The COVID-19 Reality in Long Term Care: A Retrospective and Prospective

By: Caroline J. Berdzik, Esquire
Jacqueline Genesio, Esquire

Introduction:

The COVID-19 public health crisis has particularly negatively impacted elderly and/or infirm residents of long-term and skilled-nursing care facilities, assisted living communities, and other senior care environments, including independent living. Under evolving CMS, CDC, and WHO guidance and other credible medical/scientific studies, the residents of these facilities and communities were foreseeably prone to adverse outcomes, including, but not limited to death, as a result of contracting the virus. As of mid-February 2021, there were more than 27.3 million cases of COVID-19 in the United States and over 500,000 deaths (150,000 of these deaths have been of residents in long-term care facilities). This paper is an overview of what long-term providers have learned over the last year during a rapidly evolving set of circumstances as evidenced by the frequent and conflicting guidance provided by federal and state agencies, how litigation against these providers is starting to shape up and the potential defenses which may be available in these cases, the risk of regulatory and criminal actions, as well as insurance coverage issues that are coming into play as the lawsuits gets filed.

Pre-COVID 19 Catastrophic Events for Facilities

There was no playbook for a pandemic. While facilities have grappled with flu outbreaks, H1N1 and other infections, pandemic preparedness was not something at the front and center of CMS' mind. So much focus had been devoted to emergency preparedness based on handlings of past natural disasters like:

- Hurricane Katrina
- Superstorm Sandy
- Hurricane Irma
- California wildfires

Likewise, the litigation, regulatory and criminal actions that dogged long term care providers after these events provide a good preview for what we are seeing emerge from the pandemic.

The Perfect Storm

Long term care facilities were the perfect storm for COVID-19 for a variety of reasons. The demographics in these facilities are older and infirm individuals in a congregate setting. While jails and college campuses also were subject to outbreaks of COVID-19, no other setting came close to experiencing the same rate of death.

Some other factors which contributed to the spread in long term care facilities:

- Personnel in long term care (multiple jobs)

- Location of facility (i.e. city or suburban hot spot-community spread)
- No testing available at outset
- Inadequate or no PPE
- Architecture/design of buildings
- Silent asymptomatic spread of COVID-19

The Early Days of the Pandemic-A Provider's Perspective:

In late February 2020 after the first known outbreak of COVID-19 at a facility in Kirkland, Washington where 37 died, many long term care providers created a task force to plan for what was to come, as government guidance was not available. In early March 2020, these communities started closing to the outside world. During this time, there were no strict closing regulations or Executive Orders in effect that communities could rely on. Although within a few weeks, states and licensing agencies had stringent restrictions, including prohibiting non-essential visitors, communities were initially told they could be cited for failure to allow non-essential visitors. It became essential for providers to define their policies and procedures and to ensure robust communication both internally and externally.

Screening

Providers started consulting with infectious disease physicians and trying to develop their own screening tools, with little guidance from the regulatory agencies. Screening tools were developed to screen all incoming persons, including once-per-shift temperature and symptom screening of all associates. Staffing communities with sufficient personnel to handle the screening while still sending people home who posed a potential risk became a challenge. The ever-evolving list of COVID-19 symptoms also made it more difficult to screen effectively.

PPE Shortages

PPE was in short supply. One provider established a corporate PPE center and a dedicated national procurement resource. Other smaller providers did their best to procure PPE and distribute as appropriate. Discussions ensued about how to conserve PPE safely. During March 2020, testing was mostly unavailable—symptoms and temperatures were monitored and used as the basis for PPE allotment. Resident family members were objecting to rules, refusing to be screened and attempting entry through balconies. Residents were refusing to mask—and some with dementia were unable to understand the purpose of masking and this became a concern.

Creating Isolation Areas

Architecture of most nursing homes did not permit isolation areas. In assisted living, this was an even more difficult concept. Review and supplementation of infection control policies was critical.

Staffing

Staffing remained a hot-button issue throughout the pandemic for a multitude of reasons. Providers had to develop surge staffing plans, questions arose about cohorting of staff, and prohibitions were enacted prohibiting crossover between levels of care. Associates were removed from the schedule due to any symptom of illness. Outside agency resources posed their own issues and concerns, including educating that staff on facility policies and procedures, which were evolving by the hour. There was fierce competition to secure outside staff. Corporate licensed staff was deployed to communities.

First Positive Cases and Contact Tracing

When the first positive cases started to occur, contract tracing became critical. Again, very little guidance was available, and these facilities had to develop their own systems, which included many of the following:

A. Contact tracing maps to identify the associates who could have had contact; identify all possible contacts (e.g., assisted living (AL) nurse assisted independent living (IL) resident up after a fall)

    1. Identifying and excluding persons with whom a positive person had contact

        a. Refining the time period of quarantine

        b. Requiring isolation for symptomatic residents; associates remained out of work until cleared

B. Managing associate gatherings and associate behavior outside the workplace

C. Monitoring social media postings and resident/family expectations

D. What is a significant contact?

    During this time, regulations and CDC guidance were changing, often daily. Tracking the changes and providing appropriate guidance to community leadership was around the clock.

E. Resident health and the primary concern

    1. Attempting to provide new activities and modalities for residents to remain engaged

    2. Conversion to 100% in-room meal service for <u>all meals</u>; staffing to do so

    3. Risks of isolation

    4. Increased attention on weight loss, falls, depression, keeping residents engaged

F. Residents and Families- Independent Living

1. Balance between providing for an independent resident population with limitations on what we can require and ask

2 Residents leaving the community for non-essential purposes

Timeline of Agency Responses

The following timeline illustrates the rapidly evolving agency response to the COVID-19 outbreak.

- February 1, 2020 – CDC health alert network ("HAN") – 00427. https://emergency.cdc.gov/han/han00427.asp. Interim guidance to State and local health departments provides guidance to clinicians caring for patients with COVID-19, testing and updated infection prevention and control guidance. Testing guidance was revised on March 4, 9, and 24, April 27 and May 3.

- February 4, 2020 – CMS encourages facilities to review their procedures to ensure compliance with CMS infection control and CDC guidelines. *See* Exhibit B.

- March 4, 2020 – CMS QSO-20-14-NH Infection Control and Prevention of COVID-19

- March 11, 2020 – World Health Organization characterizes COVID-19 outbreak as a pandemic.

- March 13, 2020 – President Trump declares a national emergency.

- March 20, 2020 – CDC issues guidance for healthcare facilities.

- March 23, 2020 – CMS announces the suspension of routine survey inspections and a focus on immediate jeopardy and infection control inspections

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-14-NH

DATE: **March 13, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Guidance for Infection Control and Prevention of Coronavirus Disease 2019 (COVID-19) in Nursing Homes ***(REVISED)***

Memorandum Summary

- ***CMS is committed*** to taking critical steps to ensure America's health care facilities and clinical laboratories are prepared to respond to the threat of the COVID-19.
- **Guidance for Infection Control and Prevention of COVID-19 -** CMS is providing additional guidance to nursing homes to help them improve their infection control and prevention practices to prevent the transmission of COVID-19, *including revised guidance for visitation*.
- **Coordination with the Centers for Disease Control (CDC) and local public health departments -** We encourage all nursing homes to monitor the CDC website for information and resources and contact their local health department when needed (CDC Resources for Health Care Facilities: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html).

Background

The Centers for Medicare & Medicaid Services (CMS) is responsible for ensuring the health and safety of nursing home residents by enforcing the standards required to help each resident attain or maintain their highest level of well-being. In light of the recent spread of COVID-19, we are providing additional guidance to nursing homes to help control and prevent the spread of the virus.

Guidance

Facility staff should regularly monitor the CDC website for information and resources (links below). They should contact their local health department if they have questions or suspect a resident of a nursing home has COVID-19. Per CDC, prompt detection, triage and isolation of potentially infectious residents are essential to prevent unnecessary exposures among residents, healthcare personnel, and visitors at the facility. Therefore, facilities should continue to be vigilant in identifying any possible infected individuals. Facilities should consider frequent

CDC Resources:

- Infection preventionist training: https://www.cdc.gov/longtermcare/index.html
- CDC Resources for Health Care Facilities: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html
- CDC Updates: https://www.cdc.gov/coronavirus/2019-ncov/whats-new-all.html
- CDC FAQ for COVID-19: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/infection-prevention-control-faq.html
- *Information on affected US locations: https://www.cdc.gov/coronavirus/2019-ncov/cases-in-us.html*

CMS Resources:

- Guidance for use of Certain Industrial Respirators by Health Care Personnel: https://www.cms.gov/files/document/qso-20-17-all.pdf
- Long term care facility – Infection control self-assessment worksheet: https://qsep.cms.gov/data/252/A_NursingHome_InfectionControl_Worksheet11-8-19508.pdf
- Infection control toolkit for bedside licensed nurses and nurse aides ("Head to Toe Infection Prevention (H2T) Toolkit"): https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/LTC-CMP-Reinvestment
- Infection Control and Prevention regulations and guidance: 42 CFR 483.80, Appendix PP of the State Operations Manual. See F-tag 880: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Downloads/Appendix-PP-State-Operations-Manual.pdf

Contact: Email DNH_TriageTeam@cms.hhs.gov

NOTE: The situation regarding COVID-19 is still evolving worldwide and can change rapidly. Stakeholders should be prepared for guidance from CMS and other agencies (e.g., CDC) to change. Please monitor the relevant sources regularly for updates.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators immediately.

/s/
David R. Wright

cc: Survey and Operations Group Management

Page 6 of 6

- April 2, 2020 – CMS "call to action" for LTC and governments: reinforcing infection control and urging coordination access to testing and PPE
- April 3, 2020 – CDC preparedness checklist for LTC facilities
- April 7, 2020 – CDC releases PPE burn rate calculator
- April 19, 2020 – CMS QSO-20-20-26-NH. CMS "upcoming requirements" for notification of confirmed COVID-19 cases among residents and staff in LTC (nursing homes only)
- April 27, 2020 – CDC releases key strategies to prepare for COVID-19 in LTC
- April 28, 2020 – CDC guidance for cleaning and disinfecting your facility

- April 30, 2020 – CDC discontinuation of transmission-based precautions and disposition of patients with COVID-19 in healthcare settings (interim guidance)

https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html

- April 30, 2020 – CDC criteria for return to work for healthcare personnel with suspected or confirmed COVID-19

https://www.cdc.gov/coronavirus/2019-ncov/hcp/return-to-work.html

- April 30, 2020 – CDC strategies to mitigate healthcare personnel staffing shortages

https://www.cdc.gov/coronavirus/2019-ncov/hcp/mitigating-staff-shortages.html

- April 30, 2020 – CDC-designate COVID-19 unit responding to coronavirus (COVID-19) in LTC

https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-responding.html

CMS and CDC did not start collecting data about COVID-19 spread in facilities until May 17, 2020. The federal government will not require the collection and reporting of data prior (May 1, 2020).

- May 5, 2020 – Occupational Safety and Health Administration

https://www.osha.gov/Publications/OSHA4025.pdf

- May 6, 2020 – CMS QSO-20-29-NH – Interim final rule updating requirements for notification of confirmed and suspected COVID-19 cases among residents and staff in LTC

- May 8, 2020 – CDC infection prevention and control assessment tool for LTC

- May 10, 2020 – Gov. Cuomo of New York signed Executive Order 202.30 requiring testing of all personnel of nursing homes and adult care twice a week

- May 12, 2020 – CDC considerations for memory care units

- May 13, 2020 – CMS issues toolkit on State actions to mitigate COVID-19 prevalence in LTC

- May 14, 2020 – Alert to keep Nursing Home and LTC facility workers safe during coronavirus pandemic

https://www.osha.gov/news/newsreleases/national/O5142020-1

- May 18, 2020 – CMS news release re: QSO-20-30-NH-LTCF reopening recommendations for State and local officials

https://www.cms.gov/files/document/qso-20-30-nh.pdf

- CDC National Healthcare Safety Network Reporting under 42 CFR 483.80(g)(2)
- Family/Representative Reporting under 42 CFR 483.80(g)(3)

- May 19, 2020 – COVID-19 testing in LTC

https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-facility-wide-testing.html

- May 19, 2020 – Interim testing guidance in response to suspected or confirmed COVID-19 in residents and healthcare employees

https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html

- June 13, 2020 – CDC testing guidelines for LTC residents and healthcare personnel

https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html

- June 16, 2020 – U.S. House of Representatives launches investigation

"The Subcommittee is concerned that lax oversight by the Centers for Medicare and Medicaid Services (CMS) and the federal government's failure to provide testing supplies and personal protective equipment to nursing homes and long-term care facilities may have contributed to the spread of the coronavirus and the deaths of more than 40,000 Americans in these facilities. …"

https://skillednursingnews.com/2020/06//house-launches-probe-into-cms-operator-response – to-covid-19-in-nursing-homes

- June 23, 2020 – CMS frequently asked questions (FAQs) on visitation
cms.gov/files/document/covid-visitation-nursing-home-residents.pdf

More guidance continued to emerge after June 2020 and continue to emerge as vaccinations have come into play, COVID-19 has become endemic, and visitation has started to open in communities.

Claims and Immunity Defenses

It is estimated that over 15,000 COVID-19 lawsuits have been filed, and there are approximately 400 healthcare and medical related filings as of March 2021. However, it only about 150 of those suits were filed against long term care facilities at this time. This number is likely to increase. COVID-19 related death claims are being filed by residents' families, as well as employees. During the next two years, facilities anticipate secondary claims related to how

facilities had to operate during the pandemic (pressure wounds, falls, dehydration, choking, progression of dementia due to isolation).

The Public Readiness Emergency Preparedness Act (PREP Act) was enacted by Congress in 2005. In short, this Act authorizes the Secretary of the U.S. Department of Health and Human Services to issue a PREP Act declaration in response to a public health emergency. The PREP Act authorizes the Secretary of Health and Human Services (HHS) to declare that certain "covered persons" are immune from liability for taking certain "covered countermeasures" that are necessary to combat a public health emergency such as COVID-19.

On March 10, 2020, HHS Secretary Alex Azar issued such a Declaration, retroactive to February 4, 2020. (*See* Exhibit C.) On April 3, 2020, the FDA issues some emergency use authorizations, including Hydroxychloroquine in the use of COVID-19 treatment. On April 14, 2020, HHS General Counsel issued an advisory opinion stating that federal immunity may apply to certain countermeasures, even if not technically covered by the PREP Act.

The March 10, 2020 Declaration has been amended seven times. It has gotten broader with each amendment, including amendments on June 8, 2020 and August 24, 2020 (it now covers vaccines other than COVID). (*See* Exhibits D-J).

On October 23, 2020, the HHS Advisory Opinion was amended again, highlighting the breadth of PREP Act immunity. The Fourth Amendment—which was effective as of December 3, 2020—incorporated all four of the prior advisory opinions and stated that immunity applies to non-administration due to limited availability. Further, HHS Advisory Opinion 21-01 (issued January 8, 2021) began to address some lawsuits that had been filed against long-term care facilities. In short, the Advisory Opinion stated that removal was proper, even for non-use claims, so long as it is a product of a decision-making process. (*See* Exhibit L). The Fifth Amendment (February 2, 2021), Sixth Amendment (February 16, 2021) and Seventh Amendment (March 16, 2021) all were issued after President Biden's inauguration. These amendments also support the breadth of PREP Act immunity.

In short, PREP Act immunity includes any claim under state and federal law for a loss that has a causal relationship with the administration to, or use by, an individual covered by a countermeasure. Loss is defined to include death, personal injury, property damage, etc. The protection is drafted very broadly. However, immunity from liability is not available for death or serious physical injury caused by willful misconduct.

A covered person includes program planners (entities and individuals who plan, administer and supervise programs for distribution of a countermeasure). Qualified persons are defined as licensed health care professionals or other individuals authorized to prescribe, administer or dispense covered countermeasures under the law of the state in which the countermeasure was administered. This includes officials, agents and employees of any of these entities or individuals.

Administration is defined as the "Physical provision of the countermeasures to recipients or activities and decisions directly relating to public and private delivery, distribution and dispensing of countermeasures to recipients; managements and operation of countermeasure

programs; or management and operation of locations for purposes of distributing and dispensing countermeasures."

Despite the foregoing, removal by long term care defendants to federal courts has not been very successful as of April 2021. Many federal courts are remanding to state court. It appears that distribution of PPE or other scarce resources may not be sufficient to convey jurisdiction in the federal courts. Only one case to date has upheld removal. *Garcia v. Welltower OpCo Group LLC* (C.D. Ca. Feb. 10, 2021). Further, the motion to dismiss filed by the facility was granted. An appeal has been submitted to the Ninth Circuit. In another case in Kansas, a judge denied the motion to dismiss, but said a motion for summary judgment may not be precluded. *Hatcher v. HCP Prairie Village KS OPCO, LLC* 2021 WL 733326 (U.S. District Court, D. Kansas January 27, 2021).

States have also immunity laws, although those vary greatly. New York recently eliminated immunity, although it is not retroactive. Many other states have immunity, with exceptions for willful violations or actions. These may act as a good defense to claims. Immunity laws exist in states such as: New Hampshire, Vermont, New York, New Jersey, Massachusetts, Connecticut, Rhode Island, Pennsylvania, Maryland, Ohio, Indiana, Michigan, North Carolina, South Carolina, Kentucky, Tennessee, Florida, Georgia, Alabama, Mississippi, Louisiana, Missouri, Tennessee, and others.

We will see how these defenses play out in these cases and if their immunity will protect long term care facilities from COVID-19 related death claims.

Criminal Actions

There are also criminal citations and cases being filed. Any criminal matters need to be closely monitored when handling civil claims. This is similar to nursing home criminal actions that followed after Katrina and other natural disasters. Massachusetts filed a criminal complaint against individuals running the Soldiers Home in Holyoke. https://www.mass.gov/news/ag-healey-announces-criminal-charges-against-superintendent-and-former-medical-director-of Citations are also being issued elsewhere.

https://www.9news.com/article/news/health/coronavirus/covid-denver-public-health-citations-court/73-1e5e4685-7e13-4813-a8db-51f7d2a591fc

When defending civil claims, one has to be careful of the consequences of entering a guilty plea for a pending criminal matter. Long term care facilities should retain criminal counsel if they have criminal citations related to COVID-19 to coordinate the response with civil counsel.

Regulatory Actions

In 2020, CMS and state surveyors conducted at least one COVID-19 focused inspection survey at the nation's 15,600 nursing homes. 3% of these facilities were cited for immediate jeopardy for infection control violations. Many of these are being challenged (mask fell off staff member, incomplete screening paperwork). Again, it is critical to engage regulatory counsel to IDR these citations and also to coordinate with civil counsel. Plaintiffs' firms have cited these

citations to demonstrate that some standard of care was violated, giving rise to allegations of negligence per se.

OSHA also has conducted surveys of healthcare facilities, including nursing homes, related to COVID-19 outbreaks among staff and staff deaths. Healthcare is an area of focus for OSHA and they are expected to continue issuing fines to long term care facilities for actions that occurred during the pandemic. Long term care facilities are advised to seek guidance when confronted with OSHA citations.

Ensuring we will be able to craft our narrative and the COVID-19 playbook

Recommendations for Defense

Develop the timeline with the facility and identify people with the most knowledge. Gather the following documents:

i. Communications to residents and families about positive cases, deaths, what the facility was doing to address the pandemic;

ii. Communications to employees;

iii. Any web communications that came in through the community or corporate site; any replies;

iv. External and internal facing sites that contained COVID-related information; many facilities had FAQs available to the public as well;

v. Any agreements with third parties supplying staff;

vi. Visitor/Vendor screening logs for symptoms and temperatures

vii. Associate screening logs

viii. Internal tracking documents for COVID positive results; test results

ix. Survey findings related to COVID

x. Programming—what were they doing to provide engagement for residents

xi. Progress Notes—be prepared for gaps that may have occurred due to responding in real-time

    1. 24-hour reports or other documentation that may not have been part of the chart may be able to fill gaps

xii. Other items to request from the facility for the time period at issue:

    1. All policies (and all versions) related to COVID

2. All training (and all versions) related to COVID

3. Pendant/call bell reports

4. Reports submitted to the state

5. Survey results and plans of correction

The retention of experts early in the matter is going to be key in assessing potential liability. Some suggestions, include, but are not limited to:

1. If no immunity statute or executive order, the facility should retain nursing and infectious disease standard-of-care experts to render opinions regarding the alleged acts or omissions the claimant alleges caused or contributed to his or her contraction of COVID-19.

2. To defend claims sounding in corporate negligence, the facility should retain nursing and infectious disease experts to render opinions regarding the policies and procedures and training the facility provided to prevent avoidable infection.

3. To defend claims of inadequate screening or untimely facilitation of medical care, the facility should retain experts in the fields of infectious disease, geriatrics, and fields particular to a resident's preexisting comorbidities to render opinions regarding whether the claimant's adverse outcome was unavoidable and not substantially caused or contributed to by the facility's alleged breach of the standard of care. Experts should consider whether a claimant's age and/or comorbid conditions resulted in an unavoidable adverse outcome.

Our New Reality

As we move forward, long term care facilities will need to stay focused on these issues and continuously assess each of the following issues:

a. Who is tested and how often

b. Navigating the multitude of state and licensing regulations and executive orders—where we saw no action initially, we are now inundated with individual mandates

c. Visitation

d. Vaccines

i. Resident enthusiasm for the vaccine; disappointment if the state was not acting quickly

ii. Associate participation and reluctance

iii. Resident preferences for caregivers who have been vaccinated

iv. Incentives?

EXHIBIT A

This is an official

CDC HEALTH UPDATE

Distributed via the CDC Health Alert Network
February 1, 2020, 0900 ET (9:00 AM ET)
CDCHAN-00427

Update and Interim Guidance on Outbreak of 2019 Novel Coronavirus (2019-nCoV)

Summary
The Centers for Disease Control and Prevention (CDC) continues to closely monitor an outbreak of respiratory illness caused by a novel coronavirus (2019-nCoV) that was initially detected in Wuhan City, Hubei Province, China in December 2019.

This CDC Health Alert Network (HAN) Update provides a situational update and interim guidance to state and local health departments that supersedes guidance in CDC's HAN 426 distributed on January 17, 2020. It also adds

- guidance for clinicians caring for patients with 2019-nCoV (https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-guidance-management-patients.html),
- and for public health officials on the evaluation and testing of patients under investigation (PUIs) for 2019-nCoV (https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html), and
- updated infection prevention and control guidance specific to 2019-nCoV (https://www.cdc.gov/coronavirus/2019-nCoV/hcp/infection-control.html).

Early in the outbreak, many of the patients with respiratory illness caused by 2019-nCoV in China had exposure to a large seafood and live animal market, suggesting animal-to-human transmission. More recently, cases have been confirmed with no exposure to animal markets, indicating that person-to-person spread of the virus has occurred. Chinese officials report that sustained person-to-person spread in the community is occurring in China.

The first US case-patient was identified on January 21, 2020, and had recently traveled from Wuhan, China. Since that time, six additional cases have been confirmed in the United States, four among persons who traveled from Wuhan, and one a close contact of a confirmed case. Globally, reported illnesses in people with 2019-nCoV have ranged from mild (no or few signs and symptoms), to severe, including death. These findings are consistent with other coronaviruses, including Severe Acute Respiratory Syndrome (SARS) (https://www.cdc.gov/sars/) and Middle East Respiratory Syndrome (MERS) (https://www.cdc.gov/coronavirus/mers/index.html). Additional information about 2019-nCoV is needed to better understand transmission, disease severity, and risk to the general population. The goal of the ongoing US public health response is to identify and contain this outbreak and prevent sustained spread of 2019-nCoV in the United States.

