**Change Request for**

“National Healthcare Safety Network (NHSN) Patient Impact Module for Coronavirus (COVID-19)

Surveillance in Healthcare Facilities”

**(OMB Control No. 0920-1290)**

**Expiration Date: 09/30/2020**

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**Submission Date:** April 16, 2020

**Circumstances of Change Request for OMB 0920-1290**

The Centers for Disease Control and Prevention (CDC), Division of Healthcare Quality Promotion (DHQP) requests a nonmaterial/non-substantive of the currently approved Information Collection Request: “National Healthcare Safety Network (NHSN) Patient Impact Module for Coronavirus (COVID-19) Surveillance in Healthcare Facilities.”

DHQP recently released a new COVID-19 Module in NHSN as part of its existing web-based surveillance system designed for healthcare facilities to report healthcare-associated infections and antimicrobial resistance. The COVID-19 Module in NHSN’s Patient Safety Component utilizes three forms to collect daily counts of confirmed and suspected cases of COVID-19 from hospitals, measures of hospital capacity such as availability of ICU beds and ventilators, and data on shortages in healthcare workers and shortages in supplies. Currently, CDC has Office of Management and Budget, Office of Information and Regulatory Affairs approval for these web-based, manual and CSV-uploadable forms.

In further response to the COVID-19 pandemic—and more acutely to the particular challenges facing nursing homes during this crisis—CDC is developing a COVID-19 Module in the existing NHSN Long Term Care (LTC) Component that will be used to collect data from long term care facilities (LTCFs) on confirmed and suspected resident COVID-19 cases and deaths, number of beds and access to testing, staff and personnel shortages and cases of COVID-19 and deaths, personal protective equipment availability, and ventilator availability. This new form is included as attachment 9.

As with the initial data collection tool approved under OMB 0920-1290, facility-level data collected through NHSN as part of the COVID-19 Modules are being made available to a broader set of federal, state, and local agency data users than data typically collected by NHSN. Specifically, COVID-19 data at the state, county, territory, and facility level submitted to NHSN will continue to be used for public health emergency response activities by CDC’s emergency COVID-19 response, by the U.S. Department of Health and Human Services’ (HHS) COVID-19 tracking system maintained in the Office of the Assistant Secretary of Preparedness and Response as part of the National Response Coordination Center at the Federal Emergency Management Agency (FEMA), and by the White House Coronavirus Task Force.

COVID-19 poses an unprecedented threat to older populations living in long-term care facilities, as well as healthcare and non-healthcare workers taking care of these residents and their homes. Examples of LTCFs include nursing homes, chronic care facilities for the developmentally disabled, skilled nursing facilities, and assisted living facilities. As rates of infection and resulting mortality across LTCFs continue to rise across the nation, LTCFs are facing significant barriers in facility capacity, staffing, and supplies, such as personal protective equipment. These barriers pose significant risk of COVID-19 transmission and infections. Understanding the facilitators and barriers that impact these vulnerable populations is critical to the effective pandemic response across LTCFs.

The objectives of the data collection are to: 1) determine the impact of COVID-19 among residents and facility workers, including morbidity and mortality 2) determine the nursing home capacity for housing suspected and confirmed cases, including in-house testing abilities; 3) identify staffing shortages among care givers and other facility personnel; 4) identify personal protective availability in the facility; and 5) to identify the availability and use of mechanical ventilators in LTCF with ventilator dependent units.

While NHSN’s LTC Component has seen remarkable growth in participation during its three years in operation, only 20 percent of U.S. nursing homes are enrolled in NHSN. CDC’s Secure Access Management Services (SAMS), which authenticates all NHSN users, has historically presented a barrier for nursing homes to enroll in NHSN due to staff turnover and a 2-6 week completion timeframe for SAMS credentialing. Therefore, NHSN’s development of the LTCF COVID-19 Module will be completed in a new NHSN environment with a separate SAMS security threshold which will enable currently enrolled nursing homes quick access and new nursing homes to enroll and begin reporting data in under an hour. NHSN is able to utilize this approach for the LTCF COVID-19 Module because PII will not be collected. CDC staff will have immediate access to data submitted from each participating LTCF. Resident-level identifiers, such as name, date of birth, medical record number, gender, or social security number are excluded from the data collection form. Nursing homes that are currently enrolled in NHSN—of which there are currently 3,080—will be able to report COVID-19 data directly into NHSN in about 10-14 days when the new LTC COVID-19 Module is released. The attached NHSN forms will be used for data collection in the LTC COVID-19 Module.

