National Healthcare Safety Network (NHSN) Patient Impact Module for Coronavirus (COVID-19) Surveillance in Healthcare Facilities

Request for OMB approval of a New Information Collection

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Supporting Statement B

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1. Respondent Universe and Sampling Methods

NHSN is an ongoing surveillance system that does not employ probability sampling methods for selecting participating hospitals. The respondent universe for NHSN is potentially all institutions in the United States that provide healthcare, including, but not limited to, acute or long-term care facilities, long-term acute care facilities, oncology facilities, inpatient rehabilitation facilities, inpatient psychiatric facilities, outpatient dialysis centers, and ambulatory surgery centers. According to the March 2019 Medicare Payment Advisory Commission Report to Congress on the Medicare Payment Policy (http://www.medpac.gov/docs/default-source/reports/mar19 medpac entirereport sec.pdf), in 2017 there were roughly 4,700 acute care facilities; 7,000 dialysis facilities; 1,180 inpatient rehabilitation facility (IRF) units; 390 long-term acute care facilities (LTAC/LTCHs); 5,600 ambulatory surgery centers (ASCs); and over 15,000 long-term care and skilled nursing facilities (LTCFs) that billed for Medicare reimbursement.

The Centers for Medicare and Medicaid Services (CMS) began requiring hospitals to report healthcare-associated infection (HAI) data to NHSN in January 2011, as part of their Hospital Inpatient Quality Reporting (IQR) Program. As the IQR program has grown, along with additional quality reporting and incentive programs for other healthcare facility types, NHSN enrollment has continuously increased. CDC works alongside CMS to enable the use of NHSN data in CDC's surveillance and prevention programs and CMS's quality improvement, public reporting, and payment programs. CDC reports NHSN data to CMS on behalf of thousands of healthcare facilities that report HAI data to NHSN and participate in CMS's quality programs. As of March 2020, NHSN has over 25,000 enrolled healthcare facilities and over 22,500 actively reporting healthcare facilities across the U.S. Of these, there are over 5,700 acute care facilities; 8,100 dialysis facilities; 600 long-term acute care facilities, 430 free-standing inpatient rehabilitation facilities; 800 inpatient psychiatric facilities; over 3,800 long-term care facilities; and 5,580 ambulatory surgery facilities.

2. Procedures for the Collection of Information

A "suspected COVID-19" count is defined as a patient without a laboratory confirmed COVID-19 diagnosis who has signs and symptoms compatible with COVID-19 (most patients with confirmed COVID-19 have developed fever and/or symptoms of acute respiratory illness, such as cough, difficulty

breathing). A "confirmed COVID-19" count is defined as a patient with a laboratory confirmed COVID-19 diagnosis. Suspected or confirmed COVID-19 counts will be monitored daily across all inpatient care locations in acute care facilities and reported to NHSN by infection preventionists (IPs). This includes the patients with laboratory-confirmed or clinically diagnosed COVID-19. Data entered must meet the case definitions provided in the associated tables of instructions (Attachment 4b). Data will be entered into the NHSN web application either manually or via comma-separated values (CSV).

3. Methods to Maximize Response Rates and Deal with No Response

Participation in NHSN is open to all healthcare institutions with patient population groups that are addressed by the NHSN modules. Participating institutions have complete autonomy on the choice of modules to use, and modules are reported each year. Healthcare institutions must apply for membership in NHSN by completing a series of forms that include identifying and contact information and agree to collect and report data using the NHSN protocols. However, many stakeholders external to CDC encourage or require participation in NHSN for varying purposes. The flexibility of NHSN that permits healthcare institutions to choose from a wide array of options while participating in a national surveillance system that will permit them to comply with accreditation requirements and provide confidentiality to them and their patients have resulted in increasing numbers of participants. Three examples are provided below.

- As of March 2020, 36 states, the District of Columbia, and Philadelphia require facilities in their jurisdictions to join NHSN to comply with legal requirements including but not limited to state or federal laws, regulations, or other requirements for mandatory reporting of healthcare facility-specific adverse event, prevention practice adherence, and other public health purposes.
- The U.S. Centers for Medicare and Medicaid Services (CMS) has identified NHSN as the surveillance mechanism to enable healthcare facilities to report HAI and prevention practice adherence data in fulfillment of CMS's quality measurement reporting requirements for those data.
- Hospitals accredited by The Joint Commission (TJC) are required to conduct ongoing hospital
 infection surveillance, but the surveillance methodology or patient groups to be included in the
 surveillance are not specified. The Joint Commission accepts participation in NHSN to satisfy
 their surveillance requirements.

4. Tests of Procedures or Methods to be undertaken

NHSN is a surveillance system has integrated legacy patient and healthcare personnel safety surveillance systems managed by the Division of Healthcare Quality Promotion (DHQP) at CDC, which has served as the successful pilot tests of the NHSN surveillance methods. Those systems were the National Nosocomial Infection Surveillance (NNIS) system, the National Surveillance System for Healthcare Workers (NaSH), and the Dialysis Surveillance Network (DSN).

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

It is the responsibility of the CDC Division of Healthcare Quality Promotion, Surveillance Branch staff to manage and analyze data collected through NHSN. Also, facilities and groups of facilities (quality improvement organizations, state health departments, prevention collaborative) can analyze their data for their purposes.

List of Attachments

Attachment 1a – 42 USC 242b

Attachment 1b – 42 USC 242k

Attachment 1c - 42 USC 242m

Attachment 2 – Draft 60-day FRN

Attachment 3 – PIA

Attachment 4a – COVID-19 Patient Impact Module Form

Attachment 4b – Instructions for COVID-19 Patient Impact Module Form

Attachment 4c – How to Enter and Access COVID-19 Summary Data

Attachment 5 – Closure of CDC Protocol #4062

Attachment 6 – NHSN Report of End of Human Research Review