, a survey of office-based physicians (NEHRS, OMB #0920-1015). The questions were developed by experts from the Office of the National Coordinator for Health Information Technology. Although three of the four new telehealth questions will also be used for the National Hospital Care Survey (NHCS, OMB #0920-0212) in the ED setting, the reference period for the questions is different. The NHAMCS reference period is the past four weeks, while NHCS uses the current calendar year as the reference period.

COVID-19 Questions Update Justification

To collect data on the challenges faced during the COVID-19 pandemic and the pandemic's impact on patient care and infection prevention efforts within health care facilities across the United States, a short block of questions was added to the 2021 NHAMCS. Due to the changing landscape in mitigating the pandemic since it was first proclaimed as a national emergency on March 13, 2020 (including the availability of COVID-19 vaccinations), the questions have been updated to reflect the current developments of the COVID-19 pandemic.

On December 11, 2020 the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) for Pfizer-BioNtech COVID-19 Vaccine. On December 18, 2020 the FDA issued an EUA for the use of the Moderna COVID-19 Vaccine and on February 27, 2021 the FDA issued an EUA for the Janssen COVID-19 Vaccine. On August 23, 2021, the FDA approved the first COVID-19 vaccine, known as the Pfizer-BioNtech COVID-19 Vaccine². As a result of these new advancements in COVID-19 vaccine authorizations, the current NHAMCS COVID-19 questions will be updated to evaluate these developments. This includes adding three questions about COVID-19 vaccination status among health care personnel. The new questions will assess whether: (1) the hospital has ever required or mandated COVID-19 vaccines for its staff; (2) the hospital has ever offered COVID-19 vaccinations to health care personnel/staff; (3) and the name of the COVID-19 vaccine that was offered. These questions will begin with data collection during 2022 NHAMCS.

Simultaneously, the updates to the COVID-19 questions will also include the removal of eight of nine existing questions that assessed whether EDs: (1) encountered shortages in personal protective

² U.S. Food and Drug Administration. (2021, October 26). *COVID-19 Frequently Asked Questions*. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-frequently-asked-questions#biologics

equipment (PPE), (2) created areas outside ED entrances to screen for COVID-19, and (3) had any health care providers at their facilities that tested positive for COVID-19. As the COVID-19 pandemic and strategies to address it continue to evolve, specifically as attention moves to towards COVID-19 vaccination as a primary form of prevention, more relevant questions are needed to be included. Thus, these questions will be removed to make room for questions centered on prioritized interests such as COVID-19 vaccination status and bridging care through telemedicine.

To continue assessment of the pandemic's impact on ED burden and emergency care, the question assessing whether an ED has turned away or referred elsewhere suspected positive COVID-19 patients will be retained; however, the question will be modified to replace the word "presumptive" with the word "suspected" to align with the common health care terminology that is currently used to categorize cases.

The inclusion of these new and updated COVID-19 related questions will continue as long as such data related to COVID-19 and health care provision are still relevant. It is expected that health care provision at hospital EDs for the virus will be ongoing and cumulative. Therefore, it is imperative that we plan to collect data on hospital ED experiences with COVID-19 in 2021 and beyond.

Other hospital-based surveillance systems such as the National Healthcare Safety Network (NHSN, OMB#0920-0666) have created reporting systems for more real-time data for surveillance purposes. Although NHSN has questions about COVID-19 in the hospital setting, none of them are duplicative of the questions proposed for NHAMCS. NHSN asks if the facility is a COVID-19 vaccination provider, however, the proposed NHAMCS question asks specifically about whether the facility provides COVID-19 vaccination for healthcare personnel/staff. Additionally, NHSN asks about which vaccination healthcare personnel/staff received; however the question asks about vaccination received any place while our proposed question is about vaccination made available at the hospital facility for healthcare personnel/staff only. NHAMCS already collects characteristics and information about the hospital and ED. In addition, the methodological rigor of NHAMCS and its large sample size is expected to result in enough statistical power to yield reliable data.

Conglomerate Justification

To improve the collection of survey responses, limit burden, and to increase the efficiency of the recruitment process of sampled hospitals in NHAMCS, three questions (including one sub-question) either confirming the hospital's association with a conglomerate or hospital group or confirming the hospital's association with a named conglomerate or hospital group (if the name is available) will be added. The hospital respondents will also have the opportunity to either update or enter the name of their conglomerate. By getting information about the hospital's conglomerate, NHAMCS can work with the conglomerate's central contact to accommodate the induction of all sampled hospitals that share the same conglomerate simultaneously; and in doing so streamline the recruitment process and eliminate some redundancy that at times may add unnecessary burden.