In support of filling the gaps in COVID-19 data from nursing homes, the Centers for Medicare and Medicaid Services (CMS) and CDC are partnering in an unprecedented data coordination effort with U.S. nursing homes to help fight COVID-19. On April 19, 2020, CMS announced new regulatory requirements that will require nursing homes to report cases of COVID-19 directly to CDC via NHSN (see announcement linked [here](https://www.cms.gov/newsroom/press-releases/trump-administration-announces-new-nursing-homes-covid-19-transparency-effort)). CMS’ memo also reiterates nursing homes’ longstanding requirements to report cases of infectious disease to their State and local health departments. Finally, CMS will also require nursing homes to fully cooperate with CDC surveillance efforts around COVID-19 spread and will make the data publicly available. Failure to report a case of COVID-19 or persons under investigation (PUI), CMS warns in its guidance, may result in an enforcement action. CMS is now requiring LTCFs report at a minimum the following data to NHSN no less than weekly:

1. Facility name, address and CMS Certification Number;
2. Number of beds in the facility;
3. Current census of the facility;
4. Number of current residents who are confirmed cases;
5. Number of current residents who are suspected cases; and
6. Number of deaths among residents who are either confirmed COVID-19 cases or suspected COVID-19 cases.
7. Number of staff with suspected and confirmed COVID-19
8. Staffing shortages
9. PPE shortages

CMS is introducing this reporting requirement for national surveillance of COVID-19 in nursing homes. Long-term care facilities are primarily responsible for ensuring, in real time, they have adequate staffing and are taking measures to mitigate any infectious disease occurrences among residents or staff. CMS’ role is to hold facilities accountable for the care they provide to their residents. CMS is also providing technical assistance to nursing homes through a variety of mechanisms based on needs identified via this data collection. Finally, the associated enforcement is focused on ensuring facilities report their data to NHSN in order inform CDC, FEMA, the White House Coronavirus Task Force, and public health departments at all levels of the magnitude of the pandemic, as well as resource allocation and medical capacity in nursing homes.

**Description of changes:**

This change request includes the addition of four data collection instruments:

1. Attachment 9 – COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form
2. Attachment 10 – COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form
3. Attachment 11 – COVID-19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form
4. Attachment 12 – COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form

**Increase in Annualized Total Burden Hours:**

As of April 14, 2020, there are approximately 15,446 long term care facilities listed in the CMS Nursing Home Compare database. Since CMS will require these facilities to participate in data collection and reporting, we estimate that 95% of these facilities will report COVID-19 case data. This estimate is based on previous response rates for data collections within NHSN completed by NHSN enrolled facilities.

We have estimated that the COVID-19 LTCF formswill take an average of 55 minutes to complete weekly, knowing that the reporting burden includes surveillance and data entry. We further estimate that LTCF users will report these data on a weekly basis. The Module allows retrospective data collected from previous dates to be entered. Because OMB PRA approval is requested for 180 days, the total number of responses per respondent is 26.

