Non-Substantive Change Request to OMB Control Number 0920-1371

Program Contact
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Submission Date: 01/26/2021

CDC requests approval for a non-substantive change to OMB Control No. 0920-1317; **National Healthcare Safety Network (NHSN) Coronavirus (COVID-19) Surveillance in Healthcare Facilities**

A. Form Name: **COVID-19 Module, Long Term Care Facility: Resident Impact and Facility Capacity**

Justification for changes:
Updates are requested to evaluate COVID-19 vaccine effectiveness or impact for a resident with newly positive COVID-19 viral test result. The new questions were added to the *Vaccine Status* section and will become visible ONLY when values >0 are placed in the *Positive Tests* fields. We expect additional vaccines to be available in the coming months and will need to add those products to the form and NHSN interface as they become available.

Burden:
Estimates of annualized burden hours for this change request will increase by five minutes per response. Because there are expected to be **15,361** responses per year, the total increase in burden will be 66,564 hours per year.

Estimates of annualized burden hours for this change request are 599,079 hours. The burden estimate for the form included in OMB Control No. 0920-1317 is 45 minutes.

Description of Changes:
The changes to the form are as follows:

Users will be asked to respond to the *Vaccine Status* questions when reporting one or more *Positive Tests* using one or more of the following *Test Types: (1) Positive SARS-CoV-2 antigen test only [no other testing performed]; (2) Positive SARS-CoV-2 NAAT (PCR) only [no other testing performed]; and (3) Any other combination of SARS-CoV-2 NAAT (PCR) and/or antigen test(s) with at least one positive test*

B. Form Name: **COVID-19 Module, Long Term Care Facility: Resident Therapeutics**

Justification for changes:

This is a new form that will make up a new COVID-19 pathway, *Therapeutics*. The purpose of this form is to capture weekly usage and therapeutics inventory data for monoclonal antibodies. The U.S. Food and Drug Administration (FDA) issued emergency use authorizations (EUA) for the Lilly (bamlanivimab) and Regeneron (casirivimab/imdevimab) monoclonal antibodies therapies in November 2020, both of which remain in limited supply. Therefore, there is an urgent need to understand facility inventory and utilization in order to ensure continued equitable and efficient allocation. We expect additional therapeutics to be available in the coming months and will need to add those products to the form and NHSN interface as they become available. Users will be encouraged to respond to the questions one time during the reporting week.

Burden:

Estimates of annualized burden hours for this addition will increase by ten minutes per response. Because there are expected to be **15,361** responses per year, the total increase in burden will be 133,129 hours per year. This is a new form, so the burden estimate for the form is not currently included in OMB Control No. 0920-1317.

Description of Changes:

The changes to the form are as follows:

Users will be asked to report the number of residents treated with Bamlanivimab (Lilly) and Casirivimab plus Imdevimab (Regeneron) during the reporting week. For each therapy, users are also asked how many residents were treated from stock stored at this facility and how many from stock stored at another facility.

	Form Name	No. of Respondents	No. of responses per respondent	Avg. burden per response (hours)	Total burden (hours)
Approved	Resident Impact and Facility Capacity	15,361	52	40/60	534,248
Requested	Resident Impact and Facility Capacity	15,361	52	45/60	599,079
Approved	Resident Therapeutics	0	0	0	0
Requested	Resident Therapeutics	15,361	52	10/60	133,129