Recommendations for Screening of Patients for 2019-nCoV in Healthcare Facilities
Recommendations for screening of patients for possible 2019-nCoV infection are based on (1) current knowledge of the characteristics of clinical illness observed in early cases, and (2) the geographic distribution of current cases. They reflect the current public health goal of rapidly containing and preventing transmission of 2019-nCoV illness.

Patients presenting to healthcare facilities should be assessed for exposures associated with risk of 2019-nCoV infections (e.g., travel to China or close contact with a confirmed case) and for symptoms consistent with 2019-nCoV infection (https://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-

criteria.html). The assessment is intended to allow healthcare providers to make decisions about appropriate infection control and management of patients. Note that the signs and symptoms of 2019-nCoV overlap with those associated with other viral respiratory tract infections. Given the time of year, common respiratory illnesses, including influenza, should also be considered in patients who are screened. (Figure 1)

Clinicians should ask:

- Does the person have fever or symptoms of lower respiratory infection, such as cough or shortness of breath?

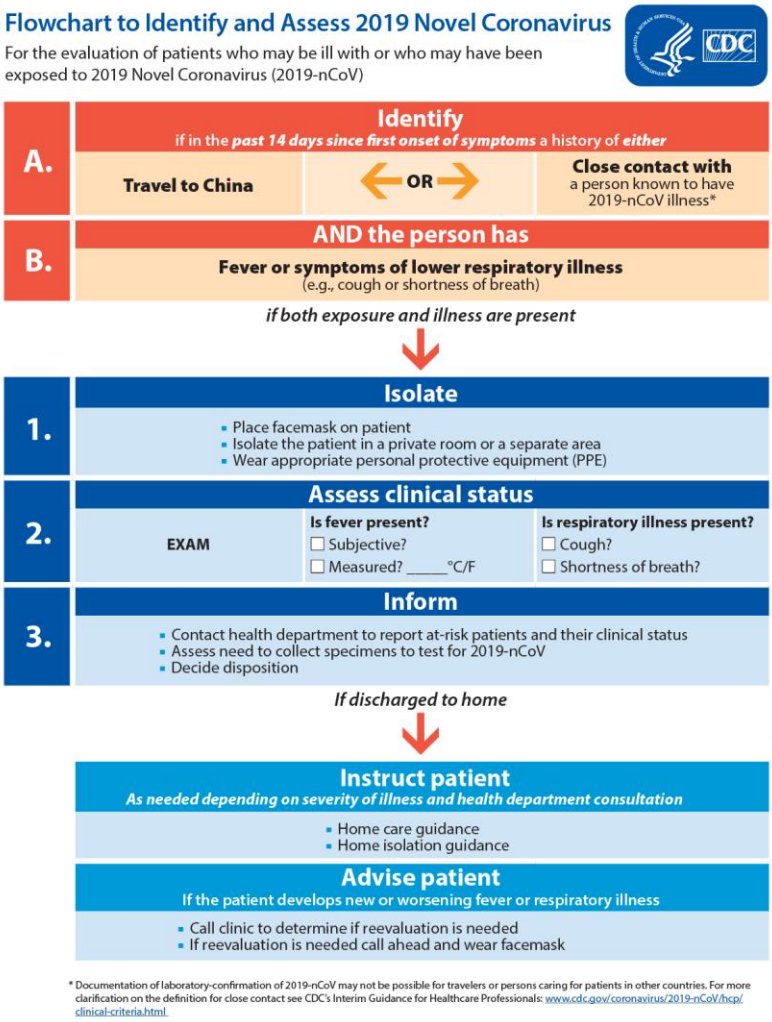
AND

- Has the patient traveled to mainland China within 14 days of symptom onset?

OR

- Has the patient had close contact[1] with a person confirmed with 2019-nCoV infection?

Figure 1.



If a patient meets these criteria:

- To minimize the risk that other people will be exposed to individuals who may have 2019-nCoV, patients who report having these symptoms should be asked to wear a surgical mask as soon as they are identified and directed to a separate area, if possible, with at least 6 feet (2 meters) separation from other persons. Patients should be evaluated in a private room with the door closed, ideally an airborne infection isolation room (AIIR), if available. Healthcare personnel entering the room should use standard precautions, contact precautions, airborne precautions, and use eye protection (e.g., goggles or a face shield). For more information about this, see CDC's *Interim Infection Prevention and Control Recommendations for Patients with Known or Patients Under Investigation for 2019 Novel Coronavirus (2019-nCoV) in a Healthcare Setting* (https://www.cdc.gov/coronavirus/2019-nCoV/hcp/infection-control.html).

Clinicians should immediately notify the healthcare facility's infection control personnel and local health department. The health department will determine if this patient needs to be considered a PUI for 2019-nCoV and be tested for infection.

Criteria to Guide Evaluation and Testing of Patients Under Investigation (PUI) for 2019-nCoV
Local health departments, in consultation with clinicians, should determine whether a patient is a PUI for 2019-nCoV. The CDC clinical criteria for 2019-nCoV PUIs have been developed based on available information about this novel virus, as well as what is known about SARS and MERS. These criteria are subject to change as additional information becomes available.

Clinical Features	AND	Epidemiologic Risk
Fever[2] **or** signs/symptoms of lower respiratory illness (e.g. cough or shortness of breath)	**AND**	Any person, including health care workers, who has had close contact[1] with a laboratory-confirmed[3] 2019-nCoV patient within 14 days of symptom onset
Fever[2] **and** signs/symptoms of a lower respiratory illness (e.g., cough or shortness of breath)	**AND**	A history of travel from **Hubei Province**, China within 14 days of symptom onset
Fever[2] **and** signs/symptoms of a lower respiratory illness (e.g., cough or shortness of breath) requiring hospitalization[4]	**AND**	A history of travel from mainland **China** within 14 days of symptom onset

These criteria are intended to serve as guidance for evaluation and testing. Patients should be evaluated and discussed with public health departments on a case-by-case basis for possible 2019-nCoV infection. Testing decisions might be further informed by the clinical presentation or exposure history (e.g., uncertain travel or exposure), and the presence of an alternative diagnosis that explains their clinical presentation.

Recommendations for Reporting, Testing, and Specimen Collection
Healthcare providers should **immediately** notify infection control personnel at their healthcare facility if a patient is classified a PUI for 2019-nCoV. State health departments that have identified a PUI should immediately contact CDC's Emergency Operations Center (EOC) at 770-488-7100 and complete a 2019-nCoV PUI case investigation form (https://www.cdc.gov/coronavirus/2019-ncov/hcp/clinical-criteria.html#reporting-testing-specimen-collection). CDC's EOC will assist local and state health departments with obtaining, storing, and shipping appropriate specimens to CDC, including afterhours or on weekends or holidays. Currently, diagnostic testing for 2019-nCoV can be done only at CDC. Testing for other respiratory pathogens should not delay specimen shipping to CDC.

For initial diagnostic testing for 2019-nCoV, CDC recommends collecting and testing upper respiratory (nasopharyngeal AND oropharyngeal swabs), and lower respiratory (sputum, if possible)) for those patients with productive coughs. Induction of sputum is not indicated. Specimens should be collected as soon as possible once a PUI is identified, regardless of the time of symptom onset. See *Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Patients Under Investigation (PUIs) for 2019 Novel Coronavirus (2019-nCoV)* (https://www.cdc.gov/coronavirus/2019-nCoV/lab/guidelines-clinical-specimens.html).

Recommendations for Healthcare Providers
No vaccine or specific treatment for 2019-nCoV infection is available. At present, medical care for patients with 2019-nCoV is supportive.

Persons with confirmed or suspected 2019-nCoV infection who are hospitalized should be evaluated and cared for in a private room with the door closed, ideally an airborne infection isolation room, if available. For more information, see *Interim Infection Prevention and Control Recommendations for Patients with Known or Patients Under Investigation for 2019 Novel Coronavirus (2019-nCoV) in a Healthcare Setting* (https://www.cdc.gov/coronavirus/2019-nCoV/hcp/infection-control.html).

Home care and isolation may be an option, based on clinical and public health assessment, for some persons. Please see *Interim Guidance for Preventing the Spread of 2019 Novel Coronavirus (2019-nCoV) in Homes and Communities* (https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-prevent-spread.html).

Those isolated at home should be monitored by public health officials to the extent possible. Refer to *Interim Guidance for Implementing Home Care of People Not Requiring Hospitalization for 2019 Novel Coronavirus (2019-nCoV)* (https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-home-care.html) for more information.

Notes
[1]Close contact is defined as:
a) being within approximately 6 feet (2 meters), or within the room or care area, of a 2019-nCoV case for a prolonged period of time while not wearing recommended personal protective equipment or PPE (e.g., gowns, gloves, NIOSH-certified disposable N95 respirator, eye protection); close contact can include caring for, living with, visiting, or sharing a health care waiting area or room with a 2019-nCoV case
- or -
b) having direct contact with infectious secretions of a 2019-nCoV case (e.g., being coughed on) while not wearing recommended personal protective equipment.
[2]Fever may be subjective or confirmed

See CDC's updated *Interim Infection Prevention and Control Recommendations for Patients with Known or Patients Under Investigation for 2019 Novel Coronavirus (2019-nCoV) in a Healthcare Setting* (https://www.cdc.gov/coronavirus/2019-ncov/infection-control.html).

Data to inform the definition of close contact are limited. Considerations when assessing close contact include the duration of exposure (e.g., longer exposure time likely increases exposure risk) and the clinical symptoms of the person with 2019-nCoV (e.g., coughing likely increases exposure risk as does exposure to a severely ill patient). Special consideration should be given to those exposed in health care settings.

[3] Documentation of laboratory-confirmation of 2019-nCoV may not be possible for travelers or persons caring for patients in other countries.

[4] Category also includes any member of a cluster of patients with severe acute lower respiratory illness (e.g., pneumonia, ARDS) of unknown etiology in which 2019-nCoV is being considered that requires hospitalization. Such persons should be evaluated in consultation with state and local health departments regardless of travel history.

For More Information

More information is available at the 2019 Novel Coronavirus website (https://www.cdc.gov/coronavirus/2019-ncov/index.html) or by calling 800-CDC-INFO | (800-232-4636) | TTY: (888) 232-6348

The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.

Categories of Health Alert Network messages:

Health Alert	Requires immediate action or attention; highest level of importance
Health Advisory	May not require immediate action; provides important information for a specific incident or situation
Health Update	Unlikely to require immediate action; provides updated information regarding an incident or situation
HAN Info Service	Does not require immediate action; provides general public health information

##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, epidemiologists, HAN coordinators, and clinician organizations##

Flowchart to Identify and Assess 2019 Novel Coronavirus

For the evaluation of patients who may be ill with or who may have been exposed to 2019 Novel Coronavirus (2019-nCoV)

A. Identify

if in the ***past 14 days since first onset of symptoms*** a history of ***either***

Travel to China	← OR →	**Close contact with** a person known to have 2019-nCoV illness*

B. AND the person has

Fever or symptoms of lower respiratory illness
(e.g., cough or shortness of breath)

if both exposure and illness are present

↓

1. Isolate

- Place facemask on patient
- Isolate the patient in a private room or a separate area
- Wear appropriate personal protective equipment (PPE)

2. Assess clinical status

EXAM	**Is fever present?**	**Is respiratory illness present?**
	☐ Subjective?	☐ Cough?
	☐ Measured? _____°C/F	☐ Shortness of breath?

3. Inform

- Contact health department to report at-risk patients and their clinical status
- Assess need to collect specimens to test for 2019-nCoV
- Decide disposition

If discharged to home

↓

Instruct patient

As needed depending on severity of illness and health department consultation

- Home care guidance
- Home isolation guidance

Advise patient

If the patient develops new or worsening fever or respiratory illness

- Call clinic to determine if reevaluation is needed
- If reevaluation is needed call ahead and wear facemask

* Documentation of laboratory-confirmation of 2019-nCoV may not be possible for travelers or persons caring for patients in other countries. For more clarification on the definition for close contact see CDC's Interim Guidance for Healthcare Professionals: www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html

EXHIBIT B

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Quality, Safety, and Oversight Group

Ref: QSO 20-09-ALL

DATE: **February 6, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality Safety and Oversight Group

SUBJECT: Information for Healthcare Facilities Concerning 2019 Novel Coronavirus Illness (2019-nCoV)

Memorandum Summary

- ***Information Regarding Patients with Possible Coronavirus Illness:*** the U.S. Centers for Disease Control and Prevention (CDC) has issued information on the respiratory illness caused by the 2019 Novel Coronavirus (2019-nCoV). Links to these documents are provided.

- ***Healthcare Facility Expectations:*** CMS strongly urges the review of CDC's guidance and encourages facilities to review their own infection prevention and control policies and practices to prevent the spread of infection.

The Centers for Medicare & Medicaid Services (CMS) is committed to the protection of patients and residents of healthcare facilities from the spread of infectious disease. Every Medicare participating facility in the Nation's healthcare system must adhere to standards for infection prevention and control in order to provide safe, high quality care. As concerns arise with the emerging 2019 Novel Coronavirus (2019-nCoV) threat, CMS encourages all healthcare facilities to carefully review the information provided by our partners at the U.S. Centers for Disease Control and Prevention (CDC). CDC has issued an updated interim Health Alert Network (HAN) Advisory, information about CDC's response to 2019-nCoV as well as recommendations for healthcare facilities. Because coronavirus infections can rapidly appear and spread, facilities must take steps to prepare, including reviewing their infection control policies and practices to prevent the spread of infection.

CMS recognizes the need to consider "emerging infectious diseases" in a provider's emergency preparedness plans as required by the 2016 Emergency Preparedness Final Rule (81 FR 63860, 63862, September 16, 2016). Recent public health events such as the Ebola virus, 2009 pandemic H1N1 influenza, and Zika outbreaks highlight the critical need for providers to be prepared by planning for infectious disease response within their organizations. In February 2019, CMS updated guidance to emphasize the need for preparation and now we are seeing the importance of this effort. Patients expect quality care from their healthcare providers and part of that means being ready for emergency situations that might arise. Understanding all of the

various hazards to prepare for emergencies, such as 2019-nCoV, improves patient outcomes and provides protection to patients, family members as well as staff in healthcare settings.

To ensure health and safety, CMS also expects healthcare staff and surveyors (contractors, Federal, State, and Local) to comply with basic infection control practices. For 2019 novel coronavirus, CDC is currently advising adherence to Standard, Contact, and Airborne Precautions, including the use of eye protection (for more information, see CDC's Interim Infection Control Recommendations for 2019-nCoV). Healthcare staff should also adhere to CDC recommendations on standard hand hygiene practices, using alcohol-based hand rub/hand sanitizer (ABHR/ABHS) as the preferred method of hand hygiene in most clinical situations. If hands are visibly soiled, wash with soap and water for at least 20 seconds. Healthcare facilities should ensure that hand hygiene supplies are readily available see CDC Hand Hygiene in Healthcare Settings for more detailed information.

In addition to the review of CDC information by healthcare facilities, we encourage the review of appropriate personal protective equipment (PPE) use and availability, such as gloves, gowns, respirators, and eye protection. CMS regularly observes these infection control practices as part of the normal survey process and notes that applying the basic principles of hand hygiene and using appropriate PPE protects lives. Medicare participating healthcare facilities should also have PPE measures and protocols within their emergency plans, especially in the event of potential surge situations.

To assist facilities in self-assessment and review of their own practices, CMS provides several resources listed below including online courses developed in conjunction with CDC, focusing on universal infection control practices.

CMS continues to work diligently with CDC, Accrediting Organizations (AO) and State Survey Agencies to clarify, emphasize, and ensure that healthcare facility infection control programs meet minimum health and safety standards. This collaboration will support the CDC Clean Hands Count campaign which aims to improve healthcare provider adherence to hand hygiene recommendations. Additionally, during surveys in 2020, CMS and AO acute care surveyors will be alert to healthcare staff hand hygiene practices, including the use of ABHR/ABHS, in an effort to raise awareness of the need for hand hygiene and improve compliance. We know that adherence to basic infection control and prevention practices such as hand hygiene can help reduce the risk of infectious disease spread in all healthcare settings.

In light of the 2019-nCoV outbreak, the Office for Civil Rights (OCR) at the U.S. Department of Health and Human Services has issued guidance to serve as a reminder of the ways that patient information may be shared so that the protections of the HIPAA Privacy Rule are not set aside during an emergency: https://www.hhs.gov/sites/default/files/february-2020-hipaa-and-novel-coronavirus.pdf

CMS will continue to monitor the 2019-nCoV situation and support efforts of our partners at the CDC. For the most current information please refer to the CDC website: https://www.cdc.gov/coronavirus/2019-ncov/index.html

Additional information related to CMS requirements and training are located at the following links:

CMS Emergency Preparedness Website: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertEmergPrep

CMS Hospital Infection Control Self-assessment tool: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-15-12-Attachment-1.pdf

CMS Universal Infection Control Training Course:
https://qsep.cms.gov/pubs/CourseMenu.aspx?cid=0CMSUIPC_ONL

CMS Nursing Home Infection Preventionist Training:
https://www.train.org/cdctrain/training_plan/3814

Nursing Home Infection Control Worksheet:
https://qsep.cms.gov/data/252/A._NursingHome_InfectionControl_Worksheet11-8-19508.pdf

CDC Clean Hands Count for Safe Healthcare
https://www.cdc.gov/features/handhygiene/index.html

Questions about this memorandum should be addressed to QSOG_EmergencyPrep@cms.hhs.gov. Questions about the 2019-nCoV guidance/screening criteria should be addressed to the State Epidemiologist or other responsible state or local public health officials in your state.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers, and the State/Regional Office training coordinators immediately.

/s/
David Wright

cc: Survey & Certifications Group Management

Long-Term Care and Other Residential Facilities Pandemic Influenza Planning Checklist

Planning for pandemic influenza is critical for ensuring a sustainable healthcare response. The Department of Health and Human Services (HHS) and the Centers for Disease Control and Prevention (CDC) have developed this checklist to help long-term care and other residential facilities assess and improve their preparedness for responding to pandemic influenza. Based on differences among facilities (e.g., patient/resident characteristics, facility size, scope of services, hospital affiliation), each facility will need to adapt this checklist to meet its unique needs and circumstances. This checklist should be used as one tool in developing a comprehensive pandemic influenza plan. Additional information can be found at www.pandemicflu.gov. Information from state, regional, and local health departments, emergency management agencies/authorities, and trade organizations should be incorporated into the facility's pandemic influenza plan. Comprehensive pandemic influenza planning can also help facilities plan for other emergency situations.

This checklist identifies key areas for pandemic influenza planning. Long-term care and other residential facilities can use this tool to self-assess the strengths and weaknesses of current planning efforts. Links to websites with helpful information are provided throughout this document. However, it will be necessary to actively obtain information from state and local resources to ensure that the facility's plan complements other community and regional planning efforts.

1. Structure for planning and decision making.

Completed	In Progress	Not Started	
❑	❑	❑	**Pandemic influenza has been incorporated into emergency management planning and exercises for the facility.**
❑	❑	❑	**A multidisciplinary planning committee or team[1] has been created to specifically address pandemic influenza preparedness planning.**
			(List committee's or team's name.) _____
❑	❑	❑	**A person has been assigned responsibility for coordinating preparedness planning, hereafter referred to as the pandemic influenza response coordinator. (Insert name, title and contact information.)** _____
			_____
❑	❑	❑	**Members of the planning committee include (as applicable to each setting) the following: (Develop a list of committee members with the name, title, and contact information for each personnel category checked below and attach to this checklist.)**
			❑ Facility administration
			❑ Medical director
			❑ Nursing administration
			❑ Infection control
			❑ Occupational health
			❑ Staff training and orientation
			❑ Engineering/maintenance services
			❑ Environmental (housekeeping) services
			❑ Dietary (food) services
			❑ Pharmacy services
			❑ Occupational/rehabilitation/physical therapy services
			❑ Transportation services
			❑ Purchasing agent
			❑ Facility staff representative
			❑ Other member(s) as appropriate (e.g., clergy, community representatives, department heads, resident and family representatives, risk managers, quality improvement, direct care staff, collective bargaining agreement union representatives)

1. An existing emergency or disaster preparedness team may be assigned this responsibility.

1. Structure for planning and decision making *(continued).*

Completed	In Progress	Not Started	
❑	❑	❑	Local and state health departments and provider/trade association points of contact have been identified for information on pandemic influenza planning resources. (Insert name, title and contact information for each.) Local health department contact: _____ State health department contact: _____ State long-term care professional/trade association: _____ _____
❑	❑	❑	Local, regional, or state emergency preparedness groups, including bioterrorism/communicable disease coordinators points of contact have been identified. (Insert name, title and contact information for each.) City: _____ County: _____ Other regional: _____
❑	❑	❑	Area hospitals points of contact have been identified in the event that facility residents require hospitalization or facility beds are needed for hospital patients being discharged in order to free up needed hospital beds. (Attach a list with the name, title, and contact information for each hospital.)
❑	❑	❑	The pandemic influenza response coordinator has contacted local or regional pandemic influenza planning groups to obtain information on coordinating the facility's plan with other influenza plans.

2. Development of a written pandemic influenza plan.

Completed	In Progress	Not Started	
❑	❑	❑	Copies have been obtained of relevant sections of the HHS Pandemic Influenza Plan (available at www.hhs.gov/pandemicflu/plan/) and available state, regional, or local plans are reviewed for incorporation into the facility's plan.
❑	❑	❑	The facility plan includes the elements listed in #3 below.
❑	❑	❑	The plan identifies the person(s) authorized to implement the plan and the organizational structure that will be used.

3. Elements of an influenza pandemic plan.

Completed	In Progress	Not Started	
❑	❑	❑	**A plan is in place for surveillance and detection of the presence of pandemic influenza in residents and staff.**

❑ A person has been assigned responsibility for monitoring public health advisories (federal and state), and updating the pandemic response coordinator and members of the pandemic influenza planning committee when pandemic influenza has been reported in the United States and is nearing the geographic area. For more information, see www.cdc.gov/flu/weekly/fluactivity.htm. (Insert name, title and contact information of person responsible.) _____

_____

❑ A written protocol has been developed for weekly or daily monitoring of seasonal influenza-like illness in residents and staff. For more information, see www.cdc.gov/flu/professionals/diagnosis/. (Having a system for tracking illness trends during seasonal influenza will ensure that the facility can detect stressors that may affect operating capacity, including staffing and supply needs, during a pandemic.)

❑ A protocol has been developed for the evaluation and diagnosis of residents and/or staff with symptoms of pandemic influenza.

❑ Assessment for seasonal influenza is included in the evaluation of incoming residents. There is an admission policy or protocol to determine the appropriate placement and isolation of patients with an influenza-like illness. (The process used during periods of seasonal influenza can be applied during pandemic influenza.)

