**Change Memo for**

National Healthcare Safety Network (NHSN)

Coronavirus (COVID-19)

Surveillance in Healthcare Facilities

(OMB Control No. 0920-1317)

Expiration Date: 01/31/2024

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The Centers for Disease Control and Prevention (CDC), Division of Healthcare Quality Promotion (DHQP) requests a non-substantive of an approved Information Collection Request:

National Healthcare Safety Network (NHSN) Coronavirus (COVID-19) Surveillance in Healthcare Facilities (OMB Control No. 0920-1317)

Within this Information Collection Request, we are making updates to the following forms:

1. Dialysis COVID-19 form (57.510)
2. LTCF Veterans Affairs Staff and Personnel COVID-19 Event form (57.160)
3. LTCF Veterans Affairs Resident COVID-19 Event form (57.159)
4. LTCF Point of Care Testing Results Tool (57.155)
5. LTCF Resident Impact and Facility Capacity form (57.144)
6. LTCF healthcare associated infections event form (57.142)
7. Weekly COVID-19 Vaccination Data Collection Forms & Monthly Reporting Plans:

57.203, 57.141, 57.509, 57.219, 57.218

Each form change and associated burden are described below.

Dialysis Component, COVID-19 Module

The goal of this form change is to improve the usefulness and quality of data that is gathered regarding residents with newly positive SARS-CoV-2 viral test results and their vaccination status. This will also likely aid in improving the quality of data which can be used regarding break-through cases.

Additional variables have been added to the vaccination status section of the form. These variables aim to collect further stratified data regarding the time frame of when a vaccine was received if the manufacturer is unspecified for residents with a newly positive SARS-CoV-2 viral test result. Additional questions have also been added to the form to gather data regarding additional or booster doses administered to residents with a newly positive SARS-CoV-2 viral test result. The responses to the questions will give insight to federal, state, and local partners regarding how many doses of COVID-19 Vaccine a resident with a newly positive SARS-CoV-2 viral test result has received.

Burden increase: 10 minutes.

Long-Term Care Component, COVID-19 Module (57.159, 57.160)

CDC is adding two new fields to two forms in the Long-Term Care (LTC) Facility COVID-19 Module: (1) Veterans Affairs Staff and Personnel COVID-19 Event form and (2) Veterans Affairs Resident COVID-19 Event form. The following two fields will be added as options for questions of Race and Ethnicity on the Point of Care (POC) Test Reporting form (57.159) and (now) the LTC Healthcare-Associated Infections form (57.142).

* Declines to Respond
* Unknown

Justification for POC form changes:

Understanding the impacts and incidence of COVID-19 on various segments of the population is important for prevention and response efforts.  Through the course of the pandemic, it has become clear that race and ethnicity are important factors for consideration of risk as well as prevention efforts.  For this reason, race and ethnicity are required fields on the NHSN Point of Care Test Reporting Tool for COVID-19 in Long-term Care Facilities.  We have learned from user feedback that some persons tested for COVID-19—whether staff in LTC facilities, residents of the facilities or visitors—decline to provide information related to their race or ethnicity, even when educated as to the importance of the data.  For this reason, not having an option to indicate that the individual declines to answer is problematic.  Sometimes, a resident may not be cognitively able to provide this information and no family is available to provide the information.  In these cases, an “unknown” option is needed.  For these reasons, we want to add these two options to enable complete reporting of test results in nursing homes wishing to report to NHSN.

There is no anticipated burden addition related to the addition of these fields.  They simply provide additional necessary options for completing the fields with accurate information.

For level of effort reasons, the NHSN Development Team found it necessary to also add these fields to ALL of the patient-level LTC event forms as the POC Tool lies within the LTC Component.  However, the Race and Ethnicity fields are optional fields on those forms.  There would be no additional reporting burden for these as well.  The justification is very similar and is provided below:

Justification for LTC Event Forms:

Understanding the impact of race and ethnicity on the incidence of HAIs may be important for prevention and response efforts.  We have learned from user feedback in COVID-19 surveillance that some individuals decline to provide information related to their race or ethnicity, even when educated as to the importance of the data.  For this reason, not having an option to indicate that the individual declines to answer is problematic.  Sometimes, a resident may not be cognitively able to provide this information and no family is available to provide the information.  In these cases, an “unknown” option is needed.  For these reasons, we want to add these two options to enable complete reporting of test results in nursing homes wishing to report to NHSN. There is no anticipated burden addition related to the addition of these fields.  They simply provide additional necessary options for completing the fields with accurate information.

Burden Updates: Therapeutics

The Centers for Medicare and Medicaid Services (CMS) Interim Final Rule 42 CFR 483.80(g)(1)(viii)-(ix) released May 11, 2021 now requires all CMS-certified skilled nursing facilities to report COVID-19 vaccination data for residents and staff as well as therapeutics data for residents. Reporting these data elements to NHSN was previously optional, thus the burden estimates have been increased to account for the required reporting by all CMS-certified skilled nursing facilities.