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| --- | --- | --- | --- | --- | --- |
| Type of Respondent | Form Name | No. of Respondents | No. Responses per Respondent | Avg. Burden per response (in hrs.) | Total Burden (in hrs.) |
| LTCF personnel | COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form | 9,782 | 26 | 15/60 | 63,583 |
| Business and financial operations occupations | COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form | 2,446 | 26 | 15/60 | 15,899 |
| State and local health department occupations | COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form | 2,446 | 26 | 15/60 | 15,899 |
| LTCF personnel | COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form | 9,782 | 26 | 20/60 | 84,777 |
| Business and financial operations occupations | COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form | 2,446 | 26 | 20/60 | 21,199 |
| State and local health department occupations | COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form | 2,446 | 26 | 20/60 | 21,199 |
| LTCF personnel | COVID-19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form | 9,782 | 26 | 5/60 | 21,194 |
| Business and financial operations occupations | COVID-19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form | 2,446 | 26 | 5/60 | 5,300 |
| State and local health department occupations | COVID-19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form | 2,446 | 26 | 5/60 | 5,300 |
| LTCF personnel | COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form | 9,782 | 26 | 15/60 | 63,583 |
| Business and financial operations occupations | COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form | 2,446 | 26 | 15/60 | 15,899 |
| State and local health department occupations | COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form | 2,446 | 26 | 15/60 | 15,899 |

The original burden calculated for this data collection consisted of 701,325 hours. As a result of the changes proposed in this change request, the new burden will consist of 1,051,056 hours. An updated burden table is included below. 349,731

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| Type of Respondent | Form Name | No. of Respondents | No. Responses per Respondent | Avg. Burden per response (in hrs.) | Total Burden (in hrs.) |
| Microbiologist (IP) | COVID-19 Patient Impact Module Form | 2079 | 180 | 25/60 | 155,925 |
| Business and financial operations occupations | COVID-19 Patient Impact Module Form | 519 | 180 | 25/60 | 38,925 |
| State and local health department occupations | COVID-19 Patient Impact Module Form | 519 | 180 | 25/60 | 38,925 |
| Microbiologist (IP) | COVID-19 Healthcare Worker Form | 2079 | 180 | 25/60 | 155,925 |
| Business and financial operations occupations | COVID-19 Healthcare Worker Form | 519 | 180 | 25/60 | 38,925 |
| State and local health department occupations | COVID-19 Healthcare Worker Form | 519 | 180 | 25/60 | 38,925 |
| Microbiologist (IP) | COVID-19 Supplies Form | 2079 | 180 | 25/60 | 155,925 |
| Business and financial operations occupations | COVID-19 Supplies Form | 519 | 180 | 25/60 | 38,925 |
| State and local health department occupations | COVID-19 Supplies Form | 519 | 180 | 25/60 | 38,925 |
| LTCF personnel | COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form | 9,782 | 26 | 15 | 63,583 |
| Business and financial operations occupations | COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form | 2,446 | 26 | 15/60 | 15,899 |
| State and local health department occupations | COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form | 2,446 | 26 | 15/60 | 15,899 |
| LTCF personnel | COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form | 9,782 | 26 | 20/60 | 84,777 |
| Business and financial operations occupations | COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form | 2,446 | 26 | 20/60 | 21,199 |
| State and local health department occupations | COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form | 2,446 | 26 | 20/60 | 21,199 |
| LTCF personnel | COVID-19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form | 9,782 | 26 | 5/60 | 21,194 |
| Business and financial operations occupations | COVID-19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form | 2,446 | 26 | 5/60 | 5,300 |
| State and local health department occupations | COVID-19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form | 2,446 | 26 | 5/60 | 5,300 |
| LTCF personnel | COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form | 9,782 | 26 | 15/60 | 63,583 |
| Business and financial operations occupations | COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form | 2,446 | 26 | 15/60 | 15,899 |
| State and local health department occupations | COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form | 2,446 | 26 | 15/60 | 15,899 |
| **Total** |  | 1,051,056 |

**Attachments**

Attachment 9 – COVID-19 Module, Long Term Care Facility: Staff and Personnel Impact form

Attachment 10 – COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity form

Attachment 11 – COVID-19 Module, Long Term Care Facility: Ventilator Capacity & Supplies form

Attachment 12 – COVID-19 Module, Long Term Care Facility: Supplies & Personal Protective Equipment form