3. Elements of an influenza pandemic plan *(continued).*

Completed	In Progress	Not Started	
			❑ A system is in place to monitor for, and internally review transmission of, influenza among patients and staff in the facility. Information from this monitoring system is used to implement prevention interventions (e.g., isolation, cohorting). (This system will be necessary for assessing pandemic influenza transmission.)
❑	❑	❑	**A facility communication plan has been developed.** **For more information, see www.hhs.gov/pandemicflu/plan/sup10.htm.**
			❑ Key public health points of contact during an influenza pandemic influenza have been identified. (Insert name, title and contact information for each.)
			❑ Local health department contact: _____
			❑ State health department contact: _____
			❑ A person has been assigned responsibility for communications with public health authorities during a pandemic. (Insert name, title and contact information.) _____
			❑ A person has been assigned responsibility for communications with staff, residents, and their families regarding the status and impact of pandemic influenza in the facility. (Having one voice that speaks for the facility during a pandemic will help ensure the delivery of timely and accurate information.)
			❑ Contact information for family members or guardians of facility residents is up-to-date.
			❑ Communication plans include how signs, phone trees, and other methods of communication will be used to inform staff, family members, visitors, and other persons coming into the facility (e.g., sales and delivery people) about the status of pandemic influenza in the facility.
			❑ A list has been created of other healthcare entities and their points of contact (e.g., other long-term care and residential facilities, local hospitals' emergency medical services, relevant community organizations [including those involved with disaster preparedness]) with whom it will be necessary to maintain communication during a pandemic. (Insert location of contact list and attach a copy to the pandemic plan.)
			❑ A facility representative(s) has been involved in the discussion of local plans for inter-facility communication during a pandemic.
❑	❑	❑	**A plan is in place to provide education and training to ensure that all personnel, residents, and family members of residents understand the implications of, and basic prevention and control measures for, pandemic influenza.**
			❑ A person has been designated with responsibility for coordinating education and training on pandemic influenza (e.g., identifies and facilitates access to available programs, maintains a record of personnel attendance). (Insert name, title, and contact information.) _____
			❑ Current and potential opportunities for long-distance (e.g., web-based) and local (e.g., health department or hospital-sponsored) programs have been identified. See www.cdc.gov/flu/professionals/training/.
			❑ Language and reading-level appropriate materials have been identified to supplement and support education and training programs (e.g., available through state and federal public health agencies such as www.cdc.gov/flu/groups.htm and through professional organizations), and a plan is in place for obtaining these materials.
			❑ Education and training includes information on infection control measures to prevent the spread of pandemic influenza.
			❑ The facility has a plan for expediting the credentialing and training of non-facility staff brought in from other locations to provide patient care when the facility reaches a staffing crisis.
			❑ Informational materials (e.g., brochures, posters) on pandemic influenza and relevant policies (e.g., suspension of visitation, where to obtain facility or family member information) have been developed or identified for residents and their families. These materials are language and reading-level appropriate, and a plan is in place to disseminate these materials in advance of the actual pandemic. For more information, see www.cdc.gov/flu/professionals/infectioncontrol/index.htm and www.cdc.gov/flu/groups.htm.

3. Elements of an influenza pandemic plan *(continued).*

Completed	In Progress	Not Started	
❑	❑	❑	**An infection control plan is in place for managing residents and visitors with pandemic influenza that includes the following: (For information on infection control recommendations for pandemic influenza, see www.hhs.gov/pandemicflu/plan/sup4.html.)**
❑	❑	❑	An infection control policy that requires direct care staff to use Standard (www.cdc.gov/ncidod/dhqp/gl_isolation_standard.html) and Droplet Precautions (i.e., mask for close contact) (www.cdc.gov/ncidod/dhqp/gl_isolation_droplet.html) with symptomatic residents.
❑	❑	❑	A plan for implementing Respiratory Hygiene/Cough Etiquette throughout the facility. (See www.cdc.gov/flu/professionals/infectioncontrol/resphygiene.htm.)
❑	❑	❑	A plan for cohorting symptomatic residents or groups using one or more of the following strategies:[2] 1) confining symptomatic residents and their exposed roommates to their room, 2) placing symptomatic residents together in one area of the facility, or 3) closing units where symptomatic and asymptomatic residents reside (i.e., restricting all residents to an affected unit, regardless of symptoms). The plan includes a stipulation that, where possible, staff who are assigned to work on affected units will not work on other units.
❑	❑	❑	Criteria and protocols for closing units or the entire facility to new admissions when pandemic influenza is in the facility have been developed.
❑	❑	❑	Criteria and protocols for enforcing visitor limitations have been developed.
❑	❑	❑	**An occupational health plan for addressing staff absences and other related occupational issues has been developed that includes the following:**
❑	❑	❑	❑ A liberal/non-punitive sick leave policy that addresses the needs of symptomatic personnel and facility staffing needs. The policy considers: - The handling of personnel who develop symptoms while at work. - When personnel may return to work after having pandemic influenza. - When personnel who are symptomatic, but well enough to work, will be permitted to continue working. - Personnel who need to care for family members who become ill.
			❑ A plan to educate staff to self-assess and report symptoms of pandemic influenza before reporting for duty.
			❑ A list of mental health and faith-based resources that will be available to provide counseling to personnel during a pandemic.
			❑ A system to monitor influenza vaccination of personnel.
			❑ A plan for managing personnel who are at increased risk for influenza complications (e.g., pregnant women, immunocompromised workers) by placing them on administrative leave or altering their work location.
❑	❑	❑	**A vaccine and antiviral use plan has been developed.**
			❑ CDC and state health department websites have been identified for obtaining the most current recommendations and guidance for the use, availability, access, and distribution of vaccines and antiviral medications during a pandemic. For more information, see www.hhs.gov/pandemicflu/plan/sup6.html and www.hhs.gov/pandemicflu/plan/sup7.html.
			❑ HHS guidance has been used to estimate the number of personnel and residents who would be targeted as first and second priority for receipt of pandemic influenza vaccine or antiviral prophylaxis. For more information, see www.hhs.gov/pandemicflu/plan/sup6.html and www.hhs.gov/pandemicflu/plan/sup7.html.
			❑ A plan is in place for expediting delivery of influenza vaccine or antiviral prophylaxis to residents and staff as recommended by the state health department.

2. CDC guidance on preventing and controlling influenza transmission in long-term care facilities will be a useful resource during pandemic influenza. (See www.cdc.gov/flu/professionals/infectioncontrol/longtermcare.htm.)

3. Elements of an influenza pandemic plan *(continued).*

Completed	In Progress	Not Started	
❑	❑	❑	**Issues related to surge capacity during a pandemic have been addressed.**
			❑ A contingency staffing plan has been developed that identifies the minimum staffing needs and prioritizes critical and non-essential services based on residents' health status, functional limitations, disabilities, and essential facility operations.
			❑ A person has been assigned responsibility for conducting a daily assessment of staffing status and needs during an influenza pandemic. (Insert name, title and contact information.)
			_____
			❑ Legal counsel and state health department contacts have been consulted to determine the applicability of declaring a facility "staffing crisis" and appropriate emergency staffing alternatives, consistent with state law.
			❑ The staffing plan includes strategies for collaborating with local and regional planning and response groups to address widespread healthcare staffing shortages during a crisis.
			❑ Estimates have been made of the quantities of essential materials and equipment (e.g., masks, gloves, hand hygiene products, intravenous pumps) that would be needed during a six-week pandemic.
			❑ A plan has been developed to address likely supply shortages, including strategies for using normal and alternative channels for procuring needed resources.
			❑ Alternative care plans have been developed for facility residents who need acute care services when hospital beds become unavailable.
			❑ Surge capacity plans include strategies to help increase hospital bed capacity in the community. - Signed agreements have been established with area hospitals for admission to the long-term care facility of non-influenza patients to facilitate utilization of acute care resources for more seriously ill patients. - Facility space has been identified that could be adapted for use as expanded inpatient beds and information provided to local and regional planning contacts.
			❑ A contingency plan has been developed for managing an increased need for post mortem care and disposition of deceased residents.
			❑ An area in the facility that could be used as a temporary morgue has been identified.
			❑ Local plans for expanding morgue capacity have been discussed with local and regional planning contacts.

Coronavirus Disease 2019 (COVID-19) Preparedness Checklist for Nursing Homes and other Long-Term Care Settings

Nursing homes and other long-term care facilities can take steps to assess and improve their preparedness for responding to coronavirus disease 2019 (COVID-19). Each facility will need to adapt this checklist to meet its needs and circumstances based on differences among facilities (e.g., patient/resident characteristics, facility size, scope of services, hospital affiliation). This checklist should be used as one tool in developing a comprehensive COVID-19 response plan. Additional information can be found at www.cdc.gov/COVID-19. Information from state, local, tribal, and territorial health departments, emergency management agencies/authorities, and trade organizations should be incorporated into the facility's COVID-19 plan. Comprehensive COVID-19 planning can also help facilities plan for other emergency situations.

This checklist identifies key areas that long-term care facilities should consider in their COVID-19 planning. Long-term care facilities can use this tool to self-assess the strengths and weaknesses of current preparedness efforts. Additional information is provided via links to websites throughout this document. However, it will be necessary to actively obtain information from state, local, tribal, and territorial resources to ensure that the facility's plan complements other community and regional planning efforts. This checklist does not describe mandatory requirements or standards; rather, it highlights important areas to review to prepare for the possibility of residents with COVID-19.

A preparedness checklist for hospitals, including long-term acute care hospitals is available.
https://www.cdc.gov/coronavirus/2019-ncov/downloads/hospital-preparedness-checklist.pdf

Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings:
https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html

Strategies to Prevent the Spread of COVID-19 in Long-Term Care Facilities (LTCF):
https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/prevent-spread-in-long-term-care-facilities.html

1. Structure for planning and decision making

	Completed	In Progress	Not Started
▪ COVID-19 has been incorporated into emergency management planning for the facility.	☐	☐	☐
▪ A multidisciplinary planning committee or team* has been created to specifically address COVID-19 preparedness planning.	☐	☐	☐

List committee's or team's name:

**An existing emergency or disaster preparedness team may be assigned this responsibility.*

continue on next page

cont.

	Completed	In Progress	Not Started
▪ People assigned responsibility for coordinating preparedness planning, hereafter referred to as the COVID-19 response coordinator.	☐	☐	☐

Insert name(s), title(s), and contact information:

▪ Members of the planning committee include the following: (Develop a list of committee members with the name, title, and contact information for each personnel category checked below and attach to this checklist.) ▪ Facility administration ▪ Medical director ▪ Director of Nursing ▪ Infection control ▪ Occupational health ▪ Staff training and orientation ▪ Engineering/maintenance services ▪ Environmental (housekeeping) services ▪ Dietary (food) services ▪ Pharmacy services ▪ Occupational/rehabilitation/physical therapy services ▪ Transportation services ▪ Purchasing agent ▪ Facility staff representative ▪ Other member(s) as appropriate (e.g., clergy, community representatives, department heads, resident and family representatives, risk managers, quality improvement, direct care staff including consultant services, union representatives)	☐	☐	☐
▪ The facility's COVID-19 response coordinator has contacted local or regional planning groups to obtain information on coordinating the facility's plan with other COVID-19 plans.	☐	☐	☐

Insert groups and contact information:

2. Development of a written COVID-19 plan.

	Completed	In Progress	Not Started
▪ A copy of the COVID-19 preparedness plan is available at the facility and accessible by staff.	☐	☐	☐
▪ Relevant sections of federal, state, regional, or local plans for COVID-19 or pandemic influenza are reviewed for incorporation into the facility's plan.	☐	☐	☐
▪ The facility plan includes the Elements listed in #3 below.	☐	☐	☐
▪ The plan identifies the person(s) authorized to implement the plan and the organizational structure that will be used.	☐	☐	☐

3. Elements of a COVID-19 plan.

	Completed	In Progress	Not Started
General:			
▪ A plan is in place for protecting residents, healthcare personnel, and visitors from respiratory infections, including COVID-19, that addresses the elements that follow.	☐	☐	☐
▪ A person has been assigned responsibility for monitoring public health advisories (federal and state) and updating the COVID-19 response coordinator and members of the COVID-19 planning committee when COVID-19 is in the geographic area. For more information, see https://www.cdc.gov/coronavirus/2019-ncov/index.html.	☐	☐	☐
Insert name, title, and contact information of person responsible.			
▪ The facility has a process for inter-facility transfers that includes notifying transport personnel and receiving facilities about a resident's suspected or confirmed diagnosis (e.g., presence of respiratory symptoms or known COVID-19) prior to transfer.	☐	☐	☐
▪ The facility has a system to monitor for, and internally review, development of COVID-19 among residents and healthcare personnel (HCP) in the facility. Information from this monitoring system is used to implement prevention interventions (e.g., isolation, cohorting), see CDC guidance on respiratory surveillance: https://www.cdc.gov/longtermcare/pdfs/LTC-Resp-OutbreakResources-P.pdf.	☐	☐	☐
▪ The facility has infection control policies that outline the recommended Transmission-Based Precautions that should be used when caring for residents with respiratory infection. (In general, for undiagnosed respiratory infection, Standard, Contact, and Droplet Precautions with eye protection are recommended unless the suspected diagnosis requires Airborne Precautions; see: https://www.cdc.gov/infectioncontrol/guidelines/isolation/appendix/type-duration-precautions.html.) For recommended Transmission-Based Precautions for residents with suspected or confirmed COVID-19, the policies refer to CDC guidance; see: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html.	☐	☐	☐
▪ The facility periodically reviews specific IPC guidance for healthcare facilities caring for residents with suspected or confirmed COVID-19 (available here: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html) and additional long-term care guidance (available here: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/prevent-spread-in-long-term-care-facilities.html).	☐	☐	☐
Facility Communications:			
▪ Key public health points of contact during a COVID-19 outbreak have been identified. (Insert name, title, and contact information for each.)	☐	☐	☐
Local health department contact:			
State health department contact:			
State long-term care professional/trade association:			

continue on next page

cont.	Completed	In Progress	Not Started
▪ A person has been assigned responsibility for communications with public health authorities during a COVID-19 outbreak. **Insert name and contact information:**	☐	☐	☐
▪ Key preparedness (e.g., Healthcare coalition) points of contact during a COVID-19 outbreak have been identified. **Insert name, title, and contact information for each:**	☐	☐	☐
▪ A person has been assigned responsibility for communications with staff, residents, and their families regarding the status and impact of COVID-19 in the facility. (Having one voice that speaks for the facility during an outbreak will help ensure the delivery of timely and accurate information.)	☐	☐	☐
▪ Contact information for family members or guardians of facility residents is up to date.	☐	☐	☐
▪ Communication plans include how signs, phone trees, and other methods of communication will be used to inform staff, family members, visitors, and other persons coming into the facility (e.g., consultants, sales and delivery people) about the status of COVID-19 in the facility.	☐	☐	☐
▪ A list has been created of other healthcare entities and their points of contact (e.g., other long-term care and residential facilities, local hospitals and hospital emergency medical services, relevant community organizations—including those involved with disaster preparedness) with whom it will be necessary to maintain communication during an outbreak. Attach a copy of contact list.	☐	☐	☐
▪ A facility representative(s) has been involved in the discussion of local plans for inter-facility communication during an outbreak.	☐	☐	☐
Supplies and resources:			
The facility provides supplies necessary to adhere to recommended IPC practices including:			
▪ Alcohol-based hand sanitizer for hand hygiene is available in every resident room (ideally both inside and outside of the room) and other resident care and common areas (e.g., outside dining hall, in therapy gym).	☐	☐	☐
▪ Sinks are well-stocked with soap and paper towels for hand washing.	☐	☐	☐
▪ Signs are posted immediately outside of resident rooms indicating appropriate IPC precautions and required personal protective equipment (PPE).	☐	☐	☐
▪ Facility provides tissues and facemasks for coughing people near entrances and in common areas with no-touch receptacles for disposal.	☐	☐	☐
▪ Necessary PPE is available immediately outside of the resident room and in other areas where resident care is provided. **continue on next page**	☐	☐	☐

cont.	Completed	In Progress	Not Started
▪ Facilities should have supplies of facemasks, respirators (if available *and* the facility has a respiratory protection program with trained, medically cleared, and fit-tested HCP), gowns, gloves, and eye protection (i.e., face shield or goggles).	☐	☐	☐
▪ Trash disposal bins should be positioned near the exit inside of the resident room to make it easy for staff to discard PPE after removal, prior to exiting the room, or before providing care for another resident in the same room.	☐	☐	☐
▪ Facility ensures HCP have access to EPA-registered hospital-grade disinfectants to allow for frequent cleaning of high-touch surfaces and shared resident care equipment. ▫ *Products with EPA-approved emerging viral pathogens claims are recommended for use against COVID-19. If there are no available EPA-registered products that have an approved emerging viral pathogen claim for COVID-19, products with label claims against human coronaviruses should be used according to label instructions.*	☐	☐	☐
▪ The facility has a process to monitor supply levels.	☐	☐	☐
▪ The facility has a contingency plan, that includes engaging their health department and healthcare coalition when they experience (or anticipate experiencing) supply shortages. Contact information for healthcare coalitions is available here: https://www.phe.gov/Preparedness/planning/hpp/Pages/find-hc-coalition.aspx	☐	☐	☐
Identification and Management of Ill Residents:			
▪ The facility has a process to identify and manage residents with symptoms of respiratory infection (e.g., cough, fever, sore throat) upon admission and daily during their stay in the facility, which include implementation of appropriate Transmission-Based Precautions.	☐	☐	☐
▪ The facility has criteria and a protocol for initiating active surveillance for respiratory infection among residents and healthcare personnel. CDC has resources for performing respiratory surveillance in long-term care facilities during an outbreak, see: https://www.cdc.gov/longtermcare/pdfs/LTC-Resp-OutbreakResources-P.pdf	☐	☐	☐
▪ Plans developed on how to immediately notify the health department for clusters of respiratory infections, severe respiratory infections, or suspected COVID-19.	☐	☐	☐
▪ The facility has criteria and a protocol for: limiting symptomatic and exposed residents to their room, halting group activities and communal dining, and closing units or the entire facility to new admissions.	☐	☐	☐
▪ The facility has criteria and a process for cohorting residents with symptoms of respiratory infection, including dedicating HCP to work only on affected units.	☐	☐	☐
Considerations about Visitors:			
▪ The facility has plans and material developed to post signs at the entrances to the facility instructing visitors not to visit if they have fever or symptoms of a respiratory infection.	☐	☐	☐
▪ The facility has criteria and protocol for when visitors will be limited or restricted from the facility. **continue on next page**	☐	☐	☐

cont.	Completed	In Progress	Not Started
▪ Should visitor restrictions be implemented, the facility has a process to allow for remote communication between the resident and visitor (e.g., video-call applications on cell phones or tablets) and has policies addressing when visitor restrictions will be lifted (e.g., end of life situation).	☐	☐	☐
For more information about managing visitor access and movement in the facility see: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html			
Occupational Health:			
▪ The facility has sick leave policies that are non-punitive, flexible, and consistent with public health policies that allow ill healthcare personnel (HCP) to stay home.	☐	☐	☐
▪ The facility instructs HCP (including consultant personnel) to regularly monitor themselves for fever and symptoms of respiratory infection, as a part of routine practice.	☐	☐	☐
▪ The facility has a process to actively screen HCP for fever and symptoms when they report to work.	☐	☐	☐
▪ The facility has a process to identify and manage HCP with fever and symptoms of respiratory infection.	☐	☐	☐
▪ The facility has a plan for monitoring and assigning work restrictions for ill and exposed HCP. (See: https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-risk-assesment-hcp.html)	☐	☐	☐
▪ The facility has a respiratory protection plan that includes medical evaluation, training, and fit testing of employees.	☐	☐	☐
Education and Training:			
▪ The facility has plans to provide education and training to HCP, residents, and family members of residents to help them understand the implications of, and basic prevention and control measures for, COVID-19. Consultant HCP should be included in education and training activities.	☐	☐	☐
▪ A person has been designated with responsibility for coordinating education and training on COVID-19 (e.g., identifies and facilitates access to available programs, maintains a record of personnel attendance).	☐	☐	☐
Insert name, title, and contact information:			
▪ Language and reading-level appropriate materials have been identified to supplement and support education and training programs to HCP, residents, and family members of residents (e.g., available through state and federal public health agencies such and through professional organizations), and a plan is in place for obtaining these materials.	☐	☐	☐

continue on next page

cont.	Completed	In Progress	Not Started
▪ Plans and material developed for education and job-specific training of HCP which includes information on recommended infection control measures to prevent the spread of COVID-19, including: ▪ Signs and symptoms of respiratory illness, including COVID-19. ▪ How to monitor residents for signs and symptoms of respiratory illness. ▪ How to keep residents, visitors, and HCP safe by using correct infection control practices including proper hand hygiene and selection and use of PPE. Training should include return demonstrations to document competency. ▪ Staying home when ill. ▪ HCP sick leave policies and recommended actions for unprotected exposures (e.g., not using recommended PPE, an unrecognized infectious patient contact).	☐	☐	☐
▪ See: "Strategies to prevent the spread of COVID-19 in long-term care facilities," available at: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/prevent-spread-in-long-term-care-facilities.html	☐	☐	☐
▪ The facility has a plan for expediting the credentialing and training of non-facility HCP brought in from other locations to provide resident care when the facility reaches a staffing crisis.	☐	☐	☐
▪ Informational materials (e.g., brochures, posters) on COVID-19 and relevant policies (e.g., suspension of visitation, where to obtain facility or family member information) have been developed or identified for residents and their families. These materials are language and reading-level appropriate, and a plan is in place to disseminate these materials in advance of the actual pandemic.	☐	☐	☐
Surge Capacity:			
Staffing			
▪ A contingency staffing plan has been developed that identifies the minimum staffing needs and prioritizes critical and non-essential services based on residents' health status, functional limitations, disabilities, and essential facility operations.	☐	☐	☐
▪ A person has been assigned responsibility for conducting a daily assessment of staffing status and needs during a COVID-19 outbreak.	☐	☐	☐
Insert name, title, and contact information: ☐			
▪ Legal counsel and state health department contacts have been consulted to determine the applicability of declaring a facility "staffing crisis" and appropriate emergency staffing alternatives, consistent with state law.	☐	☐	☐
▪ The staffing plan includes strategies for collaborating with local and regional planning and response groups to address widespread healthcare staffing shortages during a crisis.	☐	☐	☐

continue on next page

cont.	Completed	In Progress	Not Started
Consumables and durable medical equipment and supplies			
▪ Estimates have been made of the quantities of essential resident care materials and equipment (e.g., intravenous pumps and ventilators, pharmaceuticals) and personal protective equipment (e.g., masks, respirators, gowns, gloves, and hand hygiene products), that would be needed during an eight-week outbreak.	☐	☐	☐
▪ Estimates have been shared with local, regional, and tribal planning groups to better plan stockpiling agreements.	☐	☐	☐
▪ A plan has been developed to address likely supply shortages (e.g., personal protective equipment), including strategies for using normal and alternative channels for procuring needed resources.	☐	☐	☐
▪ A strategy has been developed for how priorities would be made in the event there is a need to allocate limited resident care equipment, pharmaceuticals, and other resources.	☐	☐	☐
▪ A process is in place to track and report available quantities of consumable medical supplies including PPE.	☐	☐	☐
Postmortem care:			
▪ A contingency plan has been developed for managing an increased need for postmortem care and disposition of deceased residents.	☐	☐	☐
▪ An area in the facility that could be used as a temporary morgue has been identified.	☐	☐	☐
▪ Local plans for expanding morgue capacity have been discussed with local and regional planning contacts.	☐	☐	☐

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-12-All

DATE: **March 4, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Suspension of Survey Activities

Memorandum Summary

- ***CMS is committed*** to taking critical steps to ensure America's health care facilities are prepared to respond to the threat of the 2019 Novel Coronavirus (COVID-19).
- The Centers for Medicare & Medicaid Services (CMS) CMS is committed to taking critical steps to ensure America's health care facilities are prepared to respond to the threat of the COVID-19 and other respiratory illnesses.