Resident Impact and Facility Capacity form (57.144)

CDC is requesting the following form changes for the LTC COVID-19 Module, Resident Impact and Facility Capacity Form (57.144):

The goal of this form change is to improve the usefulness and quality of data that is gathered regarding residents with newly positive SARS-CoV-2 viral test results and their vaccination status. This will also likely aid in improving the quality of data which can be used regarding break-through cases.

Additional variables have been added to the vaccination status section of the form. These variables aim to collect further stratified data regarding the time frame of when a vaccine was received if the manufacturer is unspecified for residents with a newly positive SARS-CoV-2 viral test result. Additional questions have also been added to the form to gather data regarding additional or booster doses administered to residents with a newly positive SARS-CoV-2 viral test result. The responses to the questions will give insight to federal, state, and local partners regarding how many doses of COVID-19 Vaccine a resident with a newly positive SARS-CoV-2 viral test result has received.

Burden increase: 10 minutes.

**Weekly COVID-19 Vaccination Data Collection Forms & Monthly Reporting Plans:**

**57.203, 57.141, 57.509, 57.219, 57.218**

CDC revised the weekly data collection forms for the COVID-19 vaccination modules. These changes were made in preparation for facilities to meet CMS reporting requirements beginning in October 2021. A summary of the changes is listed below.

1. Data on the current healthcare personnel categories for question #1 will no longer be collected. New categories will now include:

* **Employees**: Staff on facility payroll
* **Licensed independent practitioners**: Contracted physicians, advanced practice nurses, and physician assistants
* **Adult students/trainees and volunteers**: Non-employee students/trainees and volunteers aged 18 or older
* **Other contract personnel**: Contracted staff who do not fall into any of the other denominator categories

2. Question #3.2 (offered but declined COVID-19 vaccine) and question #3.3 (unknown COVID-19 vaccination status) will now be required.

3. Facilities will need to create a monthly reporting plan before entering data into NHSN on healthcare personnel of non-long-term care facilities and healthcare personnel and residents of long-term care facilities. The monthly reporting plan collects data on the modules and month(s) the facility plans to participate.

**Burden Estimate:** With the addition of these healthcare personnel categories, we estimate that the burden for completing the Weekly Healthcare Personnel COVID-19 Vaccination Cumulative Summary form will be approximately one hour and thirty minutes. (Please note the number of facilities listed in the table below are current as of September 2021. These numbers reflect facilities with CCNs in the CDC dataset and are restricted to active, non-testing facilities. These numbers are not derived from the CMS Finder File.) Facilities that are already reporting in the HPS module for influenza vaccination coverage summary data (acute care hospitals and inpatient rehabilitation facilities) will not incur additional burden for adding COVID-19 vaccination data to the monthly reporting plan. Facilities that are newly reporting in the HPS module (dialysis and inpatient psychiatric facilities) will experience a burden of 5 minutes or less to complete the monthly reporting plan.

For the first quarter of reporting (Q4: October – December 2021), NHSN will auto-populate the HPS monthly reporting plan for dialysis facilities and CMS-certified SNFs to relieve some burden during the initial reporting period.

Burden Estimates

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| --- | --- | --- | --- | --- |
| Form Name | No. of Respondents | No. Responses per Respondent | Avg. Burden per response (in hrs.) | Total Burden (in hrs.) |
| Dialysis COVID-19 Outpatient Facility | 7,700 | 104 | 25/60 | 333,667 |
| LTCF VA Resident COVID-19 Event Form | 188 | 36 | 40/60 | 4,512 |
| LTCF VA Staff and Personnel COVID-19 Event Form | 188 | 36 | 25/60 | 2,820 |
| Resident Impact and Facility Capacity form | 16,512 | 52 | 60/60 | 858,624 |
| Weekly Healthcare Personnel COVID-19 Vaccination Cumulative Summary | \* 12,600 | 52 | 90/60 | 982,800 |
| Weekly Resident COVID-19 Vaccination Cumulative Summary for Long-Term Care Facilities | \*\*16,864 | 52 | 75/60 | 1,096,160 |
| Weekly Patient COVID-19 Vaccination Cumulative Summary for Dialysis Facilities | 7,700 | 52 | 75/60 | 500,500 |
| Monthly Reporting Plan form for Long-term Care Facilities | \*\*16,864 | 9 | 5/60 | 12,648 |
| Healthcare Personnel Safety  Monthly Reporting Plan – completed by dialysis facilities | 7,700 | 9 | 5/60 | 5,775 |
| Healthcare Personnel Safety  Monthly Reporting Plan – completed by inpatient psychiatric facilities | 394 | 12 | 5/60 | 394 |
| COVID-19 Long Term Care Facility: Resident Therapeutics | 16,512 | 52 | 10/60 | 143,104 |

\* Total of 7,706 dialysis facilities + 3,831 acute care facilities + 663 inpatient psychiatric facilities + 394 inpatient rehabilitation facilities

\*\* total of 16,512 CMS-certified SNFs + 352 non-CMS-certified SNFs/Assisted living facilities/Facilities for developmentally disabled persons that optionally report