Eligibility Status Validation Justification

In addition, five new ROOFS questions that will improve the verification process of an emergency service area's (ESA) eligibility status in the survey will be added. This assessment process, known internally as the ROOFS criteria, has been included as part of the NHAMCS interviewers' training to help the interviewers determine an ESA's eligibility in the survey. However, starting in 2022 NHAMCS, these criteria will be formally incorporated into the instrument as a validation tool to help assess whether each ESA in the ED is eligible for NHAMCS.

An ESA is eligible for participation if they meet the following criteria:

- **Revenue:** All revenues from the satellite facility are forwarded directly to the hospital in sample.
- **Ownership:** The satellite facility is owned by the hospital in sample.
- **Operation:** The satellite facility is operated by the hospital in sample.
- <u>Federal tax ID</u>: The federal tax ID of the hospital and satellite facility should be the same. An exception to this is when a health system owns several hospitals that all have the same federal tax ID. In this case, only ESAs associated with the sample hospital should be included.
- Staff: The staff should either be paid directly by the hospital or contracted by the hospital.

Questions verifying these criteria will be added to better capture this eligibility validation, based on learned experiences in the field during the induction phase, and its addition will help to prevent the inclusion of ESAs that are ineligible for participation in NHAMCS which will subsequently improve the survey's data quality.

Separate Medical Records Question Justification

Currently there are three questions that assess the respondents' merger status. The first question asks whether a hospital respondent has merged or separated from any other hospital in the past two years, the second question confirms whether it was a merger or separation, and the third question determines whether the hospital has its own medical records department that is separate from the other hospital(s) it has either merged with or separated from.

To improve the assessment and/or determination of a merger hospital's inclusion in the survey, a new question (**Attachment A**, #4) will be added that asks about the status of a merged or separated sampled hospitals' medical records. This question will help determine whether the medical records from the merged or separated sampled hospital can be identified and separated from the other hospital(s) medical records for purposes of NHAMCS abstractions. In answering this question, the ability to abstract eligible patient visits from a merged or separated hospital respondent can be better determined.

The responses to all the new questions will be collected as part of the computerized interviews using a secure computer laptop. The additional data collected from these questions will pose only a minimal burden on respondents; and as noted above, will be absorbed in the OMB burden previously approved for the applicable NHAMCS data collection instruments (OMB No. 0920-0278, Exp. Date: 09/30/2023).

This survey is conducted under authority of Section 306 of the Public Health Service Act (2 USC 242k). We are requesting this non-substantive change to include these questions in the 2022 NHAMCS data collection, as well as subsequent data collection years provided collection of COVID-19 data using the proposed related questions is still considered relevant.

Changes to the NHAMCS Hospital Induction are documented in **Attachment A.** Changes to the NHAMCS Ambulatory Unit Induction Interview are documented in **Attachment B.** Changes to the NHAMCS ED PRF are documented in **Attachment C.** The updated NHAMCS Hospital Induction Questionnaire is shown in **Attachment D.** The updated NHAMCS Ambulatory Unit Induction Questionnaire is shown in **Attachment E.**

Patient Record Form (PRF)

To formally collect diagnostic services information related to COVID-19 in the ED PRF, new selection options dedicated to COVID-19 testing will be added to the diagnostic services section. Two types of COVID-19 tests – SARS-CoV-2 (COVID-19) testing and SARS-CoV-2 (COVID-19) antibody testing – will be added as answer choice options to the new subsection.

A2. Purpose and Use of Information Collection

The data collected under this information collection request will be made available to data users as part of the NHAMCS through the Research Data Center with the remainder of the Hospital and Ambulatory Unit Induction data. As previously highlighted, these data will improve the quality of data collected on eligible ESAs and allow researchers to answer important questions pertaining to the impact and type of telehealth services provided in the ED, and COVID-19 vaccination status among health care personnel.

We are requesting to include these new questions in the 2022 NHAMCS data collection and for subsequent data years if such data are still deemed relevant to be collected. Due to changing developments in the pandemic, eight COVID-19 questions are no longer applicable and will be removed and replaced with three questions regarding COVID-19 vaccination status among health care personnel and telehealth utilization.

To further enhance the richness of the data collected, the selection options in the diagnostic services section of the ED PRF will be expanded to include COVID-19 testing.