Background

CMS is committed to taking critical steps to ensure America's health care facilities and clinical laboratories are prepared to respond to the threat of the COVID-19 and other respiratory illness. Specifically, CMS is suspending non-emergency inspections across the country, allowing inspectors to turn their focus on the most serious health and safety threats like infectious diseases and abuse. This shift in approach will also allow inspectors to focus on addressing the spread of the coronavirus disease 2019 (COVID-19). CMS is issuing this memorandum to State Survey Agencies to provide important guidelines for the inspection process in situations in which a COVID-19 is suspected.

Discussion

Effective immediately, survey activity is limited to the following (in Priority Order):

- All immediate jeopardy complaints (cases that represents a situation in which entity noncompliance has placed the health and safety of recipients in its care at risk for serious injury, serious harm, serious impairment or death or harm) and allegations of abuse and neglect;
- Complaints alleging infection control concerns, including facilities with potential COVID-19 or other respiratory illnesses;

- Statutorily required recertification surveys (Nursing Home, Home Health, Hospice, and ICF/IID facilities);
- Any re-visits necessary to resolve current enforcement actions;
- Initial certifications;
- Surveys of facilities/hospitals that have a history of infection control deficiencies at the immediate jeopardy level in the last three years;
- Surveys of facilities/hospitals/dialysis centers that have a history of infection control deficiencies at lower levels than immediate jeopardy.

Due to the dynamic nature of this situation, we will be posting updated FAQs in real-time at the following website: https://www.cms.gov/medicare/quality-safety-oversight-general-information/coronavirus

For survey of facilities with Complaints alleging infection control concerns, including facilities with potential COVID-19 or other respiratory illness, please refer to the attached (Attachment A- Survey Planning in Facilities with Active or Suspected Cases of COVID-19 Cases; Attachment B- Infection Prevention, Control & Immunizations).

Contact: Questions about this document should be addressed to QSOG_EmergencyPrep@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators within 30 days of this memorandum.

/s/
David R. Wright

Attachment A- Survey Planning in Facilities with Active or Suspected Cases of COVID-19 Cases
Attachment B- Infection Prevention, Control & Immunizations

cc: Survey and Operations Group Management

Attachment A- Survey Planning in Facilities with Active or Suspected Cases of COVID-19 Cases

I. Protocols for Coordination and Investigation of Facilities with Actual or Suspected COVID-19 Cases

When a COVID-19 confirmed case or presumptive positive case (e.g., positive local test but pending confirmatory test), is identified in a Medicare/Medicaid certified provider or supplier, State Survey Agencies and Accrediting Organizations (AO) are requested to do the following:

- Notify the appropriate CMS Regional Office (if they are not already aware) of the facility and date of patient/resident COVID-19 or presumptive respiratory illness or confirmed status;
- Coordinate on initiating any Federal complaint or recertification survey of the impacted facility until CDC (and any other relevant Federal/State/Local response agencies) have cleared the facility for survey. The CMS Regional Office will then authorize a survey, if necessary;
- Ensure surveyors have all necessary Personal Protective Equipment (PPE) appropriate to allow a survey of the facility; Refer to CDC Infection Control resources for the most up to date guidance.
- Suspend any Federal enforcement action for any deficiencies identified until reviewed and approved by the CMS Regional Office to ensure consistent and appropriate action.

These protocols will be updated as circumstances warrant. We are asking Accrediting Organizations to copy their CMS AO liaison on any communications with the CMS Regional Office.

II. Focused Surveying – Prioritizing Threats

In all cases, concerns of **Immediate Jeopardy** (IJ) (cases that represents a situation in which entity noncompliance has placed the health and safety of recipients in its care at risk for serious injury, serious harm, serious impairment or death or harm) and cases of abuse and neglect allegations from complaints will continue to receive high priority for survey. Non-emergency surveys will be suspended.

III. Survey Planning in Facilities with Active or Suspected Cases of COVID-19 Infection

Introduction: Under What Circumstances Will CMS Authorize an On-site Survey/Investigation of a Facility With Persons who are Known or Suspected of Being COVID-19 Positive

When a COVID-19 confirmed case or presumptive positive case (e.g., positive local test but pending confirmatory test), is identified in a Medicare/Medicaid certified provider or supplier, State Survey Agencies and Accrediting Organizations must notify the appropriate CMS Regional location (if they are not already aware) of the facility and date of patient/resident COVID-19 presumptive or confirmed status.

Before initiating any Federal complaint or recertification survey of the impacted facility, CMS will coordinate with the CDC (and any other relevant Federal/State/Local response agencies) to approve the facility for survey.

The CMS Regional locations will authorize an on-site survey if reported conditions at the facility are triaged at immediate jeopardy. Immediate jeopardy means there are conditions at the facility that are causing or are likely to cause on or more recipients of care to suffer serious injury, harm, impairment or death. CMS Regional locations will also authorize on-site surveys where the complaint or facility reported incident involves infection control concerns in the facility.

If conditions at such facilities do not rise to the immediate jeopardy level, then desk audits will be performed, and on-site investigations may be authorized once all active or suspected cases of COVID-19 have been cleared from the facility.

I. Before Survey Entry

Determine survey team composition for minimal but optimal number of surveyors required to efficiently and effectively conduct the onsite observations required. Generally, one to two surveyors for an abbreviated complaint survey focusing on the COVID-19 infection control and/or quality of care issues would be sufficient. Do not include any surveyors who are currently ill or have underlying health conditions that may make them particularly vulnerable to COVID-19.

A. Personal Protective Equipment Considerations

Ensure survey team members have needed personal protective equipment (PPE) that may be required onsite to observe resident care in close quarters. If the facility has gowns, gloves, face shields or other eye protection that may be used by surveyors, such PPE may be used onsite by surveyors. However, if observation of care provided to symptomatic patients/residents who are confirmed or presumed to be COVID-19 positive is anticipated, then survey agencies and accrediting organizations should refer to the CDC Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings: https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html.

This guidance indicates, “Respirator use must be in the context of a complete respiratory protection program in accordance with Occupational Safety and Health Administration (OSHA) Respiratory Protection standard 29 CFR 1910.134). Staff should be medically cleared and fit-tested if using respirators with tight-fitting face-pieces (e.g., a NIOSH-certified disposable N95) and trained in the proper use of respirators, safe removal and disposal, and medical contraindications to respirator use…” More information on the use of respirators may be found here: https://www.osha.gov/SLTC/etools/respiratory/respirator_basics.html

B. Offsite Planning Considerations

Conduct offsite planning based on available information from: (1) facility-reported information; (2) CDC information and guidance from its onsite visit before the SA/CMS investigation; (3) available hospital information regarding patients transferred to the hospital; and/or (4) complaint allegations. Determine and prioritize key observations that should be conducted. Compile a preliminary list of the likely interviews with various facility staff and the types of records,

policies or other documents that may be needed. This may be revised after onsite observations and interviews, which may lead to additional areas of investigation.

II. Onsite Survey Activities

Upon entry, notify the facility administrator of the limited nature of the planned survey. Coordinate with the facility staff a plan and timeline for conducting the needed observations. Plan to conduct as many observations on the entry day. If by the end of the first day, the surveyors were not able to completed necessary observations, coordinate with the facility when the observations may be completed by the next day. Unless there are extenuating circumstances, plan to complete all onsite observations and corresponding interviews within two days. When possible during observations, if symptomatic patients/residents are able to tolerate wearing face masks, this will reduce the need for surveyors to wear respirator masks.

Coordinate with the facility on how to gather medical record information, with the goal to conduct as much record review offsite as possible. If the facility has an electronic health record (EHR) system that may be accessed remotely, request remote access to the EHR to review needed records for a limited period of time. If this is not an option, discuss with the facility the best options to get needed medical record information, such as fax, secure website, encrypted email, etc.

Adhere to Standard, Contact and Airborne Precautions and refer to the CDC Interim Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease 2019 (COVID-19) or Persons Under Investigation for COVID-19 in Healthcare Settings.

During onsite observation and investigation, focus on concerns with:

- Improper transmission precautions procedures
- Lack of staff knowledge of transmission precautions
- Improper staff use of PPE and/or inadequate hand hygiene
- High-risk, significant environmental cleaning issues
- Ineffective and/or improper laundering of linens
- Possible IC surveillance program issues - also consider how influenza & pneumococcal programs are managed

Conduct concurrent interviews of staff with observations during or directly after observations as appropriate. Conduct needed interviews with patients/residents onsite, as these may be difficult to obtain offsite. Patients may be discharged. Residents may have a difficult time responding to questions by telephone. While onsite, if there are periods of time when no observations can be made, attempt to conduct other needed interviews and review medical records.

For nursing home investigations, use the LTC investigative protocols for infection control (IC) and the environment:

III. Complete Survey Offsite

Except for interviews that should be conducted concurrently with observations, conduct other interviews offsite with staff by telephone. If any patient/resident interviews could not be conducted while onsite, then attempt to conduct those by telephone.

After coordinating with the facility and determining what medical record review may be conducted offsite, complete as much of the record review offsite as possible. Request facility policies and procedures for review offsite.

In addition, consider investigating Governing Body and Quality Assurance Performance Improvement requirements that may relate to infection control or care issues offsite through telephone interviews and additional record review.

After completing all investigative procedures, determine compliance status and conduct any survey exit discussion with the facility by telephone. Draft the CMS-2567 offsite.

III: Enforcement Activities

Surveys resulting in deficiencies will have the imposition of some type of enforcement action ranging from request for corrective action plans to termination depending on the circumstances surrounding deficiencies.

Attachment B- Infection Prevention, Control & Immunizations

Infection Control: *This facility task must be used to investigate compliance at F880, F881, and F883. For the purpose of this task, "staff" includes employees, consultants, contractors, volunteers, and others who provide care and services to residents on behalf of the facility. The Infection Prevention and Control Program (IPCP) program must be facility-wide and include all departments and contracted services. If a specific care area concern is identified, it should be evaluated under the specific care area, such as for pressure ulcers, respiratory care, catheter care, and medication pass observations which include central lines, peripheral IVs, and oral/IM/respiratory medications.*

Coordination:

☐ One surveyor coordinates the facility task to review for:

- The overall Infection Prevention and Control Program (IPCP);
- The annual review of the IPCP policies and practices;
- The review of the surveillance and antibiotic stewardship programs; and
- Tracking influenza/pneumococcal immunization of residents.

☐ Team assignments must be made to include the review of:

- Laundry services;
- A resident on transmission-based precautions, if any;
- Five sampled residents for influenza/pneumococcal immunizations; and
- Other care-specific observations if concerns are identified.

☐ Every surveyor assesses IPCP compliance throughout the survey and communicates any concerns to the team.

Hand Hygiene:

☐ Staff implement standard precautions (e.g., hand hygiene and the appropriate use of personal protective equipment (PPE)).

☐ Appropriate hand hygiene practices are followed.

☐ Alcohol-based hand rub (ABHR) is readily accessible and placed in appropriate locations. These may include:

- Entrances to resident rooms;
- At the bedside (as appropriate for resident population);
- In individual pocket-sized containers by healthcare personnel;
- Staff work stations; and
- Other convenient locations.

☐ Staff wash hands with soap and water when their hands are visibly soiled (e.g., blood, body fluids), or after caring for a resident with known or suspected C. difficile infection (CDI) or norovirus during an outbreak, or if endemic rates of CDI are high. ABHR is not appropriate to use under these circumstances.

☐ Staff perform hand hygiene (even if gloves are used) in the following situations:

- Before and after contact with the resident;

- After contact with blood, body fluids, or visibly contaminated surfaces or other objects and surfaces in the resident's environment;
- After removing personal protective equipment (e.g., gloves, gown, facemask); and
- Before performing a procedure such as an aseptic task (e.g., insertion of an invasive device such as a urinary catheter, manipulation of a central venous catheter, and/or dressing care).

☐ When being assisted by staff, resident hand hygiene is performed after toileting and before meals.

☐ Interview appropriate staff to determine if hand hygiene supplies are readily available and who they contact for replacement supplies.

☐ Soap, water, and a sink are readily accessible in appropriate locations including, but not limited to, resident care areas, food and medication preparation areas.

1. Did staff implement appropriate hand hygiene? ☐ Yes ☐ **No F880**

Personal Protective Equipment (PPE):

☐ Determine if staff appropriately use and discard PPE including, but not limited to, the following:

- Gloves are worn if potential contact with blood or body fluid, mucous membranes, or non-intact skin;
- Gloves are removed after contact with blood or body fluids, mucous membranes, or non-intact skin;
- Gloves are changed and hand hygiene is performed before moving from a contaminated body site to a clean body site during resident care;
- A gown is worn for direct resident contact if the resident has uncontained secretions or excretions;
- A facemask is worn if contact (i.e., within 3 feet) with a resident with new acute cough or symptoms of a respiratory infection (e.g., influenza-like illness);
- Appropriate mouth, nose, and eye protection (e.g., facemasks, face shield) is worn for performing aerosol-generating and/or procedures that are likely to generate splashes or sprays of blood or body fluids;
- PPE is appropriately discarded after resident care, prior to leaving room, followed by hand hygiene; and
- Supplies necessary for adherence to proper PPE use (e.g., gloves, gowns, masks) are readily accessible in resident care areas (i.e., nursing units, therapy rooms).

☐ Interview appropriate staff to determine if PPE supplies are readily available and who they contact for replacement supplies.

2. Did staff implement appropriate use of PPE? ☐ Yes ☐ **No F880**

Transmission-Based Precautions:

☐ Determine if appropriate transmission-based precautions are implemented, including but not limited to:

- PPE use by staff (i.e., don gloves and gowns before contact with the resident and/or his/her environment while on contact precautions; don facemask within three feet of a resident on droplet precautions; don a fit-tested N95 or higher level respirator prior to room entry of a resident on airborne precautions;

- Dedicated or disposable noncritical resident-care equipment (e.g., blood pressure cuffs, blood glucose monitor equipment) is used, or if not available, then equipment is cleaned and disinfected according to manufacturers' instructions using an EPA-registered disinfectant prior to use on another resident;
- The least restrictive TBP possible under the circumstances;
- Objects and environmental surfaces that are touched frequently and in close proximity to the resident (e.g., bed rails, over-bed table, bedside commode, lavatory surfaces in resident bathrooms) are cleaned and disinfected with an EPA-registered disinfectant for healthcare use at least daily and when visibly soiled.

☐ Interview appropriate staff to determine if they are aware of processes/protocols for transmission-based precautions and how staff is monitored for compliance.

☐ If concerns are identified, expand the sample to include more residents with transmission-based precautions.

3. Did the staff implement appropriate transmission-based precautions? ☐ Yes ☐ **No F880** ☐ NA

Laundry Services:

☐ Determine whether staff handle, store, and transport linens appropriately including, but not limited to:

- Using standard precautions (i.e., gloves) and minimal agitation for contaminated linen;
- Holding contaminated linen and laundry bags away from his/her clothing/body during transport;
- Bagging/containing contaminated linen where collected, and sorted/rinsed only in the contaminated laundry area (double bagging of linen is only recommended if outside of the bag is visibly contaminated or is observed to be wet on the outside of the bag);
- Transporting contaminated and clean linens in separate carts; if this is not possible, the contaminated linen cart should be thoroughly cleaned and disinfected per facility protocol before being used to move clean linens. Clean linens are transported by methods that ensure cleanliness, e.g., protect from dust and soil;
- Ensuring mattresses, pillows, bedding, and linens are maintained in good condition and are clean (Refer to F584); and
- If a laundry chute is in use, laundry bags are closed with no loose items.

☐ Laundry Rooms – Determine whether staff:

- Maintain/use washing machines/dryers according to the manufacturer's instructions for use;
- If concerns, request evidence of maintenance log/record; and
- Use detergents, rinse aids/additives, and follow laundering directions according to the manufacturer's instructions for use.

4. Did the facility store, handle, transport, and process linens properly? ☐ Yes ☐ **No F880**

Infection Prevention, Control & Immunizations

Policy and Procedure:

☐ The facility established a facility-wide IPCP including written IPCP standards, policies, and procedures that are current and based on national standards.

☐ The policies and procedures are reviewed at least annually.

☐ Concerns must be corroborated as applicable including the review of pertinent policies/procedures as necessary.

5. Did the facility develop and implement an overall IPCP including policies and procedures that are reviewed annually?
☐ Yes ☐ **No F880**

Infection Surveillance:

☐ The facility has established/implemented a surveillance plan, based on a facility assessment, for identifying, tracking, monitoring and/or reporting of infections.

☐ The plan includes early detection, management of a potentially infectious, symptomatic resident and the implementation of appropriate transmission-based precautions.

☐ The plan uses evidence-based surveillance criteria (e.g., CDC NHSN Long-Term Care or revised McGeer Criteria) to define infections and the use of a data collection tool.

☐ The plan includes ongoing analysis of surveillance data and review of data and documentation of follow-up activity in response.

☐ The facility has a process for communicating the diagnosis, antibiotic use, if any, and laboratory test results when transferring a resident to an acute care hospital or other healthcare provider; and obtaining pertinent notes such as discharge summary, lab results, current diagnoses, and infection or multidrug-resistant organism colonization status when residents are transferred back from acute care hospitals.

☐ The facility has a current list of reportable communicable diseases.

☐ Staff can identify to whom and when communicable diseases, healthcare-associated infections (as appropriate), and potential outbreaks must be reported.

☐ Prohibiting employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit disease.

☐ Interview appropriate staff to determine if infection control concerns are identified, reported, and acted upon.

6. Did the facility provide appropriate infection surveillance? ☐ Yes ☐ **No F880**

Antibiotic Stewardship Program:

☐ Determine whether the facility has an antibiotic stewardship program that includes:

- Written antibiotic use protocols on antibiotic prescribing, including the documentation of the indication, dosage, and duration of use of antibiotics;
- Protocols to review clinical signs and symptoms and laboratory reports to determine if the antibiotic is indicated or if adjustments to therapy should be made and identify what infection assessment tools or management algorithms are used for one or more infections (e.g., SBAR tool for urinary tract infection (UTI) assessment, Loeb minimum criteria for initiation of antibiotics);
- A process for a periodic review of antibiotic use by prescribing practitioners: for example, review of laboratory and medication orders, progress notes and medication administration records to determine whether or not an infection or communicable disease has been documented and whether an appropriate antibiotic has been prescribed for the recommended length of time. Determine whether the antibiotic use monitoring system is reviewed when the resident is new to the facility, when a prior resident returns or is transferred from a hospital or other facility, during each monthly drug regimen review when the resident has been prescribed or is taking an antibiotic, or any antibiotic drug regimen review as requested by the QAA committee;
- Protocols to optimize the treatment of infections by ensuring that residents who require antibiotics are prescribed the appropriate antibiotic;
- A system for the provision of feedback reports on antibiotic use, antibiotic resistance patterns based on laboratory data, and prescribing practices for the prescribing practitioner.

7. Did the facility conduct ongoing review for antibiotic stewardship? ☐ Yes ☐ **No F881**

Influenza and Pneumococcal Immunizations:

☐ Select five residents in the sample to review for the provision of influenza/pneumococcal immunizations.

☐ Document the names of residents selected for review.

☐ Give precedence in selection to those residents whom the survey team has selected as sampled residents.

☐ Review the records of the five residents sampled for documentation of:

- Screening and eligibility to receive the vaccine;
- The provision of education related to the influenza or pneumococcal immunizations (such as the benefits and potential side effects)*;*
- The administration of pneumococcal and influenza vaccine, in accordance with national recommendations. Facilities must follow the CDC and ACIP recommendations for vaccines; and
- Allowing a resident or representative to refuse either the influenza and/or pneumococcal vaccine. If not provided, documentation as to why the vaccine was not provided.

☐ For surveys occurring during influenza season, unavailability of the influenza vaccine can be a valid reason why a facility has not implemented the influenza vaccine program, especially during the early weeks of the influenza season. Ask the facility to demonstrate that:

- The vaccine has been ordered and the facility received a confirmation of the order indicating that the vaccine has been shipped or that the product is not available but will be shipped when the supply is available; and
- Plans are developed on how and when the vaccines are to be administered.

Infection Prevention, Control & Immunizations

☐ As necessary, determine if the facility developed influenza and pneumococcal vaccine policies and procedures, including the identification and tracking/monitoring of all facility residents' vaccination status.

8. Did the facility provide influenza and/or pneumococcal immunizations as required or appropriate? ☐ Yes ☐ **No F883**

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Quality, Safety & Oversight Group

Ref: QSO-20-20-All
UPDATE: 09/28/2020

DATE: **March 20, 2020**

TO: State Survey Agency Directors

FROM: Director
Quality, Safety & Oversight Group

SUBJECT: Prioritization of Survey Activities

Memorandum Summary

- ***The Centers for Medicare & Medicaid Services (CMS) is committed*** to taking critical steps to ensure America's health care facilities are prepared to respond to the threat of disease caused by the 2019 Novel Coronavirus (COVID-19).
- On Friday, March 13, 2020, the President declared a national emergency, which triggers the Secretary's ability to authorize waivers or modifications of certain requirements pursuant to section 1135 of the Social Security Act (the Act). Under section 1135(b)(5) of the Act, CMS is prioritizing surveys by authorizing modification of timetables and deadlines for the performance of certain required activities, delaying revisit surveys, and generally exercising enforcement discretion for three weeks.
- During this three-week timeframe, **only** the following types of surveys will be prioritized and conducted:
- Complaint/facility-reported incident surveys: State survey agencies (SSAs) will conduct surveys related to complaints and facility-reported incidents (FRIs) that are triaged at the Immediate Jeopardy (IJ) level. A streamlined Infection Control review tool will also be utilized during these surveys, regardless of the Immediate Jeopardy allegation.
- Targeted Infection Control Surveys: Federal CMS and State surveyors will conduct targeted Infection Control surveys of providers identified through collaboration with the Centers for Disease Control and Prevention (CDC) and the HHS Assistant Secretary for Preparedness and Response (ASPR). They will use a streamlined review checklist to minimize the impact on provider activities, while ensuring providers are implementing actions to protect the health and safety of individuals to respond to the COVID-19 pandemic.
- Self-assessments: The Infection Control checklist referenced above will also be shared with all providers and suppliers to allow for voluntary self-assessment of their Infection Control plan and protections.

Memorandum Summary Continued

- During the prioritization period, the following surveys will not be authorized: Standard surveys for long term care facilities (nursing homes), hospitals, home health agencies (HHAs), intermediate care facilities for individuals with intellectual disabilities (ICF/IIDs), and hospices. This includes the life safety code and Emergency Preparedness elements of those standard surveys; and revisits that are not associated with IJ.
- Furthermore, for Clinical Laboratory Improvement Amendments (CLIA), we intend to prioritize immediate jeopardy situations over recertification surveys, and generally intend to use enforcement discretion, unless immediate jeopardy situations arise.
- Finally, initial certification surveys will continue to be authorized in accordance within current guidance and prioritization.

Background

CMS is committed to taking critical steps to ensure America's health care facilities, providers, and clinical laboratories are prepared to respond to the threat of COVID-19 and other respiratory illness. Specifically, under section 1135(b)(5) of the Act, CMS is prioritizing and suspending certain federal and SSA surveys, and delaying revisit surveys, pursuant to federal requirements for the next three weeks, beginning March 20, 2020, for all certified provider and supplier types. Also, for Clinical Laboratory Improvement Amendments (CLIA), we intend to prioritize immediate jeopardy situations over recertification surveys, and generally intend to use enforcement discretion, unless immediate jeopardy situations arise. During this three-week timeframe, SSAs and CMS surveyors will prioritize and conduct surveys (including revisit surveys) related to complaints and facility reported incidents (FRIs) that are triaged at the Immediate Jeopardy (IJ) level, for all allegations, in addition to a review with a Focused Infection Control survey. Federal surveyors will perform targeted Infection Control surveys of facilities in those areas most in need of additional oversight, as identified through collaboration with the CDC and ASPR.

If state or federal surveyors are unable to meet the Personal Protective Equipment (PPE) expectations outlined by the latest CDC guidance to safely perform an onsite survey due to lack of appropriate PPE supplies, they are instructed to refrain from entering the /provider, and obtain information necessary remotely, to the extent possible. Surveyors should continue the survey once they have the necessary PPE to do so safely.

The Focused Infection Control Survey is available to every provider in the country to make them aware of Infection Control priorities during this time of crisis, and providers and suppliers may perform a voluntary self-assessment of their ability to meet these priorities.

This shift in approach will allow health care providers time to implement the most recent infection control guidance from both CMS and the Centers for Disease Control and

Prevention (CDC). At the same time, we are doing our duty to protect patients from harm, and ensuring providers are implementing actions to prevent the spread of COVID-19.

Therefore, during the prioritization period, the following surveys will **not** be authorized:

- Standard surveys for long term care facilities (nursing homes), hospitals, home health agencies (HHAs), intermediate care facilities for individuals with intellectual disabilities (ICF/IIDs), and hospices. This includes the life safety code and Emergency Preparedness elements of those standard surveys;

- Revisits that are not associated with IJ. As a result, the following enforcement actions will be suspended, until revisits are again authorized:
- For nursing homes – Imposition of Denial of Payment for New Admissions (DPNA), including situations where facilities that are not in substantial compliance at 3 months, will be lifted to allow for new admissions during this time;
- For HHAs – Imposition of suspension of payments for new admissions (SPNA) following the last day of the survey when termination is imposed will be lifted to allow for new admissions during this time;
- For nursing homes and HHAs – Suspend per day civil money penalty (CMP) accumulation, and imposition of termination for facilities that are not in substantial compliance at 6 months.

- For CLIA, we intend to prioritize immediate jeopardy situations over recertification surveys.

This announcement follows previous action to focus survey activity on infection control. On March 4, 2020, CMS announced a suspension of inspections for federal and state inspectors (https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and/suspension-survey-activities). This earlier announcement focused on immediate jeopardy complaints, complaints alleging infection control concerns – especially COVID-19 – statutorily required surveys, revisit surveys to resolve enforcement actions, initial certifications, inspections for facilities with histories of infection control deficiencies in the last three years, and inspections of facilities with histories of infection control deficiencies at low levels of severity. This action supersedes the March 4th announcement, and prioritizes surveys related to complaints and FRIs triaged at the IJ level, while suspending the other types of surveys.

Prioritization of Surveys

When conducting surveys related to complaints and facility-reported incidents (FRIs) that are triaged at the Immediate Jeopardy (IJ) level, and revisit surveys necessary to verify removal of IJ which has been previously cited, surveyors and CMS Regional Offices should adhere to the following guidelines:

1. SSAs follow their normal process for triaging complaints and FRIs:

a. If a complaint or FRI is triaged at the IJ level, the state should follow the normal policies and procedures for surveying the provider. For example, a survey of a long term care facility (LTC) would be conducted within two business days of receipt of the allegation (State Operations Manual (SOM), Chapter 5, Section 5075.9).
b. If a complaint or FRI is triaged at the non- IJ level, the state would enter the allegation into the ASPEN Complaints/Incidents Tracking System (ACTS) per the instructions in the SOM Chapter 5. An onsite survey will not be conducted during the prioritization period. CMS will issue guidance related to these non-IJ complaints or FRIs in the next few weeks.
c. This normal complaint triaging process also applies to CLIA complaints.

2. For facilities that have been cited for IJ-level deficiencies and that surveyors have not verified that the IJ has been removed, surveyors would proceed as normal, and conduct a revisit survey to verify the IJ is removed.
    a. If the revisit survey determines there is continuing noncompliance, but not at the IJ level, surveyors would not conduct another onsite revisit survey. The provider may submit a plan of correction (POC), but an onsite revisit survey will not be conducted during the prioritization period, and these cases will be held. The provider may delay submission of a plan of correction until this prioritization period is over.
    b. If a survey is conducted because a complaint or FRI was triaged at the IJ level, and the provider is cited for noncompliance, but not at the IJ level (e.g., Level 3 – actual harm), surveyors would not conduct a revisit survey. The provider may submit a plan of correction (POC), but an onsite revisit survey will not be conducted during the prioritization period, and these cases will be held. The provider may delay submission of a plan of correction until this prioritization period is over.
    c. For level-3 (LTC) or condition level (Non-LTC) citations (for which an onsite revisit survey would normally be conducted), the provider <u>may</u> submit a plan of correction (POC), but an onsite revisit survey will not be conducted during the prioritization period, and these cases will be held. The provider may delay submission of a plan of correction until this prioritization period is over. CMS will issue guidance on how to verify compliance with these citations in the next few weeks.
    d. For level-2 (LTC) or standard level (non-LTC) citations, the provider <u>may</u> submits a POC, and providers and survey agencies could verify compliance through normal procedures through a desk review. The provider may delay submission of a plan of correction until this prioritization period is over.
    e. For clinical laboratories, surveyors will conduct a revisit survey to verify removal of IJ once a credible allegation of compliance has been received.

3. Federal CMS and State Surveyors will conduct focused Infection Control surveys in areas deemed necessary through collaboration with CDC and ASPR. *Please note this workload for SSAs is contingent on their ability to perform surveys based on PPE availability and fulfillment of other State Emergency Response responsibilities (such as staffing medical shelters or testing stations).*

a. Revisit surveys: Surveyors will follow the same guidance for revisit surveys explained in section 2 above.
b. Enforcement actions will also follow the guidance for all other surveys during the prioritization period explained in section 4 below.

4. Enforcement Actions:

a. For pending enforcement cycles during the prioritization period where the provider is currently not in substantial compliance or has not had a revisit survey to verify substantial compliance, and a per day civil money penalty (CMP), or DPNA (for nursing homes) or SPNA (for HHAs) was imposed for noncompliance that occurred prior to the prioritization date of surveys: These remedies will be suspended (stopped) as of the start of the survey prioritization date. In other words, the CMP will stop accruing and the DPNA/SPNA will end as of the suspension date. Additionally, CMS will not impose any new remedies to address noncompliance that occurred prior to the start of the survey prioritization period. NOTE: This does not apply to unremoved IJs. Enforcement actions will proceed as usual per the SOM for unremoved IJ deficiencies. CMS will issue guidance on how to reconcile these actions in the next few weeks.
b. For pending enforcement cycles during the prioritization period where the provider is currently not in substantial compliance or has not had a revisit survey to verify substantial compliance, and for pending enforcement cycles with new noncompliance cited after the issuance of this memo, and a per day CMP, or DPNA (for nursing homes) or SPNA (for HHAs) was imposed for <u>IJ level</u> noncompliance (where the IJ has not been removed): Surveyors will follow normal policies and procedures for removing the IJ. CMS will also follow normal policies and procedures for imposing enforcement remedies for remediating the noncompliance. For example, for noncompliance cited at the IJ level, that has not been removed at the time of the survey exit, the CMS Office will impose an enforcement remedy (e.g., CMP, 23 day termination), and the state surveyors will conduct a revisit survey. On the revisit survey, surveyors will either verify substantial compliance, or cite noncompliance at a lower level if warranted.
    i. If the IJ noncompliance is reduced and cited at level 3 (LTC) or condition level (non-LTC), an onsite revisit survey will not be conducted during the prioritization period, and these cases will be held. CMS will issue guidance on how to impose enforcement and verify compliance with these in the next few weeks (see 2.c.). ii. If the IJ noncompliance is reduced and cited at level 2 (LTC) or standard level (non-LTC), facilities and survey agencies would verify compliance through normal procedures through a desk review (see 2.d.). However, CMS should not impose remedies during the prioritization period for any noncompliance that was identified before or after the start of the survey prioritization period, unless the noncompliance is an unremoved IJ.
c. The three-month mandatory DPNA and six-month mandatory termination (nursing homes) for not being in substantial compliance (for nursing homes and HHAs) will not take place, and be deferred for an evaluation at a later

date. However, enforcement actions related to IJ remain and continue under normal procedures.

d. If CMS has previously imposed an alternative sanction (e.g., SPNA, CMP) on a HHA for noncompliance identified prior to the suspension, the six-month mandatory termination will not take place, and be deferred for an evaluation at a later date.
e. For existing CLIA enforcement cases where a civil money penalty (CMP) per day of non-compliance was imposed, accrual of CMP will stop as of the survey COVID-19 suspension date. CMS will issue guidance on how to reconcile these actions in the next few weeks. Other CLIA enforcement actions that have been initiated will be handled on a case-by-case basis with consultation DCLIQ managers and staff.

5. If during an IJ complaint or FRI survey, the surveyor identifies that there is an active COVID-19 case in the facility:

   If the COVID-19 case is, or is not, related to the IJ, surveyors should report the case and facility to their agency, the state health department (to coordinate with the Centers for Disease Control and Prevention (CDC)), and the CMS Regional Office. These agencies should coordinate and decide on any further actions that should be taken. The Infection Control focused survey process can be used to investigate noncompliance and ensure the provider takes steps to minimize transmission.

For onsite surveys that were started prior to the prioritization period and don't fall under this guidance, survey teams should end the survey and exit the facility.

Lastly, any initial certification surveys remain authorized to increase the health care capacity of the country.

Note: While CMS' directive applies to the CMS' federal surveyors and state agency surveyors, CMS also urges other surveyors, including accrediting organizations (AOs), to follow suit. Additionally, CMS' survey prioritization applies to surveys for compliance with federal regulations, not state surveys pursuant to state licensure.

Additional Instructions for Nursing Homes

We are disseminating the Infection Control survey developed by CMS and CDC so facilities can educate themselves on the latest practices and expectations. We expect facilities to use this new process, in conjunction with the latest guidance from CDC, to perform a voluntary self-assessment of their ability to prevent the transmission of COVID-19. This document may be requested by surveyors, if an onsite investigation takes place. We also encourage nursing homes to voluntarily share the results of this assessment with their state or local health department Healthcare-Associated Infections (HAI) Program. Contact information for each state's health departments is identified on the Centers for Disease Control & Prevention's (CDC's) website at: https://www.cdc.gov/HAI/state-based/index.html.

Furthermore, we remind facilities that they are required to have a system of surveillance designed to identify possible communicable diseases or infections before they can spread to

other persons in the facility, and when and to whom possible incidents of communicable disease or infections should be reported (42 CFR 483.80(a)(2)(i) and (ii)). CDC recommends that nursing homes notify their health department about residents with severe respiratory infection, or a cluster of respiratory illness (e.g., > or = 3 residents or HCP with new-onset respiratory symptoms within 72 hours). Local and state reporting guidelines or requirements may vary. Monitor the CDC website for information and resources to help prevent the introduction and spread of COVID-19 in nursing homes (CDC Preparing for COVID-19: Long-term Care Facilities, Nursing Homes: https://www.cdc.gov/coronavirus/2019ncov/healthcare-facilities/prevent-spread-in-long-term-care-facilities.html). We urge providers to review the tools and implement actions to protect the health and safety of individuals to respond to the COVID-19 pandemic.

Additional Instructions for Other (Non-Long Term Care) Provider Types Education and Signage

Where the patient/resident is sleeping at the health care facility, signage on the patient's room is important to ensuring that all staff are aware of the necessary infection control steps. https://www.cdc.gov/infectioncontrol/pdf/droplet-precautions-sign-P.pdf

In the home setting, health care staff may have little control over the home environment, but must 1) educate staff, patients and family members regarding infection control procedures and how to avoid transmission of COVID-19, and 2) maintain clean equipment and supplies and follow appropriate infection control procedures during home visits and transport of reusable patient care items. For further information refer to CDC's interim guidance for home care of people not requiring hospitalization for COVID-19 (https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidance-homecare.html).

Limitations on Visitors

To mitigate the spread of the COVID-19 virus, CMS is providing guidance to restrict visitation in health care facilities such as hospitals, critical access hospitals, psychiatric hospitals, inpatient hospice units, and intermediate care facilities for individuals with developmental disabilities. *On September 17, 2020, CMS released new guidance for nursing home visitation during the COVID-19 Public Health Emergency. See CMS memorandum QSO-20-39-NH, Nursing Home Visitation-COVID-19.*

CMS is providing the following expanded guidance to prevent the spread of COVID-19:

a) Visitors should receive the same screening as patients, including whether they have had:
   - Fever or symptoms of a respiratory infection, such as a cough and sore throat.
   - International travel within the last 14 days to CDC Level 3 risk countries. For updated information on restricted countries visit: https://www.cdc.gov/coronavirus/2019ncov/travelers/index.html
   - Contact with someone with known or suspected COVID-19.

b) Health care facilities should set limitations on visitation. For example, limitations may include restricting the number of visitors per patient, or limiting visitors to only those that provide assistance to the patient, or limiting visitors under a certain age.

c) Health care facilities should provide signage at entrances for screening individuals, provide temperature checks/ ask about fever, and encourage frequent hand washing and use of hand sanitizer before entering the facility and before and after entering patient rooms
d) If visiting and not seeking medical treatment themselves, individuals with fevers, cough, sore throat, body aches or runny nose or not following infection control guidance should be restricted from entry.
e) Facilities should screen and limit visitors for any recent trips (within the last 30 days) on cruise ships as well as close contact with a suspect or laboratory-confirmed COVID-19 patient within the last 14 days, or overseas travel from certain countries. https://www.cdc.gov/coronavirus/2019-ncov/travelers/after-travel-precautions.html, https://wwwnc.cdc.gov/travel/page/covid-19-cruise-ship
f) Facilities should instruct visitors to limit their movement within the facility (e.g., reduce walking the halls, trips to cafeteria, etc.)
g) Facilities should establish limited entry points for all visitors and/or establish alternative sites for screening prior to entry.
h) Facilities can implement measures to:
   - Increase communication with families (phone, face-time, skype, etc.).
   - Potentially offer a hotline for with a recording that is updated at set times so families can get an update on the facility's general status.
   - If appropriate, consider offering telephonic screening of recent travel and wellness prior to coming in for scheduled appointments. This may help limit the amount of visitor movement throughout the organization and congestion at entry points.
i) Consider closing common visiting areas and encouraging patients to visit with loved ones in their patient rooms.

In home and community-based settings, health care providers should advise patients with COVID19 of the CDC guidance to mitigate transmission of the virus. This includes isolating at home during illness, restricting activities except for medical care, using a separate bathroom and bedroom if possible, and prohibiting visitors who do not have an essential need to be in the home. The certified Medicare/Medicaid provider is expected to share this information with patients with the COVID-19 virus and his/her caregiver. https://www.cdc.gov/coronavirus/2019-ncov/hcp/guidanceprevent-spread.html

Some states have chosen to establish more restrictive criteria than described above. Health care providers to follow the more restrictive criteria when present.

Access for Healthcare Staff

CMS is aware that some providers (nursing homes, assisted living facilities, etc.) have significantly restricted entry for staff from other Medicare/Medicaid certified providers who are providing direct care to patients. In general, if the staff is appropriately wearing PPE, and do not meet criteria for restricted access, they should be allowed to enter and provide services to the patient (interdisciplinary hospice care, dialysis, organ procurement, home health, etc.).

For hospitals, this would also apply to organ procurement coordinators. Ensuring that individuals have continued access to life-saving organs is critical. We understand that hospitals are preparing for a potential surge in COVID-19 patients however, we would ask that donor hospitals continue

with operations in regards to allowing organ procurement coordinators into hospitals to discuss organ donation with families. Hospital and OPO leadership should communicate on risk assessments in their communities and any potential impacts for organ recovery operations.

CMS will continue to evaluate the survey prioritization in light of the situation on the ground in areas with large numbers of COVID-19 cases, to determine if CMS needs to continue this past the initial three weeks.

Section 3087 of the 21st Century Cures Act, signed into law in December 2016, added subsection (f) to section 319 of the Public Health Service Act. This new subsection gives the HHS Secretary the authority to waive Paperwork Reduction Act (PRA) (44 USC 3501 et seq.) requirements with respect to voluntary collection of information during a public health emergency (PHE), as declared by the Secretary, or when a disease or disorder is significantly likely to become a public health emergency (SLPHE). Under this new authority, the HHS Secretary may waive PRA requirements for the voluntary collection of information if the Secretary determines that: (1) a PHE exists according to section 319(a) of the PHS Act or determines that a disease or disorder, including a novel and emerging public health threat, is a SLPHE under section 319(f) of the PHS Act; and (2) the PHE/SLPHE, including the specific preparation for and response to it, necessitates a waiver of the PRA requirements. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) has been designated as the office that will coordinate the process for the Secretary to approve or reject each request.
The information collection requirements contained in this information collection request have been submitted and approved under a PRA Waiver granted by the Secretary of Health and Human Services. The waiver can be viewed at https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers .

Contact: Questions about this document should be addressed to QSOG_EmergencyPrep@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State/Regional Office training coordinators immediately.

/s/
David R. Wright

cc: Survey and Operations Group Management

COVID-19 Focused Survey for Nursing Homes

Infection Control

This survey tool must be used to investigate compliance at F880 and determine whether the facility is implementing proper infection prevention and control practices to prevent the development and transmission of COVID-19 and other communicable diseases and infections. Entry and screening procedures as well as resident care guidance has varied over the progression of COVID-19 transmission in facilities. Facilities are expected to be in compliance with CMS requirements and surveyors will use guidance that is in effect at the time of the survey. Refer to QSO memos released at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.

This survey tool provides a focused review of the critical elements associated with the transmission of COVID-19, will help surveyors to prioritize survey activities while onsite, and identify those survey activities which can be accomplished offsite. These efficiencies will decrease the potential for transmission of COVID-19, as well as lessen disruptions to the facility and minimize exposure of the surveyor. Surveyors should be mindful to ensure their activities do not interfere with the active treatment or prevention of transmission of COVID-19.

If citing for noncompliance related to COVID-19, the surveyor(s) must include the following language at the beginning of the Deficient Practice Statement or other place determined appropriate on the Form CMS-2567: "Based on [observations/interviews/record review], the facility failed to [properly prevent and/or contain – or other appropriate statement] **COVID-19**."

If surveyors see concerns related to compliance with other requirements, they should investigate them in accordance with the existing guidance in Appendix PP of the State Operations Manual and related survey instructions. Surveyors may also need to consider investigating concerns related to Emergency Preparedness in accordance with the guidance in Appendix Z of the State Operations Manual (e.g., for emergency staffing).

For the purpose of this survey tool, "staff" includes employees, consultants, contractors, volunteers, and others who provide care and services to residents on behalf of the facility. The Infection Prevention and Control Program (IPCP) must be facility-wide and include all departments and contracted services.

Surveyor(s) reviews for:

- The overall effectiveness of the Infection Prevention and Control Program (IPCP) including IPCP policies and procedures;
- Standard and Transmission-Based Precautions;
- Quality of resident care practices, including those with COVID-19 (laboratory-positive case), if applicable;
- The surveillance plan;
- Visitor entry and facility screening practices;
- Education, monitoring, and screening practices of staff; and
- Facility policies and procedures to address staffing issues during emergencies, such as transmission of COVID-19

---

1. Standard and Transmission-Based Precautions (TBPs)

CMS is aware that there is a scarcity of some supplies in certain areas of the country. State and Federal surveyors should not cite facilities for

not having certain supplies (e.g., PPE such as gowns, N95 respirators, surgical masks) if they are having difficulty obtaining these supplies for reasons outside of their control. However, we do expect facilities to take actions to mitigate any resource shortages and show they are taking all appropriate steps to obtain the necessary supplies as soon as possible. For example, if there is a shortage of PPE (e.g., due to supplier(s) shortage which may be a regional or national issue), the facility should contact their healthcare coalition for assistance (https://www.phe.gov/Preparedness/planning/hpp/Pages/find-hc-coalition.aspx), follow national and/or local guidelines for optimizing their current supply or identify the next best option to care for residents. Among other practices, optimizing their current supply may mean prioritizing use of gowns based on risk of exposure to infectious organisms, blood or body fluids, splashes or sprays, high contact procedures, or aerosol generating procedures (AGPs), as well as possibly extending use of PPE (follow national and/or local guidelines). Current CDC guidance for healthcare professionals is located at: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html and healthcare facilities is located at: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html. Guidance on strategies for optimizing PPE supply is located at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html. If a surveyor believes a facility should be cited for not having or providing the necessary supplies, the State Agency should contact the CMS Regional Location.

General Standard Precautions

☐ Are staff performing the following appropriately:

- Respiratory hygiene/cough etiquette,
- Environmental cleaning and disinfection, and
- Reprocessing of reusable resident medical equipment (e.g., cleaning and disinfection of glucometers per device and disinfectant manufacturer's instructions for use)?

Hand Hygiene

☐ Are staff performing hand hygiene when indicated?

☐ If alcohol-based hand rub (ABHR) is available, is it readily accessible and preferentially used by staff for hand hygiene?

☐ If there are shortages of ABHR, are staff performing hand hygiene using soap and water instead?

☐ Are staff washing hands with soap and water when their hands are visibly soiled (e.g., blood, body fluids)?

☐ Do staff perform hand hygiene (even if gloves are used) in the following situations:

- Before and after contact with the resident;
- After contact with blood, body fluids, or visibly contaminated surfaces;
- After contact with objects and surfaces in the resident's environment;
- After removing personal protective equipment (e.g., gloves, gown, facemask); and
- Before performing a procedure such as an aseptic task (e.g., insertion of an invasive device such as a urinary catheter, manipulation of a central venous catheter, and/or dressing care)?

☐ When being assisted by staff, is resident hand hygiene performed after toileting and before meals?

☐ Interview appropriate staff to determine if hand hygiene supplies (e.g., ABHR, soap, paper towels) are readily available and who they contact for replacement supplies.

Personal Protective Equipment (PPE)

☐ Determine if staff appropriately use PPE including, but not limited to, the following:

- Gloves are worn if potential contact with blood or body fluid, mucous membranes, or non-intact skin;
- Gloves are removed after contact with blood or body fluids, mucous membranes, or non-intact skin;
- Gloves are changed and hand hygiene is performed before moving from a contaminated body site to a clean body site during resident care; and
- An isolation gown is worn for direct resident contact if the resident has uncontained secretions or excretions.

☐ Is PPE appropriately removed and discarded after resident care, prior to leaving room (except in the case of extended use of PPE per national/local recommendations), followed by hand hygiene?

☐ If PPE use is extended/reused, is it done according to national and/or local guidelines? If it is reused, is it cleaned/decontaminated/maintained after and/or between uses?

☐ Interview appropriate staff to determine if PPE is available, accessible and used by staff.

- Are there sufficient PPE supplies available to follow infection prevention and control guidelines? In the event of PPE shortages, what procedures is the facility taking to address this issue?
- Do staff know how to obtain PPE supplies before providing care?
- Do they know who to contact for replacement supplies?