Questions concerning the eligibility status of the ESAs, the status of medical records from recently merged or separated hospital respondents, and questions concerning a hospital's association with a conglomerate or hospital group are being added to either help prevent the inclusion of ineligible ESAs, to assess whether a sampled hospital's patient records that are combined with another hospital (sampled or non-sampled) can be separated; or to improve the recruitment and participation from hospital respondents.

A10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

This submission has been reviewed by the Information Collection Review Office (ICRO), who determined that the Privacy Act does apply. The applicable System of Records Notice is 09-20-0167 Health Resources Utilization Statistics. The NCHS Privacy Act Coordinator and the NCHS Confidentiality Officer have also reviewed this package and have determined that the Privacy Act is applicable.

An assurance of confidentiality is provided to all respondents according to section 308(d) of the Public Health Service Act (42 U.S.C. 242m(d)) which states:

"No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under section...306 (NCHS legislation),...may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Secretary) to its use for such other purpose and (1) in the case of information obtained in the course of health statistical or epidemiological activities under section...306, such information may not be published or released in other form if the particular establishment or person supplying the information or described in it is identifiable unless such establishment or person has consented (as determined under regulations of the Secretary) to its publication or release in other form,..."

In addition, legislation covering confidentiality is provided according to section 513 of the Confidential Information Protection and Statistical Efficiency Act (Title III of the Foundations for Evidence-Based Policymaking Act of 2018 (Pub. L. No. 115-435, 132 Stat. 5529 § 302)) which states:

"Whoever, being an officer, employee, or agent of an agency acquiring information for exclusively statistical purposes, having taken and subscribed the oath of office, or having sworn to observe the limitations imposed by this section, comes into possession of such information by reason of his or her being an officer, employee, or agent and, knowing that the disclosure of the specific information is prohibited under the provisions of this subchapter, willfully discloses the information in any manner to a person or agency not entitled to receive it, shall be guilty of a class E felony and imprisoned for not more than 5 years, or fined not more than \$250,000, or both."

In addition, NCHS complies with the Federal Cybersecurity Act of 2015 (6 U.S.C. §§ 151 & 151 note). This law requires the federal government to protect federal computer networks by using computer security programs to identify cybersecurity risks like hacking, internet attacks, and other security weaknesses. If information sent through government networks triggers a cyber threat indicator, the information may be intercepted and reviewed for cyber threats by computer network experts working for, or on behalf of, the government.

The computerization of NHAMCS has eliminated the need to record potentially identifiable information on paper. Although medical record numbers are entered into computerized instruments, they are only used for survey operations purposes to assist FRs in abstracting data from the various record systems in the facility. Once the NHAMCS case is complete and data are ready to be transmitted to NCHS, the medical record numbers are erased from the dataset and no longer retained.

A routine set of measures are in place to safeguard the confidentiality of NHAMCS participants. Confidential data are treated in a secure manner and are not disclosed. All staff with access to confidential information are given instruction by NCHS staff on the requirement to protect confidentiality and are required annually to sign a pledge to maintain confidentiality. Only authorized personnel are allowed access to confidential records, and only when their work requires it. When confidential information is not in use, it is stored on a secure server, the Consolidated Statistical Platform (CSP), on the NCHS network. Any records that are held by U.S. Census Bureau or other NCHS agents are deleted permanently from their networks after the data has been released to the public, pursuant with the requirements of the latest IRB approval. Computerization of the survey has decreased the risk of losing confidential information; NHAMCS data are collected on a secure laptop with limited network connectivity and encrypted before transmittal.

NHAMCS visits level and some provider level data are made available to the public on our NCHS website, but the provider level data are only available through the NCHS Research Data Center (RDC). Confidential data are never released to the public. Personal identifiers, such as hospital name, address, and patients date of birth are always removed from the publicly-released data. All publicly-released data are reviewed by the NCHS Disclosure Review Board to avoid data breaches.

A12. Estimates of Annualized Burden Hours and Cost

Burden Hours

The additional questions to be added to the 2022 Hospital Induction and Ambulatory Unit Induction Interview Questionnaires will continue to represent 30 minutes and 15 minutes of burden, respectively. The current burden for 2021-2023 data collection allows for up to 410 hospitals to be sampled and is based on the maximum level of participation or response. In 2022, it is anticipated that fewer hospitals will be inducted due to ineligibility or refusals. In addition, some of the new questions do not apply to all respondents. The majority of NHAMCS questions are pre-existing and familiar to the interviewers. The five new ROOFS criteria questions are familiar to the interviewers as part of training. Two of the new questions are COVID-19 test check boxes for the patient record form. We expect the check boxes will save our interviewer's time. Currently interviewers must add COVID-19 tests in a case note which takes additional steps including access to another screen. With all factors considered, the currently approved burden hours (OMB No. 0920-0278, Exp. Date: 09/30/2023) should be able to accommodate the new questions. Therefore, the estimated annualized burden remains unchanged at 1,500 hours. The estimated annualized burden for one complete survey cycle is summarized below in Table 1.