Transmission-Based Precautions (Note: PPE use is based on availability and latest CDC guidance. See note on Pages 1-2)

☐ Determine if appropriate Transmission-Based Precautions are implemented:

- For a resident on Contact Precautions: staff don gloves and isolation gown before contact with the resident and/or his/her environment;
- For a resident on Droplet Precautions: staff don a facemask within six feet of a resident;
- For a resident on Airborne Precautions: staff don an N95 or higher level respirator prior to room entry of a resident;
- For a resident with an undiagnosed respiratory infection: staff follow Standard, Contact, and Droplet Precautions (i.e., facemask, gloves, isolation gown) with eye protection when caring for a resident unless the suspected diagnosis requires Airborne Precautions (e.g., tuberculosis);
- For a resident with known or suspected COVID-19: staff wear gloves, isolation gown, eye protection and an N95 or higher-level respirator if available. A facemask is an acceptable alternative if a respirator is not available. Additionally, if there are COVID-19 cases in the facility or sustained community transmission, staff implement universal use of facemasks while in the facility (based on availability). When COVID-19 is identified in the facility, staff wear all recommended PPE (i.e., gloves, gown, eye protection and respirator or facemask) for the care of all residents on the unit (or facility-wide based on the location of affected residents), regardless of symptoms (based on availability).

- Some procedures performed on residents with known or suspected COVID-19 could generate infectious aerosols (i.e., aerosol-generating procedures (AGPs)). In particular, procedures that are likely to induce coughing (e.g., sputum induction, open suctioning of airways) should be performed cautiously. If performed, the following should occur:
  - Staff in the room should wear an N95 or higher-level respirator, eye protection, gloves, and an isolation gown.
  - The number of staff present during the procedure should be limited to only those essential for resident care and procedure support.
  - AGPs should ideally take place in an airborne infection isolation room (AIIR). If an AIIR is not available and the procedure is medically necessary, then it should take place in a private room with the door closed.
  - Clean and disinfect the room surfaces promptly and with appropriate disinfectant. Use disinfectants on List N of the EPA website for EPA-registered disinfectants that have qualified under EPA's emerging viral pathogens program for use against SARS-COV-2 or other national recommendations;

- Dedicated or disposable noncritical resident-care equipment (e.g., blood pressure cuffs, blood glucose monitor equipment) is used, or if not available, then equipment is cleaned and disinfected according to manufacturers' instructions using an EPA-registered disinfectant for healthcare setting prior to use on another resident;
- Objects and environmental surfaces that are touched frequently and in close proximity to the resident (e.g., bed rails, over-bed table, bedside commode, lavatory surfaces in resident bathrooms) are cleaned and disinfected with an EPA-registered disinfectant for healthcare setting (effective against the organism identified if known) at least daily and when visibly soiled; and
- Is signage on the use of specific PPE (for staff) posted in appropriate locations in the facility (e.g., outside of a resident's room, wing, or facility-wide)?

☐ Interview appropriate staff to determine if they are aware of processes/protocols for Transmission-Based Precautions and how staff is monitored for compliance.

☐ If concerns are identified, expand the sample to include more residents on Transmission-Based Precautions.

1. Did staff implement appropriate Standard (e.g., hand hygiene, appropriate use of PPE, environmental cleaning and disinfection, and reprocessing of reusable resident medical equipment) and Transmission-Based Precautions (if applicable)? ☐ Yes ☐ **No F880**

---

2. Resident Care

☐ If there is sustained community transmission or case(s) of COVID-19 in the facility, is the facility restricting residents (to the extent possible) to their rooms except for medically necessary purposes? If there is a case in the facility, and residents have to leave their room, are they wearing a facemask, performing hand hygiene, limiting their movement in the facility, and performing social distancing (efforts are made to keep them at least 6 feet away from others). If PPE shortage is an issue, facemasks should be limited to residents diagnosed with or having signs/symptoms of respiratory illness or COVID-19.

☐ Has the facility cancelled group outings, group activities, and communal dining?

☐ Has the facility isolated residents with known or suspected COVID-19 in a private room (if available), or taken other actions based on national (e.g., CDC), state, or local public health authority recommendations?

☐ For the resident who develops severe symptoms of illness and requires transfer to a hospital for a higher level of care, did the facility alert emergency medical services and the receiving facility of the resident's diagnosis (suspected or confirmed COVID-19) and precautions to be taken by transferring and receiving staff as well as place a facemask on the resident during transfer (as supply allows)?

☐ For residents who need to leave the facility for care (e.g. dialysis, etc.), did the facility notify the transportation and receiving health care team of the resident's suspected or confirmed COVID-19 status?

☐ Does the facility have residents who must leave the facility regularly for medically necessary purposes (e.g., residents receiving hemodialysis and chemotherapy) wear a facemask (if available) whenever they leave their room, including for procedures outside of the facility?

2. Did staff provide appropriate resident care? ☐ Yes ☐ **No F880**

---

3. IPCP Standards, Policies and Procedures

☐ Did the facility establish a facility-wide IPCP including standards, policies, and procedures that are current and based on national standards for undiagnosed respiratory illness and COVID-19?

☐ Does the facility's policies or procedures include when to notify local/state public health officials if there are clusters of respiratory illness or cases of COVID-19 that are identified or suspected?

☐ Concerns must be corroborated as applicable including the review of pertinent policies/procedures as necessary.

3. Does the facility have a facility-wide IPCP including standards, policies, and procedures that are current and based on national standards for undiagnosed respiratory illness and COVID-19? ☐ Yes ☐ **No F880**

---

4. Infection Surveillance

☐ How many residents and staff in the facility have fever, respiratory signs/symptoms, or other signs/symptoms related to COVID-19?

☐ How many residents and staff have been diagnosed with COVID-19 and when was the first case confirmed?

☐ How many residents and staff have been tested for COVID-19? What is the protocol for determining when residents and staff should be tested?

☐ Has the facility established/implemented a surveillance plan, based on a facility assessment, for identifying (i.e., screening), tracking, monitoring and/or reporting of fever (at a minimum, vital signs are taken per shift), respiratory illness, and/or other signs/symptoms of COVID-19 and immediately isolate anyone who is symptomatic?

☐ Does the plan include early detection, management of a potentially infectious, symptomatic resident that may require laboratory testing and/or Transmission-Based Precautions/PPE (the plan may include tracking this information in an infectious disease log)?

☐ Does the facility have a process for communicating the diagnosis, treatment, and laboratory test results when transferring a resident to an acute care hospital or other healthcare provider; and obtaining pertinent notes such as discharge summary, lab results, current diagnoses, and infection or multidrug-resistant organism colonization status when residents are transferred back from acute care hospitals?

☐ Can appropriate staff (e.g., nursing and unit managers) identify/describe the communication protocol with local/state public health officials?

☐ Interview appropriate staff to determine if infection control concerns are identified, reported, and acted upon.

4. Did the facility provide appropriate infection surveillance? ☐ Yes ☐ **No F880**

---

5. Visitor Entry

☐ Review for compliance of:

- Screening processes and criteria (i.e., screening questions and assessment of illness);
- Restriction criteria; and
- Signage posted at facility entrances for screening and restrictions as well as a communication plan to alert visitors of new procedures/restrictions.

☐ For those permitted entry, are they instructed to frequently perform hand hygiene; limit their interactions with others in the facility and surfaces touched; restrict their visit to the resident's room or other location designated by the facility; and offered PPE (e.g., facemask) as supply allows? What is the facility's process for communicating this information?

☐ For those permitted entry, are they advised to monitor for signs and symptoms of COVID-19 and appropriate actions to take if signs and/or symptoms occur?

5. Did the facility perform appropriate screening, restriction, and education of visitors? ☐ Yes ☐ **No F880**

---

6. Education, Monitoring, and Screening of Staff

☐ Is there evidence the facility has provided education to staff on COVID-19 (e.g., symptoms, how it is transmitted, screening criteria, work exclusions)?

☐ How does the facility convey updates on COVID-19 to all staff?

☐ Is the facility screening all staff at the beginning of their shift for fever and signs/symptoms of illness? Is the facility actively taking their temperature and documenting absence of illness (or signs/symptoms of COVID-19 as more information becomes available)?

☐ If staff develop symptoms at work (as stated above), does the facility:

- Place them in a facemask and have them return home;
- Inform the facility's infection preventionist and include information on individuals, equipment, and locations the person came in contact with; and

- Follow current guidance about returning to work (e.g., local health department, CDC: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/hcp-return-work.html).

6. Did the facility provide appropriate education, monitoring, and screening of staff? ☐ Yes ☐ **No F880**

7. Emergency Preparedness - Staffing in Emergencies

☐ Policy development: Does the facility have a policy and procedure for ensuring staffing to meet the needs of the residents when needed during an emergency, such as a COVID-19 outbreak?

☐ Policy implementation: In an emergency, did the facility implement its planned strategy for ensuring staffing to meet the needs of the residents? (N/A if a emergency staff was not needed)

7. Did the facility develop and implement policies and procedures for staffing strategies during an emergency?

☐ **Yes** ☐ **No E0024**

Section 3087 of the 21st Century Cures Act, signed into law in December 2016, added subsection (f) to section 319 of the Public Health Service Act. This new subsection gives the HHS Secretary the authority to waive Paperwork Reduction Act (PRA) (44 USC 3501 et seq.) requirements with respect to voluntary collection of information during a public health emergency (PHE), as declared by the Secretary, or when a disease or disorder is significantly likely to become a public health emergency (SLPHE). Under this new authority, the HHS Secretary may waive PRA requirements for the voluntary collection of information if the Secretary determines that: (1) a PHE exists according to section 319(a) of the PHS Act or determines that a disease or disorder, including a novel and emerging public health threat, is a SLPHE under section 319(f) of the PHS Act; and (2) the PHE/SLPHE, including the specific preparation for and response to it, necessitates a waiver of the PRA requirements. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) has been designated as the office that will coordinate the process for the Secretary to approve or reject each request.

The information collection requirements contained in this information collection request have been submitted and approved under a PRA Waiver granted by the Secretary of Health and Human Services. The waiver can be viewed at https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers.

Summary of the COVID-19 Focused Survey for Nursing Homes

This is a summary of the COVID-19 Focused Survey for Nursing Homes and the Survey Protocol. Surveyors should review the Survey Protocol for more detailed information as well as the Focused Survey. Facilities can review the Focused Survey to determine CMS's expectations for an infection prevention and control program during the COVID-19 pandemic.

Offsite Survey Activity	Onsite Survey Activity	Facility Self-Assessment
• For facilities with an active COVID-19 case, the survey team should contact their State Survey Agency (SSA), the state health department, and CMS Regional Location to coordinate activities for these facilities. • Ensure surveyors are medically cleared, and have personal protective equipment (PPE) that could be required onsite. • Conduct offsite planning to limit interruptions to care while onsite. Obtain information on: o Facility-reported information; o CDC, state/local public health reports; o Available hospital information regarding patients transferred to the hospital; and/or o Complaint allegations. • Identify survey activities that will be conducted offsite, such as: o Medical record review o Telephonic interviews, such as: ▪ Surveillance policies ▪ First onset of symptoms ▪ Communication to facility leaders and health officials o Policy/Procedure Review ▪ Infect. Control/Prev. Plan ▪ Emerg. Prep. Plan, including contingency strategies (e.g., staffing) • Conduct survey exit discussion telephonically and draft the CMS-2567 offsite.	• Limit the onsite team to one to two surveyors. • Identify onsite assignments for activities, such as: Resident Care Observations: o Hand hygiene practices o Proper use/discarding of PPE o Cleansing medical equipment o Effective Transmission-Based Precautions Environmental observations: o Signage at entrances and resident rooms o Screening (staff at shift change, entrances, limiting nonessential staff) o Hand hygiene stations Interviews: o Policy/Procedure knowledge o Surveillance for sign/symptoms o Notifying local health officials • Adhere to all CDC guidance for infection prevention and control related to COVID-19. • Provide the facility with the COVID-19 Entrance Conference worksheet and utilize this to request necessary information. • Identify and arrange for interviews that can be done telephonically. • Be alert of other immediate jeopardy (IJ) situations that may be present, and investigate appropriately.	Facilities should utilize the COVID-19 Focused Survey for Nursing Homes as a self-assessment tool. Priority areas for self- assessment include all of the following: 1. Standard Precautions; a. Hand hygiene b. Use of PPE c. Transmission-Based Precautions 2. Resident care (including resident placement); 3. Infection prevention and control standards, policies and procedures; 4. Infection surveillance; 5. Visitor entry (i.e., screening, restriction, and education); 6. Education, monitoring, and screening of staff; and 7. Emergency preparedness – staffing in emergencies

Summary of the COVID-19 Focused Survey for Nursing Homes

Section 3087 of the 21st Century Cures Act, signed into law in December 2016, added subsection (f) to section 319 of the Public Health Service Act. This new subsection gives the HHS Secretary the authority to waive Paperwork Reduction Act (PRA) (44 USC 3501 et seq.) requirements with respect to voluntary collection of information during a public health emergency (PHE), as declared by the Secretary, or when a disease or disorder is significantly likely to become a public health emergency (SLPHE). Under this new authority, the HHS Secretary may waive PRA requirements for the voluntary collection of information if the Secretary determines that: (1) a PHE exists according to section 319(a) of the PHS Act or determines that a disease or disorder, including a novel and emerging public health threat, is a SLPHE under section 319(f) of the PHS Act; and (2) the PHE/SLPHE, including the specific preparation for and response to it, necessitates a waiver of the PRA requirements. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) has been designated as the office that will coordinate the process for the Secretary to approve or reject each request.

The information collection requirements contained in this information collection request have been submitted and approved under a PRA Waiver granted by the Secretary of Health and Human Services. The waiver can be viewed at https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers.

COVID-19 Focused Infection Control Survey: Acute and Continuing Care

General guidance: This survey tool provides a focused review of the critical elements associated with the transmission of COVID-19, will help surveyors to prioritize survey activities while onsite, and identify those survey activities which can be accomplished offsite. These efficiencies will decrease the potential for transmission of COVID-19, as well as lessen disruptions to the facility and minimize exposure of the surveyor. Surveyors should be mindful to ensure their activities do not interfere with the active treatment or prevention of transmission of COVID-19. Entry and screening procedures as well as patient care guidance has varied over the progression of COVID-19 transmission in facilities. Facilities are expected to be in compliance with CMS guidance that is in effect at the time of the survey. Refer to QSO memos released at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to-States-and-Regions.

Content within this tool may be generally applied to any setting. However, CMS recognizes that not all acute and continuing care providers have the same acuity or capacity and therfore, depending upon the setting, not all information will be applicable on every survey (e.g.; aerosol generating procedures section). If citing for noncompliance related to COVID-19, the surveyor(s) must include the following language at the beginning of the Deficient Practice Statement or other place determined appropriate on the Form CMS-2567: "Based on [observations/interviews/record review], the facility failed to [properly prevent and/or contain – or other appropriate statement] **COVID-19**."

If surveyors see concerns related to compliance with other requirements, they should investigate them in accordance with guidance in the appropriate provider/supplier appendix of the State Operations Manual and related survey instructions. Surveyors may also need to consider investigating concerns related to Emergency Preparedness in accordance with the guidance in Appendix Z of the State Operations Manual (e.g., for emergency staffing).

For purposes of this document, "staff" includes employees, consultants, contractors, volunteers, and others who provide care and services to patients on behalf of the facility. Additionally, the general term "facility" means inpatient, congregate settings, hospitals, intermediate care facilities for individuals with intellectual disabilities, dialysis facilities, and clinics, and "home" refers to settings such as hospice and home health where care is provided in the home.

Entering the Facility/Triage/Registration/Visitor Handling

Prior to entering the facility:

- Is signage posted at facility entrances with visitation restrictions and screening procedures?
- Are signs posted at entrances with instructions to individuals seeking medical care with symptoms of respiratory infection to immediately put on a mask and keep it on during their assessment, cover their mouth/nose when coughing or sneezing, use and dispose of tissues, and perform hand hygiene after contact with respiratory secretions?

Upon entering the facility:

- Are staff trained on appropriate processes (e.g., questions to ask and actions to take) to rapidly identify and isolate suspect COVID-19 cases?
- Is there a process that occurs after a suspected case is identified to include immediate notification of facility leadership/infection control?

COVID-19 Focused Infection Control Survey: Acute and Continuing Care

Visitation

- Facilities should limit visitation.
- Are facilities actively screening visitors (CDC currently recomends staff are checking for fever and signs and/or symptoms of respiratory infection, and other criteria such as travel or exposure to COVID-19)?
- What is your current screening criteria?
- For permitted visitors are they instructed to frequently perform hand hygiene; limit their interactions with others in the facility; restrict their visit to the patient's room or other location designated by the facility; and offered personal protective equipment (PPE) as supply allows?

Did the facility perform appropriate screening of visitors? ☐ Yes ☐ **No (see appropriate IPC tags for the provider/supplier type)**

Standard and Transmission-Based Precautions (TBPs)

CMS is aware that there is a scarcity of some supplies in certain areas of the country. State and Federal surveyors should not cite facilities for not having certain supplies (e.g., PPE such as gowns, N95 respirators, surgical masks) if they are having difficulty obtaining these supplies for reasons outside of their control. However, CMS does expect facilities to take actions to mitigate any resource shortages and show they are taking all appropriate steps to obtain the necessary supplies as soon as possible. For example, if there is a shortage of PPE (e.g., due to supplier(s) shortage which may be a regional or national issue), the facility should contact their healthcare coalition for assistance (https://www.phe.gov/Preparedness/planning/hpp/Pages/find-hc-coalition.aspx), follow national and/or local guidelines for optimizing their current supply or identify the next best option to care for patients. Among other practices, optimizing their current supply may mean prioritizing use of gowns based on risk of exposure to infectious organisms, blood or body fluids, splashes or sprays, high contact procedures, or aerosol generating procedures (AGPs), as well as possibly extending use of PPE (follow national and/or local guidelines). Current CDC guidance for healthcare professionals is located at: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html and healthcare facilities is located at: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/index.html. Guidance on strategies for optimizing PPE supply is located at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html. If a surveyor believes a facility should be cited for not having or providing the necessary supplies, the State Agency should contact the CMS Regional Location.

General Standard Precautions

☐ Are staff performing the following appropriately:

- Respiratory hygiene/cough etiquette,
- Environmental cleaning and disinfection, and
- Reprocessing of reusable patient medical equipment (i.e., cleaning and disinfection per device and disinfectant manufacturer's instructions for use)?

COVID-19 Focused Infection Control Survey: Acute and Continuing Care

Hand Hygiene

☐ Are staff performing hand hygiene when indicated?

☐ If alcohol-based hand rub (ABHR) is available, is it readily accessible and preferentially used by staff for hand hygiene?

☐ Staff wash hands with soap and water when their hands are visibly soiled (e.g., blood, body fluids), If there are shortages of ABHR, hand hygiene using soap and water is used instead?

☐ Do staff perform hand hygiene (even if gloves are used) in the following situations:

- Before and after contact with patients;
- After contact with blood, body fluids, or visibly contaminated surfaces or other objects and surfaces in the care environment;
- After removing personal protective equipment (e.g., gloves, gown, facemask); and
- Before performing a procedure such as an aseptic task (e.g., insertion of an invasive device such as a urinary catheter, manipulation of a central venous catheter, medication preparation, and/or dressing care).

☐ Interview appropriate staff to determine if hand hygiene supplies are readily available and who they contact for replacement supplies.

Did staff implement appropriate hand hygiene? ☐ Yes ☐ **No (see appropriate IPC tags for the provider/supplier type)**

Personal Protective Equipment (PPE)

☐ Determine if staff appropriately use PPE including, but not limited to, the following:

- Gloves are worn if potential contact with blood or body fluid, mucous membranes, or non-intact skin;
- Gloves are removed after contact with blood or body fluids, mucous membranes, or non-intact skin;
- Gloves are changed and hand hygiene is performed before moving from a contaminated site to a clean site during care (body, equipment, etc);
- An isolation gown is worn for direct patient contact if the patient has uncontained secretions or excretions;
- A facemask, gloves, isolation gown, and eye protection are worn when caring for a patient with new acute cough or symptoms of an undiagnosed respiratory infection unless the suspected diagnosis requires airborne precautions (e.g., tuberculosis)

☐ If PPE use is extended/reused, is it done according to national and/or local guidelines? If it is reused, is it cleaned/decontaminated/maintained after and/or between uses?

☐ Interview appropriate staff to determine if PPE is available, accessible and used by staff.

- Are there sufficient PPE supplies available to follow infection prevention and control guidelines? In the event of PPE shortages, what procedures is the facility taking to address this issue?
- Do staff know how to obtain PPE supplies before providing care?
- Do they know who to contact for replacement supplies?

COVID-19 Focused Infection Control Survey: Acute and Continuing Care

Aerosol – Generating Procedures

- Appropriate mouth, nose, clothing, gloves, and eye protection (e.g., N95 or higher-level respirator, if available; face shield, gowns) is worn for performing aerosol-generating and/or procedures that are likely to generate splashes or sprays of blood or body fluids and COVID-19 is suspected;
- Some procedures performed on patient with known or suspected COVID-19 could generate infectious aerosols. In particular, procedures that are likely to induce coughing (e.g., sputum induction, open suctioning of airways) should be performed cautiously. If performed, the following should occur:
    - Staff in the room should wear an N95 or higher-level respirator, eye protection, gloves, and a gown.
    - The number of staff present during the procedure should be limited to only those essential for care and procedure support.
    - AGPs should ideally take place in an airborne infection isolation room (AIIR). If an AIIR is not available and the procedure is medically necessary, then it should take place in a private room with the door closed.
    - Clean and disinfect procedure room surfaces promptly as and with appropriate disinfectant. Use disinfectants on List N of the EPA website for EPA-registered disinfectants that have qualified under EPA's emerging viral pathogens program for use against SARS-COV-2 or other national recommendations;

Did staff implement appropriate use of PPE? ☐ Yes ☐ **No (see appropriate IPC tags for the provider/supplier type)**

Transmission-Based Precautions

☐ Determine if appropriate transmission-based precautions are implemented, including but not limited to:

- Signage on the patient's room regarding need for transmission-based precautions.
- PPE use by staff (i.e., don gloves and gowns before contact with the patient and their care environment while on contact precautions; don facemask within three feet of a patient on droplet precautions; for facilities that use/have N-95 masks - don an fit-tested N95 or higher level respirator prior to room entry of a patient on airborne precautions);
- Dedicated or disposable noncritical patient-care equipment (e.g., blood pressure cuffs, blood glucose monitor equipment) are used, or if not available, then equipment is cleaned and disinfected according to manufacturers' instructions using an EPA-registered disinfectant prior to use on another patient or before being returned to a common clean storage area;
- When transport or movement is medically-necessary outside of the patient room, does the patient wear a facemask?
- Contaminated surfaces, objects and environmental surfaces that are touched frequently and in close proximity to the patient (e.g., bed rails, over-bed table, bathrooms) are cleaned and disinfected with an EPA-registered disinfectant for healthcare use (effective against the organism identified if known) at least daily and when visibly soiled.

☐ Interview appropriate staff to determine if they are aware of processes/protocols for transmission-based precautions and how staff is monitored for compliance.

☐ For providers of care in the home, has the provider, educated patients and family members regarding transmission of infectious diseases and specifically mitigating transmission of COVID-19.

☐ Interview appropriate staff to determine if they are aware of processes/protocols for transmission-based precautions and how staff is monitored for compliance.

☐ If concerns are identified, expand the sample to include more patients with transmission-based precautions.

Did the staff implement appropriate transmission-based precautions? ☐ Yes ☐ **No (see appropriate IPC tags for the provider/supplier type)**

Standards, Policies and Procedures

☐ Did the facility establish a facility-wide IPCP including written standards, policies, and procedures that are current and based on national standards for undiagnosed respiratory illness and COVID-19?

☐ Does the facility's policies or procedures include when to notify local/state public health officials if there are clusters of respiratory illness or cases of COVID-19 that are identified or suspected?

☐ Concerns must be corroborated as applicable including the review of pertinent policies/procedures as necessary.

Did the facility develop and implement an overall IPCP including policies and procedures for for undiagnosed respiratory illness and COVID-19? ☐ **Yes** ☐ **No (see appropriate IPC tags for the provider/supplier type)**

Infection Surveillance

☐ Does the facility know how many patients in the facility have been diagnosed with COVID-19 (suspected and confirmed)?

☐ The facility has established/implemented a surveillance plan, based on a facility assessment, for identifying, tracking, monitoring and/or reporting of fever, respiratory illness, or other signs/symptoms of COVID-19.

☐ The plan includes early detection, management of a potentially infectious, symptomatic patient and the implementation of appropriate transmission-based precautions/PPE.

☐ The facility has a process for communicating the diagnosis, treatment, and laboratory test results when transferring patients to an acute care hospital or other healthcare provider.

☐ Can appropriate staff (e.g., nursing and leadership) identify/describe the communication protocol with local/state public health officials?

☐ Interview appropriate staff to determine if infection control concerns are identified, reported, and acted upon.

Did the facility provide appropriate infection surveillance? ☐ Yes ☐ **No (see appropriate IPC tags for the provider/supplier type)**

Education, Monitoring, and Screening of Staff

- Is there evidence the provider has educated staff on COVID-19 (e.g., symptoms, how it is transmited, screening criteria, work exclusions)?

- How does the provider convey updates on COVID-19 to all staff?
- Is the facility screening all staff at the beginning of their shift for fever and signs/symptoms of illness? Is the facility actively taking their temperature and documenting absence of illness (or signs/symptoms of COVID-19 as more information becomes available)?
- If staff develop symptoms at work (as stated above), does the facility:
  - have a process for staff to report their illness or developing symptoms;
  - place them in a facemask and have them return home for appropriate medical evaluation;
  - inform the facility's infection preventionist and include information on individuals, equipment, and locations the person came in contact with; and
  - Follow current guidance about returning to work (e.g., local health department, CDC: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/hcp-return-work.html).

Did the facility provide appropriate education, monitoring, and screening of staff? ☐ Yes ☐ **No (see appropriate IPC tags for the provider/supplier type)**

Emergency Preparedness - Staffing in Emergencies

☐ Policy development: Does the facility have a policy and procedure for ensuring staffing to meet the needs of the patients when needed during an emergency, such as a COVID-19 outbreak?

☐ Policy implementation: In an emergency, did the facility implement its planned strategy for ensuring staffing to meet the needs of the patient? (N/A if a emergency staff was not needed)

Did the facility develop and implement policies and procedures for staffing strategies during an emergency?

☐ **Yes** ☐ **No (see appropriate Emergency Preparedness tag for the provider/supplier type)**

The following sections are specific nuances to consider and assess when on survey.

Considerations Specifically for Surveys of Hospitals and Critical Access Hospitals

Patient Care

- Is the facility restricting patients (to the extent possible) to their rooms except for medically necessary purposes? If patients have to leave their room, are they wearing a facemask, performing hand hygiene, limiting their movement in the facility, and performing social distancing (stay at least 6 feet away from others). If PPE shortage is an issue, facemasks should be limited to patients diagnosed with COVID-19 or has signs/symptoms of respiratory illness or COVID-19.

- Has the facility isolated residents with known or suspected COVID-19 in a private room (if available), or taken other actions based on national (e.g., CDC), state, or local public health authority recommendations?

Did staff provide appropriate care for patients with known or suspected COVID-19? ☐ Yes ☐ No (Hospital Tag A-0747, CAH Tag C-0278)

Environmental Cleaning

- During environmental cleaning procedures, personnel wear appropriate PPE to prevent exposure to infectious agents or chemicals (PPE can include gloves, gowns, masks, and eye protection)?
- Environmental surfaces in patient care areas are cleaned and disinfected, using an EPA-registered disinfectant on a regular basis (e.g., daily), when spills occur and when surfaces are visibly contaminated? Use disinfectants on List N of the EPA website for EPA-registered disinfectants that have qualified under EPA's emerging viral pathogens program for use against SARS-COV-2 or other national recommendations;
- Cleaners and disinfectants, including disposable wipes, are used in accordance with manufacturer's instructions (e.g., dilution, storage, shelf-life, contact time).
- The hospital decontaminates spills of blood or other body fluids according to its policies and procedures, using appropriate EPA-registered hospital disinfectants?

Did staff provide appropriate environmental cleaning for facilities with known or suspected COVID-19? ☐ Yes ☐ No (Hospital Tag A-0747, CAH Tag C-0278)

Additional Considerations Specifically for Dialysis Facility Surveys

Hand Hygiene Considerations

- Perform handwashing with soap and water at dedicated handwashing sinks if hands are visibily soiled (see § 494.30(a)(1)(i))
- Remove gloves and perform hand hygiene between each patient or dialysis station

Cleaning and Disinfection Considerations

- Items taken to the dialysis station must be either disposed of, dedicated for use on a single patient or cleaned and disinfected before being taken to a common clean area or used on another patient
- Use proper aseptic technique during vascular access care, medication preparation and administration
- Proper cleaning and disinfection of the dialysis station including the dialysis machine, chair, prime waste receptacle, reuseable acid and bicarbonate containers after the previous patient fully vacates the station.

- Clean areas should be clearly designated for the preparation, handling and storage of medications and unusued supplies and equipment.
- Clean areas should be clearly separated from contaminated areas where used supplies and equipment are handled.
- Proper disposal of bio-hazard waste

Isolation Considerations

- Ensure dedicated machines, equipment, instruments, supplies, and medications that will not be used to care for non-isolation patients.

Did staff implement appropriate hand hygiene, cleaning/disinfection and isolation considerations? ☐ Yes ☐ **No (see Condition 42 CFR 494.30 and Tags V110-V148)**

Section 3087 of the 21st Century Cures Act, signed into law in December 2016, added subsection (f) to section 319 of the Public Health Service Act. This new subsection gives the HHS Secretary the authority to waive Paperwork Reduction Act (PRA) (44 USC 3501 et seq.) requirements with respect to voluntary collection of information during a public health emergency (PHE), as declared by the Secretary, or when a disease or disorder is significantly likely to become a public health emergency (SLPHE). Under this new authority, the HHS Secretary may waive PRA requirements for the voluntary collection of information if the Secretary determines that: (1) a PHE exists according to section 319(a) of the PHS Act or determines that a disease or disorder, including a novel and emerging public health threat, is a SLPHE under section 319(f) of the PHS Act; and (2) the PHE/SLPHE, including the specific preparation for and response to it, necessitates a waiver of the PRA requirements. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) has been designated as the office that will coordinate the process for the Secretary to approve or reject each request.

The information collection requirements contained in this information collection request have been submitted and approved under a PRA Waiver granted by the Secretary of Health and Human Services. The waiver can be viewed at https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers.

Summary of the COVID-19 Focused Survey for Acute and Continuing Care Providers

This is a summary of the COVID-19 Focused Survey for acute and continuing care providers (Non-Long term care facilities). Surveyors should review the Focused Infection Control Survey tool in light of the established State Operations Manual Survey Protocol for more detailed information. Facilities can review the Focused Survey to determine CMS's expectations for an infection prevention and control program during the COVID-19 pandemic.

Offsite Survey Activity		
• If the survey team plans to enter a facility with an active COVID-19 case, the survey team should contact their State Survey Agency (SA), the state health department, and CMS Regional Location to coordinate activities for these facilities. • SAs should ensure surveyors are medically cleared, trained in the appropriate use of and have needed personal protective equipment (PPE) that could be required onsite. • Conduct offsite planning to limit interruptions to care while onsite. Obtain information on: o Facility-reported information; o CDC, state/local public health reports; o Complaint allegations. • Identify survey activities that will be conducted offsite, such as: o Medical record review o Telephonic interviews o Facility Policy/Procedure review • Conduct any survey exit discussion with the facility by telephone and draft the CMS-2567 offsite.	• If the survey team identifies an active COVID-19 case after entering a facility, the survey team should contact their SA, the state health department, and CMS Regional Location to coordinate activities for the facility. • Limit the onsite team to one to two surveyors. • Identify onsite assignments for activities, such as: Observations: o Hand hygiene practices o Proper use/discarding of PPE o Cleansing medical equipment o Effective Transmission-Based Precautions Interviews: o Policy/Procedure knowledge o Surveillance for sign/symptoms o Notifying local health officials • Adhere to all CDC guidance for infection prevention and control related to COVID-19. • Identify and arrange for interviews that can be done telephonically. • Be alert of other immediate jeopardy (IJ) situations that may be present, and investigate appropriately.	Facilities should utilize the COVID-19 Focused Survey as a self-assessment tool. Priority areas for self- assessment include all of the following: 1. Standard Precautions; a. Hand hygiene b. Use of PPE c. Transmission-Based Precautions 2. Patient care (including patient placement); 3. Infection prevention and control standards, policies and procedures (hand hygiene, PPE, cleaning and disinfection, surveillance); 4. Visitor entry (i.e., screening, restriction, and education); 5. Education, monitoring, and screening of staff; and 6. Emergency preparedness – staffing in emergencies

Summary of the COVID-19 Focused Survey for Acute and Continuing Care Providers

Section 3087 of the 21st Century Cures Act, signed into law in December 2016, added subsection (f) to section 319 of the Public Health Service Act. This new subsection gives the HHS Secretary the authority to waive Paperwork Reduction Act (PRA) (44 USC 3501 et seq.) requirements with respect to voluntary collection of information during a public health emergency (PHE), as declared by the Secretary, or when a disease or disorder is significantly likely to become a public health emergency (SLPHE). Under this new authority, the HHS Secretary may waive PRA requirements for the voluntary collection of information if the Secretary determines that: (1) a PHE exists according to section 319(a) of the PHS Act or determines that a disease or disorder, including a novel and emerging public health threat, is a SLPHE under section 319(f) of the PHS Act; and (2) the PHE/SLPHE, including the specific preparation for and response to it, necessitates a waiver of the PRA requirements. The Office of the Assistant Secretary for Planning and Evaluation (ASPE) has been designated as the office that will coordinate the process for the Secretary to approve or reject each request.

The information collection requirements contained in this information collection request have been submitted and approved under a PRA Waiver granted by the Secretary of Health and Human Services. The waiver can be viewed at https://aspe.hhs.gov/public-health-emergency-declaration-pra-waivers.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop C2-21-16
Baltimore, Maryland 21244-1850

Center for Clinical Standards and Quality/Survey & Certification Group

Ref: QSO-20-38-NH

DATE: **August 26, 2020**

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Interim Final Rule (IFC), CMS-3401-IFC, Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency related to Long-Term Care (LTC) Facility Testing Requirements and Revised COVID-19 Focused Survey Tool**

Memorandum Summary

- CMS is committed to taking critical steps to ensure America's healthcare facilities continue to respond effectively to the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE).
- On August 25, 2020, CMS published an interim final rule with comment period (IFC). This rule establishes **Long-Term Care (LTC) Facility Testing Requirements for Staff and Residents.** Specifically, facilities are required to test residents and staff, including individuals providing services under arrangement and volunteers, for COVID-19 based on parameters set forth by the HHS Secretary. This memorandum provides guidance for facilities to meet the new requirements.
- **Revised COVID-19 Focused Survey Tool -** To assess compliance with the new testing requirements, CMS has revised the survey tool for surveyors. We are also adding to the survey process the assessment of compliance with the requirements for facilities to designate one or more individual(s) as the infection preventionist(s) (IPs) who are responsible for the facility's infection prevention and control program (IPCP) at 42 CFR § 483.80(b). In addition, we are making a number of revisions to the survey tool to reflect other COVID-19 guidance updates.

On August 25, 2020, CMS published an interim final rule with comment period (IFC), CMS-3401-IFC, entitled "Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments of 1988 (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency". CMS's recommendation below to test with authorized nucleic acid or antigen detection assays is an important addition to other infection prevention and control (IPC) recommendations aimed at preventing COVID-19 from entering nursing homes, detecting cases quickly, and stopping transmission. Swift identification of confirmed COVID-19 cases allows the facility to take immediate action to remove exposure risks to nursing home residents and staff. CMS has added

42 CFR § 483.80(h) which requires that the facility test all residents and staff for COVID-19. Guidance related to the requirements is located below. Noncompliance related to this new requirement will be cited at new tag F886.

§ 483.80 Infection control

* * * * *

§ 483.80(h) *COVID-19 Testing*. The LTC facility must test residents and facility staff, including individuals providing services under arrangement and volunteers, for COVID-19. At a minimum, for all residents and facility staff, including individuals providing services under arrangement and volunteers, the LTC facility must:

(1) Conduct testing based on parameters set forth by the Secretary, including but not limited to:

(i) Testing frequency;

(ii) The identification of any individual specified in this paragraph diagnosed with COVID-19 in the facility;

(iii) The identification of any individual specified in this paragraph with symptoms consistent with COVID-19 or with known or suspected exposure to COVID-19;

(iv) The criteria for conducting testing of asymptomatic individuals specified in this paragraph, such as the positivity rate of COVID-19 in a county;

(v) The response time for test results; and

(vi) Other factors specified by the Secretary that help identify and prevent the transmission of COVID-19.

(2) Conduct testing in a manner that is consistent with current standards of practice for conducting COVID-19 tests;

(3) For each instance of testing:

(i) Document that testing was completed and the results of each staff test; and

(ii) Document in the resident records that testing was offered, completed (as appropriate to the resident's testing status), and the results of each test.

(4) Upon the identification of an individual specified in this paragraph with symptoms consistent with COVID-19, or who tests positive for COVID-19, take actions to prevent the transmission of COVID-19.

(5) Have procedures for addressing residents and staff, including individuals providing services under arrangement and volunteers, who refuse testing or are unable to be tested.

(6) When necessary, such as in emergencies due to testing supply shortages, contact state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

GUIDANCE FOR F886

<u>Testing of Nursing Home Staff and Residents</u>

To enhance efforts to keep COVID-19 from entering and spreading through nursing homes, facilities are required to test residents and staff based on parameters and a frequency set forth by the HHS Secretary.

Facilities can meet the testing requirements through the use of rapid point-of-care (POC) diagnostic testing devices or through an arrangement with an offsite laboratory. POC Testing is diagnostic testing that is performed at or near the site of resident care. For a facility to conduct these tests with their own staff and equipment (including POC devices provided by the Department of Health and Human Services), the facility must have a CLIA Certificate of Waiver. Information on obtaining a CLIA Certificate of Waiver can be found here.

Facilities without the ability to conduct COVID-19 POC testing should have arrangements with a laboratory to conduct tests to meet these requirements. Laboratories that can quickly process large numbers of tests with rapid reporting of results (e.g., within 48 hours) should be selected to rapidly inform infection prevention initiatives to prevent and limit transmission.

"Facility staff" includes employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents on behalf of the facility, and students in the facility's nurse aide training programs or from affiliated academic institutions. For the purpose of testing "individuals providing services under arrangement and volunteers," facilities should prioritize those individuals who are regularly in the facility (e.g., weekly) and have contact with residents or staff. We note that the facility may have a provision under its arrangement with a vendor or volunteer that requires them to be tested from another source (e.g., their employer or on their own). However, the facility is still required to obtain documentation that the required testing was completed during the timeframe that corresponds to the facility's testing frequency, as described in Table 2 below.

Regardless of the frequency of testing being performed or the facility's COVID-19 status, the facility should continue to screen all staff (each shift), each resident (daily), and all persons entering the facility, such as vendors, volunteers, and visitors, for signs and symptoms of COVID-19.

When prioritizing individuals to be tested, facilities should prioritize individuals with signs and symptoms of COVID-19 first, then perform testing triggered by an outbreak (as specified below).

Table 1: Testing Summary

Testing Trigger	Staff	Residents
Symptomatic individual identified	Staff with signs and symptoms must be tested	Residents with signs and symptoms must be tested
Outbreak (Any new case arises in facility)	Test all staff that previously tested negative until no new cases are identified*	Test all residents that previously tested negative untilno new cases are identified*
Routine testing	According to Table 2 below	Not recommended, unless the resident leaves the facility routinely.

*For outbreak testing, all staff and residents should be tested, and all staff and residents that tested negative should be retested every 3 days to 7 days until testing identifies no new cases of

COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result. For more information, please review the section below titled, "Testing of Staff and Residents in Response to an Outbreak."

Testing of Staff and Residents with COVID-19 Symptoms or Signs

Staff with symptoms or signs of COVID-19 must be tested and are expected to be restricted from the facility pending the results of COVID-19 testing. If COVID-19 is confirmed, staff should follow Centers for Disease Control and Prevention (CDC) guidelines "Criteria for Return to Work for Healthcare Personnel with SARS-CoV2 Infection." Staff who do not test positive for COVID-19 but have symptoms should follow facility policies to determine when they can return to work.

Residents who have signs or symptoms of COVID-19 must be tested. While test results are pending, residents with signs or symptoms should be placed on transmission-based precautions (TBP) in accordance with CDC guidance. Once test results are obtained, the facility must take the appropriate actions based on the results.

Note: Concerns related to initiating and/or maintaining TBP should be investigated under F880, Infection Control.

Testing of Staff and Residents in Response to an Outbreak

An outbreak is defined as a new COVID-19 infection in any healthcare personnel (HCP) or any nursing home-onset COVID-19 infection in a resident. In an outbreak investigation, rapid identification and isolation of new cases is critical in stopping further viral transmission. A resident who is admitted to the facility with COVID-19 does not constitute a facility outbreak.

Upon identification of a single new case of COVID-19 infection in any staff or residents, all staff and residents should be tested, and all staff and residents that tested negative should be retested every 3 days to 7 days until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result. See CDC guidance "Testing Guidelines for Nursing Homes" section Non-diagnostic testing of asymptomatic residents without known or suspected exposure to an individual infected with SARS-CoV-2.

For individuals who test positive for COVID-19, repeat testing is not recommended. A symptom-based strategy is intended to replace the need for repeated testing. Facilities should follow the CDC guidance Test-Based Strategy for Discontinuing Transmission-Based PrecautionsDiscontinuing Transmission-Based Precautions for residents and Criteria for Return to Work for Healthcare Personnel with SARS-CoV2 Infection.

Routine Testing of Staff

Routine testing should be based on the extent of the virus in the community, therefore facilities should use their county positivity rate in the prior week as the trigger for staff testing frequency. Reports of COVID-19 county-level positivity rates will be available on the following website by August 28, 2020 (see section titled, "COVID-19 Testing"): https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg

Table 2: Routine Testing Intervals Vary by Community COVID-19 Activity Level

Community COVID-19 Activity	County Positivity Rate in the past week	Minimum Testing Frequency
Low	**<5%**	**Once a month**
Medium	**5% - 10%**	**Once a week***
High	**>10%**	**Twice a week***

***This frequency presumes availability of Point of Care testing on-site at the nursing home or where off-site testing turnaround time is <48 hours.**

If the 48-hour turn-around time cannot be met due to community testing supply shortages, limited access or inability of laboratories to process tests within 48 hours, the facility should have documentation of its efforts to obtain quick turnaround test results with the identified laboratory or laboratories and contact with the local and state health departments.

The facility should begin testing all staff at the frequency prescribed in the Routine Testing table based on the county positivity rate reported in the past week. Facilities should monitor their county positivity rate every other week (e.g., first and third Monday of every month) and adjust the frequency of performing staff testing according to the table above.

- If the county positivity rate increases to a higher level of activity, the facility should begin testing staff at the frequency shown in the table above as soon as the criteria for the higher activity are met.
- If the county positivity rate decreases to a lower level of activity, the facility should continue testing staff at the higher frequency level until the county positivity rate has remained at the lower activity level for at least two weeks before reducing testing frequency.

The guidance above represents the minimum testing expected. Facilities may consider other factors, such as the positivity rate in an adjacent (i.e., neighboring) county to test at a frequency that is higher than required. For example, if a facility in a county with a low positivity rate has many staff that live in a county with a medium positivity rate, the facility should consider testing based on the higher positivity rate (in scenario described, weekly staff testing would be indicated).

State and local officials may also direct facilities to monitor other factors that increase the risk for COVID-19 transmission, such as rates of Emergency Department visits of individuals with COVID-19-like symptoms. Facilities should consult with state and local officials on these factors, and the actions that should be taken to reduce the spread of the virus. https://www.cdc.gov/covid-data-tracker/index.html#ed-visits.

NOTE: Routine testing of asymptomatic residents is not recommended unless prompted by a change in circumstances, such as the identification of a confirmed COVID-19 case in the facility. Facilities may consider testing asymptomatic residents who leave the facility frequently, such as for dialysis or chemotherapy. Facilities should inform resident transportation services (such as non-emergency medical transportation) and receiving healthcare providers (such as hospitals) regarding a resident's COVID-19 status to ensure appropriate infection control precautions are followed.

Routine communication between the nursing home and other entities about the resident's status should ideally occur prior to the resident leaving the nursing home for treatment. Coordination between the nursing home and the other healthcare entity is vital to ensure healthcare staff are informed of the most up to date information relating to the resident's health status, including COVID-19 status, and to allow for proper planning of care and operations. Additionally, facilities should maintain communications with the local ambulance and other contracted providers that transport residents between facilities, to ensure appropriate infection control precautions are followed as described by the CDC.

Refusal of Testing

Facilities must have procedures in place to address staff who refuse testing. Procedures should ensure that staff who have signs or symptoms of COVID-19 and refuse testing are prohibited from entering the building until the return to work criteria are met. If outbreak testing has been triggered and a staff member refuses testing, the staff member should be restricted from the building until the procedures for outbreak testing have been completed. The facility should follow its occupational health and local jurisdiction policies with respect to any asymptomatic staff who refuse routine testing.

Residents (or resident representatives) may exercise their right to decline COVID-19 testing in accordance with the requirements under 42 CFR § 483.10(c)(6). In discussing testing with residents, staff should use person-centered approaches when explaining the importance of testing for COVID-19. Facilities must have procedures in place to address residents who refuse testing. Procedures should ensure that residents who have signs or symptoms of COVID-19 and refuse testing are placed on TBP until the criteria for discontinuing TBP have been met. If outbreak testing has been triggered and an asymptomatic resident refuses testing, the facility should be extremely vigilant, such as through additional monitoring, to ensure the resident maintains appropriate distance from other residents, wears a face covering, and practices effective hand hygiene until the procedures for outbreak testing have been completed.

Clinical discussions about testing may include alternative specimen collection sources that may be more acceptable to residents than nasopharyngeal swabs (e.g., anterior nares). Providing information about the method of testing and reason for pursuing testing may facilitate discussions with residents or resident representatives.

If a resident has symptoms consistent with COVID-19 or has been exposed to COVID-19, or if there is a facility outbreak and the resident declines testing, he or she should be placed on or remain on TBP until he or she meets the symptom-based criteria for discontinuation.

Other Testing Considerations

In keeping with current CDC recommendations staff and residents who have recovered from COVID-19 and are asymptomatic do not need to be retested for COVID-19 within 3 months after symptom onset. Until more is known, testing should be encouraged again (e.g., in response to an exposure) 3 months after the date of symptom onset with the prior infection. Facilities should continue to monitor the CDC webpages and FAQs for the latest information. The facility should consult with infectious diseases specialists and public health authorities to review all available information (e.g., medical history, time from initial positive test, Reverse Transcription-Polymerase Chain Reaction Cycle Threshold (RT-PCR Ct) values, and presence of COVID-19 signs or symptoms). Individuals who are determined to be potentially infectious

should undergo evaluation and remain isolated until they meet criteria for discontinuation of isolation or discontinuation of transmission-based precautions, depending on their circumstances.