This submission requests OMB approval for the revision of the 2022 NHAMCS Hospital and Ambulatory Unit Induction Interview Questionnaires to include 18 new questions and the removal of eight questions to improve the quality of data collected on hospital emergency service areas; to improve the recruitment process of sampled hospitals; to confirm the status of medical records obtained from a merged or separated hospital respondent; to assess the impact of telehealth utilization in the ED during the COVID-19 pandemic; and to evaluate hospitals' COVID-19 vaccination efforts for the 2022 data collection, and subsequent data years if such data are still deemed relevant to be collected.

Table 12-A. Annualized Burden to Respondents for Revised Forms in non-substantive package 2022 NHAMCS

			No. of	Average Burden	Total Response
		No. of	Responses per	per Response	Burden
Type of Respondent	Form Name	Respondents	Respondent	(in hours)	(in hours)
Hospital Chief Executive	Hospital Induction Data	137	1	30/60	69
Officer	Collection (2020)				
Hospital Chief Executive	Hospital Induction Data	410	1	30/60	205
Officer	Collection (2021-2023)				
Ancillary Service	Ambulatory Unit	273	1	15/60	68
Executive	Induction Data Collection				
	(2020)				
Ancillary Service	Ambulatory Unit	820	1	15/60	205
Executive	Induction Data Collection				
	(2021-2023)				
Total					547

Table 12-B Annualized Burden to Respondents already approved for 2022 NHAMCS

Type of Respondent	Form Name	No. of Respondents	No. of Responses per Respondent	Average Burden per Response (in hours)	Total Response Burden (in hours)
Medical Record Clerk	Retrieving Patient Records (2020)	137	100	1/60	228
Medical Record Clerk	Retrieving Patient Records (2021-2023)	410	100	1/60	683
Ancillary Service Executive	Telephone Reinterview (2020)	42	1	15/60	11
Ancillary Service Executive	Telephone Reinterview (2021-2023)	125	1	15/60	31
Total					953

Burden Cost

The reported average annual response burden cost for the data collection cycle also remains an estimated \$70,836.56³ and is summarized in Table 12-C below. This table remains unchanged from the last approved NHAMCS package (OMB No. 0920-0278, Exp. Date: 09/30/2023). Therefore, we do not expect any additional cost to the government with this proposed revision to the NHAMCS induction questionnaires, and the cost remains unchanged.

Table 12-C. Estimated Annualized Burden Cost

Type of Respondent	Form Name	Response Burden Hours	Hourly Wage Rate	Respondent Cost
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³ The hourly wage estimate was based on the Bureau of Labor Statistics May 2018 National Occupational Employment and Wage Estimates, North American Industry Classification System (NAICS) code 622100 – General Medical and Surgical Hospitals (https://www.bls.gov/oes/current/naics4_622100.htm).

Hospital Chief Executive Officer	Hospital Induction Data Collection (2020)	69	\$117.37	\$8,098.53
Hospital Chief Executive Officer	Hospital Induction Data Collection (2021-2023)	205	\$117.37	\$24,060.85
Ancillary Service Executive	Ambulatory Unit Induction Data Collection (2020)	68	\$58.88	\$4,003.84
Ancillary Service Executive	Ambulatory Unit Induction Data Collection (2021-2023)	205	\$58.88	\$12,070.40
Medical Record Clerk	Retrieving Patient Records (2020)	228	\$19.40	\$4,423.20
Medical Record Clerk	Retrieving Patient Records (2021-2023)	683	\$19.40	\$13,250.20
Ancillary Service Executive	Telephone Reinterview (2020)	11	\$117.37	\$1,291.07
Ancillary Service Executive	Telephone Reinterview (2021-2023)	31	\$117.37	\$3,638.47
Total	\$70,836.56			

A15. Explanation for Program Changes or Adjustments

As stated earlier, the addition of the questions will not change the currently approved estimated annualized burden of 1,500 hours; therefore, there is no burden change.