For residents or staff who test positive, facilities should contact the appropriate state or local entity for contact tracing.

While not required, facilities may test residents' visitors to help facilitate visitation while also preventing the spread of COVID-19. Facilities should prioritize resident and staff testing and have adequate testing supplies to meet required testing, prior to testing resident visitors.

Conducting Testing

In accordance with 42 CFR § 483.50(a)(2)(i), the facility must obtain an order from a physician, physician assistant, nurse practitioner, or clinical nurse specialist in accordance with State law, including scope of practice laws to provide or obtain laboratory services for a resident, which includes COVID-19 testing (see F773). This may be accomplished through the use of physician approved policies (e.g., standing orders), or other means as specified by scope of practice laws and facility policy.

NOTE: Concerns related to orders for laboratory and/or POC testing should be investigated under F773.

Rapid POC Testing devices are prescription use tests under the Emergency Use Authorization and must be ordered by a healthcare professional licensed under the applicable state law or a pharmacist under HHS guidance. Accordingly, the facility must have an order from a healthcare professional or pharmacist, as previously described, to perform a rapid POC COVID-19 test on an individual.

Facilities must conduct testing according to nationally recognized guidelines, outlined by the Centers for Disease Control and Prevention (CDC). This would include the following guidelines:

- Preparing for COVID-19 in Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html.
- Testing Guidelines for Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html.
- Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-facility-wide-testing.html.
- Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2: https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-healthcare-personnel.html.

A diagnostic test shows if a patient has an active coronavirus infection. As of the date of this guidance, there are two types of diagnostic tests which detect the active virus – molecular tests, such as RT-PCR tests, that detect the virus's genetic material, and antigen tests that detect specific proteins on the surface of the virus. An antibody test looks for antibodies that are made by the immune system in response to a threat, such as a specific virus. An antibody test does not identify an active coronavirus infection; therefore, conducting an antibody test on a staff or resident would not meet the requirements under this regulation.

Frequently asked questions related to the use of these testing devices in high-risk congregate

settings such as nursing homes can be found here. In addition, when testing residents, a facility's selection of a test should be person-centered.

Collecting and handling specimens correctly and safely is imperative to ensure the accuracy of test results and prevent any unnecessary exposures. The specimen should be collected and, if necessary, stored in accordance with the manufacturer's instructions for use for the test and CDC guidelines.

During specimen collection, facilities must maintain proper infection control and use recommended personal protective equipment (PPE), which includes an N95 or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown, when collecting specimens.

The CDC has provided guidance on proper specimen collection:

- See section "Recommendations for conducting swabbing" under CDC's "Considerations for Performing Facility-wide SARS-CoV-2 Testing in Nursing Homes": https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-facility-wide-testing.html.
- Influenza Specimen Collection: https://www.cdc.gov/flu/pdf/professionals/flu-specimen-collection-poster.pdf.
- Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens from Persons for Coronavirus Disease 2019 (COVID-19): (https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html).
- CDC's Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens Associated with Coronavirus Disease 2019 (COVID-19): https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html#decentralized.
- Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories: https://www.cdc.gov/coronavirus/2019-ncov/lab/lab-biosafety-guidelines.html.

For additional considerations for antigen testing, see CDC's Interim Guidance for Rapid Antigen Testing for SARS-CoV-2.

As a reminder, per 42 CFR § 483.50(a), the facility must provide or obtain laboratory services to meet the needs of its residents. If a facility provides its own laboratory services or performs any laboratory tests directly (e.g., SARS-CoV-2 point-of-care test) the provisions of 42 CFR Part 493 apply and the facility must have a current CLIA certificate appropriate for the level of testing performed within the facility. Surveyors should only verify that the facility has a current CLIA certificate and not attempt to determine compliance with the requirements in 42 CFR Part 493.

Reporting Test Results

Facilities conducting tests under a CLIA certificate of waiver are subject to regulations that require laboratories to report data for all testing completed, for each individual tested. For additional information on reporting requirements see:

- Frequently Asked Questions: COVID-19 Testing at Skilled Nursing Facilities/Nursing Homes

- CMS memorandum: Interim Final Rule (IFC), CMS-3401-IFC, Updating Requirements for Reporting of SARS-CoV-2 Test Results by Clinical Laboratory Improvement Amendments of 1988 (CLIA) Laboratories, and Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency

Surveyors should report concerns related to CLIA certificates or laboratory reporting requirements to the CMS Division of Clinical Laboratory Improvement and Quality at LabExcellence@cms.hhs.gov. When reporting concerns include the CLIA number; name and address of laboratory (facility); number of days that results were not reported, if known; and number of results not reported, if known.

In addition to reporting in accordance with CLIA requirements, facilities must continue to report COVID-19 information to the CDC's National Healthcare Safety Network (NHSN), in accordance with 42 CFR § 483.80(g)(1)–(2). See "Interim Final Rule Updating Requirements for Notification of Confirmed and Suspected COVID-19 Cases Among Residents and Staff in Nursing Homes," CMS Memorandum QSO-20-29-NH (May 6, 2020).

NOTE: Concerns related to informing residents, their representatives and families of new or suspected cases of COVID-19 should be investigated under F885.

NOTE: Concerns related to the reporting to state and local public health authority of communicable diseases and outbreaks, including for purposes such as contact tracing, should be investigated under F880.

Documentation of Testing

Facilities must demonstrate compliance with the testing requirements. To do so, facilities should do the following:

- For symptomatic residents and staff, document the date(s) and time(s) of the identification of signs or symptoms, when testing was conducted, when results were obtained, and the actions the facility took based on the results.
- Upon identification of a new COVID-19 case in the facility (i.e., outbreak), document the date the case was identified, the date that all other residents and staff are tested, the dates that staff and residents who tested negative are retested, and the results of all tests. All residents and staff that tested negative are expected to be retested until testing identifies no new cases of COVID-19 infection among staff or residents for a period of at least 14 days since the most recent positive result (see section Testing of Staff and Residents in response to an outbreak above).
- For staff routine testing, document the facility's county positivity rate, the corresponding testing frequency indicated (e.g., every other week), and the date each positivity rate was collected. Also, document the date(s) that testing was performed for all staff, and the results of each test.
- Document the facility's procedures for addressing residents and staff that refuse testing or are unable to be tested, and document any staff or residents who refused or were unable to be tested and how the facility addressed those cases.
- When necessary, such as in emergencies due to testing supply shortages, document that the facility contacted state and local health departments to assist in testing efforts, such as obtaining testing supplies or processing test results.

Facilities may document the conducting of tests in a variety of ways, such as a log of county positivity rates, schedules of completed testing, and/or staff and resident records. However, the results of tests must be done in accordance with standards for protected health information. For residents, the facility must document testing results in the medical record. For staff, including individuals providing services under arrangement and volunteers, the facility must document testing results in a secure manner consistent with requirements specified in 483.80(h)(3).

Surveying for Compliance

Compliance will be assessed through the following process using the COVID-19 Focused Survey for Nursing Homes:

1. Surveyors will ask for the facility's documentation noted in the "Documentation of Testing" section above, and review the documentation for compliance.
2. Surveyors will also review records of those residents and staff selected as a sample as part of the survey process.
3. If possible, surveyors should observe how the facility conducts testing in real-time. In this process, surveyors will assess if the facility is conducting testing and specimen collection in a manner that is consistent with current standards of practice for conducting COVID-19 tests, such as ensuring PPE is used correctly to prevent the transmission of the virus. If observation is not possible, surveyors should interview an individual responsible for testing and inquire on how testing is conducted (e.g., "what are the steps taken to conduct each test?").
4. If the facility has a shortage of testing supplies, or cannot obtain test results within 48 hours, the surveyor should ask for documentation that the facility contacted state and local health departments to assist with these issues.

Facilities that do not comply with the testing requirements in § 483.80(h) will be cited for noncompliance at F886. Additionally, enforcement remedies (such as civil money penalties) will be imposed based on the resident outcome (i.e., the scope and severity of the noncompliance), in accordance with Chapter 7 of the State Operations Manual.

If the facility has documentation that demonstrates their attempts to perform and/or obtain testing in accordance with these guidelines (e.g., timely contacting state officials, multiple attempts to identify a laboratory that can provide testing results within 48 hours), surveyors should not cite the facility for noncompliance. Surveyors should also inform the state or local health authority of the facility's lack of resources.

CMS is also continuing to assess automated methods for determining compliance with the testing requirements, which may augment the assessment of compliance through onsite surveys.

Additional Resource Links:

- Clinical Questions about COVID-19: Questions and Answers-Testing in Nursing Homes https://www.cdc.gov/coronavirus/2019-ncov/hcp/faq.html#Testing-in-Nursing-Homes
- Nursing Home Reopening Recommendations for State and Local Officials https://www.cms.gov/files/document/qso-20-30-nh.pdf-0
- Discontinuation of Transmission-Based Precautions and Disposition of Patients with COVID-19 in Healthcare Settings https://www.cdc.gov/coronavirus/2019-ncov/hcp/disposition-hospitalized-patients.html

COVID-19 Focused Survey for Nursing Homes

CMS is revising the COVID-19 Focused Survey for Nursing Homes tool to reflect the new testing requirements implemented in the IFC, as well as other updates to help ensure an effective assessment of the facility's compliance, such as selecting a number of residents as a sample to review the facility's application of the standards on that sample, and that a facility is implementing the appropriate infection prevention standards (e.g., transmission-based precautions, face coverings, etc.). We are also revising the survey process to include the assessment of compliance with the requirements for facilities to designate one or more individuals as the infection preventionist(s) (IPs) who are responsible for the facility's infection prevention and control program at 42 CFR § 483.80(b). Noncompliance related to this requirement will be cited at tag F882.

Contact: Questions related to the nursing home testing requirement may be submitted to: DNH_TriageTeam@cms.hhs.gov.

Effective Date: Immediately. This policy should be communicated with all survey and certification staff, their managers and the State Agency/CMS Branch Location training coordinators immediately.

/s/
David R. Wright

Attachments:

COVID-19 Focused Survey for Nursing Homes

COVID-19 Focused Survey for Nursing Homes

Infection Control

This survey tool must be used to investigate compliance at F880, *F882*, F884 (CMS Federal surveyors only), F885, *F886*, and E0024. Surveyors must determine whether the facility is implementing proper infection prevention and control practices to prevent the development and transmission of COVID-19 and other communicable diseases and infections. Entry and screening procedures as well as resident care guidance has varied over the progression of COVID-19 transmission in facilities. Facilities are expected to be in compliance with CMS requirements and surveyors will use guidance that is in effect at the time of the survey. Refer to QSO memos released at: https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Policy-and-Memos-to- States-and-Regions.

This survey tool provides a focused review of the critical elements associated with the transmission of COVID-19, will help surveyors to prioritize survey activities while onsite, and identifies those survey activities which can be accomplished offsite. These efficiencies will decrease the potential for transmission of COVID-19, as well as lessen disruptions to the facility and minimize exposure of the surveyor. Surveyors should be mindful to ensure their activities do not interfere with the active treatment or prevention of transmission of COVID-19.

If citing for noncompliance related to COVID-19, the surveyor(s) must include the following language at the beginning of the Deficient Practice Statement or other place determined appropriate on the Form CMS-2567: "Based on [observations/interviews/record review], the facility failed to [properly prevent and/or contain – or other appropriate statement] **COVID-19**."

If surveyors see concerns related to compliance with other requirements, they should investigate them in accordance with the existing guidance in Appendix PP of the State Operations Manual and related survey instructions. Surveyors may also need to consider investigating concerns related to Emergency Preparedness in accordance with the guidance in Appendix Z of the State Operations Manual (e.g., for emergency staffing).

For the purpose of this survey tool, "staff" includes employees, consultants, contractors, volunteers, and others who provide care and services to residents on behalf of the facility. The Infection Prevention and Control Program (IPCP) must be facility-wide and include all departments and contracted services.

Note: It is imperative that surveyors refer to the most recent information for COVID-19 testing parameters and frequency set forth by the Secretary *described in the guidance for F886. County-level data are available on the CDC website:*

https://data.cms.gov/stories/s/COVID-19-Nursing-Home-Data/bkwz-xpvg

Critical Element #8 is only for consideration by CMS Federal Survey staff. Information to determine the facility's compliance at F884 is only reported to each of the 10 CMS locations.

COVID-19 Focused Survey for Nursing Homes

Surveyor(s) reviews for:

- The overall effectiveness of the Infection Prevention and Control Program (IPCP) including IPCP policies and procedures;
- Standard and Transmission-Based Precautions *(review care of a resident under observation, suspected of, or confirmed to have COVID-19 infection);*
- Quality of resident care practices, including those *under observation, suspected of, and confirmed to have* COVID-19 *infection*, if applicable;
- The surveillance *and testing* process;
- Visitor entry and facility screening practices;
- Education, monitoring, and screening practices of staff;
- *Actions taken to prevent transmission, such as cohorting and managing care for residents suspected of having or confirmed to have COVID-19*;
- Facility policies and procedures to address staffing issues during emergencies, such as transmission of COVID-19;
- How the facility informs residents, their representatives, and families of suspected or confirmed COVID-19 cases in the facility*; and*
- *The infection preventionist role*.

The survey team will select a random sample of three residents, and if not already sampled, add one additional resident who was confirmed COVID-19 positive or had signs or symptoms consistent with COVID-19, for purposes of determining compliance.

The survey team will select a random sample of three staff, and if not already sampled, add one additional staff who was confirmed COVID-19 positive or had signs or symptoms consistent with COVID-19, for purposes of determining compliance.

---

1. Standard and Transmission-Based Precautions (TBPs)

CMS is aware that there is a scarcity of some supplies in certain areas of the country. State and Federal surveyors should not cite facilities for not having certain supplies (e.g., PPE such as gowns, N95 respirators, surgical masks) if they are having difficulty obtaining these supplies for reasons outside of their control. However, we do expect facilities to take actions to mitigate any resource shortages and show they are taking all appropriate steps to obtain the necessary supplies as soon as possible. For example, if there is a shortage of PPE (e.g., due to supplier shortage, which may be a regional or national issue), the facility should contact their healthcare coalition for assistance (https://www.phe.gov/Preparedness/planning/hpp/Pages/find-hc-coalition.aspx), follow national and/or local guidelines for optimizing their current supply, or identify the next best option to care for residents. Among other practices, optimizing their current supply may mean prioritizing use of gowns based on risk of exposure to infectious organisms, blood or body fluids, splashes or sprays, high contact procedures, or aerosol generating procedures (AGPs), as well as possibly extending use of PPE (follow national and/or local guidelines). Current CDC

guidance for healthcare professionals is located at: https://www.cdc.gov/coronavirus/2019-nCoV/hcp/index.html and healthcare facilities is located at: *https://www.cdc.gov/coronavirus/2019-ncov/hcp/us-healthcare-facilities.html*. Guidance on strategies for optimizing PPE supply is located at: https://www.cdc.gov/coronavirus/2019-ncov/hcp/ppe-strategy/index.html. If a surveyor believes a facility should be cited for not having or providing the necessary supplies, the State Agency should contact the CMS Regional Location.

General Standard Precautions:

☐ Are staff performing the following appropriately:

- Respiratory hygiene/cough etiquette,
- Environmental cleaning and disinfection, and
- Reprocessing of reusable resident medical equipment (e.g., cleaning and disinfection of glucometers per device and disinfectant manufacturer's instructions for use)?

Hand Hygiene:

☐ Are staff performing hand hygiene when indicated?

☐ If alcohol-based hand rub (ABHR) is available, is it readily accessible and preferentially used by staff for hand hygiene?

☐ If there are shortages of ABHR, are staff performing hand hygiene using soap and water instead?

☐ Are staff washing hands with soap and water when their hands are visibly soiled (e.g., blood, body fluids)?

☐ Do staff perform hand hygiene (even if gloves are used) in the following situations:

- Before and after contact with the resident;
- After contact with blood, body fluids, or visibly contaminated surfaces;
- After contact with objects and surfaces in the resident's environment;
- After removing personal protective equipment (e.g., gloves, gown, facemask); and
- Before performing a procedure such as an aseptic task (e.g., insertion of an invasive device such as a urinary catheter, manipulation of a central venous catheter, and/or dressing care)?

☐ When being assisted by staff, is resident hand hygiene performed after toileting and before meals? *How are residents reminded to perform hand hygiene?*

☐ Interview appropriate staff to determine if hand hygiene supplies (e.g., ABHR, soap, paper towels) are readily available and who they contact for replacement supplies.

Personal Protective Equipment (PPE):

☐ Determine if staff appropriately use PPE including, but not limited to, the following:

- Gloves are worn if potential contact with blood or body fluid, mucous membranes, or non-intact skin;
- Gloves are removed after contact with blood or body fluids, mucous membranes, or non-intact skin;
- Gloves are changed and hand hygiene is performed before moving from a contaminated body site to a clean body site during resident care; and
- An isolation gown, *eye protection (e.g. goggles or face shield), and an N95 or equivalent or higher-level respirator are* worn for direct resident contact if the resident has uncontained secretions or excretions *including splashes or sprays.*

☐ Is PPE appropriately removed and discarded after resident care, prior to leaving room (except in the case of extended use of PPE per national/local recommendations), followed by hand hygiene?

☐ If PPE use is extended/reused, is it done according to national and/or local guidelines? If it is reused, is it cleaned/decontaminated/maintained after and/or between uses?

☐ Interview appropriate staff to determine if PPE is available, accessible, and used by staff.

- Are there sufficient PPE supplies available to follow infection prevention and control guidelines? In the event of PPE shortages, what actions is the facility taking to address this issue?
- Do staff know how to obtain PPE supplies before providing care?
- Do they know who to contact for replacement supplies?

☐ *Are all staff wearing a facemask (e.g., a cloth face covering can be used by staff where PPE is not indicated, such as administrative staff who are not at risk of coming in contact with infectious materials)?*

☐ *When COVID-19 is present in the facility, are staff wearing an N95 or equivalent or higher-level respirator, instead of a facemask, for aerosol generating procedures?*

Source Control:

☐ *Are residents, visitors, and others at the facility donning a cloth face covering or facemask while in the facility or while around others outside?*

Transmission-Based Precautions (Note: PPE use is based on availability and latest CDC guidance. See note on Pages 1-2):

☐ Determine if appropriate Transmission-Based Precautions are implemented:

- For a resident on Contact Precautions: staff don gloves and isolation gown before contact with the resident and/or his/her environment;
- For a resident on Droplet Precautions: staff don a facemask within six feet of a resident;
- For a resident on Airborne Precautions: staff don an N95 or higher-level respirator prior to room entry of a resident;

- For a resident with an undiagnosed respiratory infection: staff follow Standard, Contact, and Droplet Precautions (i.e., facemask, gloves, isolation gown) with eye protection when caring for a resident unless the suspected diagnosis requires Airborne Precautions (e.g., tuberculosis);
- For a resident with known or suspected COVID-19: staff wear gloves, isolation gown, eye protection and an N95 or higher-level respirator if available. A facemask is an acceptable alternative if a respirator is not available. When COVID-19 is identified in the facility, staff wear all recommended PPE (i.e., gloves, gown, eye protection and respirator or facemask) for the care of all residents on the unit (or facility-wide based on the location of affected residents), regardless of symptoms (based on availability*).*
    - Some procedures performed on residents with known or suspected COVID-19 could generate infectious aerosols (i.e., aerosol-generating procedures (AGPs)). In particular, procedures that are likely to induce coughing (e.g., sputum induction, open suctioning of airways) should be performed cautiously. If performed, the following should occur:
        - Staff in the room should wear an N95 or higher-level respirator, eye protection, gloves, and an isolation gown.
        - The number of staff present during the procedure should be limited to only those essential for resident care and procedure support.
        - AGPs should ideally take place in an airborne infection isolation room (AIIR). If an AIIR is not available and the procedure is medically necessary, then it should take place in a private room with the door closed.
        - Clean and disinfect the room surfaces with *an* appropriate disinfectant. Use disinfectants on List N of the EPA website that have qualified under EPA's emerging viral pathogens program for use against SARS-CoV-2 or other national recommendations.
- Dedicated or disposable noncritical resident-care equipment (e.g., blood pressure cuffs, blood glucose monitor equipment) is used, or if not available, then equipment is cleaned and disinfected according to manufacturers' instructions using an EPA-registered disinfectant for healthcare setting *(effective against the identified organism if known)* prior to use on another resident;
- Objects and environmental surfaces that are touched frequently and in close proximity to the resident (e.g., bed rails, over-bed table, bedside commode, lavatory surfaces in resident bathrooms) are cleaned and disinfected with an EPA-registered disinfectant for healthcare setting (effective against the organism identified if known) at least daily and when visibly soiled; and
- Is signage on the use of specific PPE (for staff) posted in appropriate locations in the facility (e.g., outside of a resident's room, wing, or facility-wide)?

☐ Interview appropriate staff to determine if they are aware of processes/protocols for Transmission-Based Precautions and how staff is monitored for compliance.

☐ *Observe staff to determine if they use appropriate infection control precautions when moving between resident rooms, units and other areas of the facility.*

☐ If concerns are identified, expand the sample to include more residents on Transmission-Based Precautions.

COVID-19 Focused Survey for Nursing Homes

1. Did staff implement appropriate Standard (e.g., hand hygiene, appropriate use of PPE, environmental cleaning and disinfection, and reprocessing of reusable resident medical equipment) and Transmission-Based Precautions (if applicable)? ☐ Yes ☐ **No F880**

---

2. Resident Care

☐ *Are residents on Transmission-Based Precautions restricted* to their rooms except for medically necessary purposes? If these residents have to leave their room, are they wearing a facemask *or cloth face covering*, performing hand hygiene, limiting their movement in the facility, and performing social distancing (efforts are made to keep them at least 6 feet away from others)?

☐ *When residents not on Transmission-Based Precautions are outside of their room,are they wearing a cloth face covering or facemask as part of source control? If a cloth face covering or facemask is not tolerated, does the resident cover his/her mouth and nose with tissues and is reminded or assisted to perform hand hygiene? Is at least 6 feet maintained between residents?*

☐ *Is* the facility *ensuring only COVID-19 negative residents* and those not suspected or under observation for COVID-19 *are participating in group outings (e.g., if in phase 2 or 3 of CMS' QSO-20-30-NH- " Nursing Home Reopening Recommendations for State and Local Officials"), group activities, and communal dining following State and local official guidance if more restrictive? Is the facility ensuring that residents are maintaining social distancing (e.g., limited number of people in areas and spaced by at least 6 feet), performing hand hygiene, and wearing cloth face coverings?*

☐ *Does the facility have a plan (including appropriate placement and PPE use) to manage residents that are new/readmissions under observation, those exposed to COVID-19, and those suspected of COVID-19? Are these actions based on national (e.g., CDC), state, or local public health authority recommendations?*

☐ *Does* the facility *have a plan to prevent transmission, such as having a dedicated space in the facility for cohorting and managing care for residents with COVID-19? Are these* actions based on national (e.g., CDC), state, or local public health authority recommendations?

☐ For the resident who develops severe symptoms of illness and requires transfer to a hospital for a higher level of care, did the facility alert emergency medical services and the receiving facility of the resident's diagnosis (suspected or confirmed COVID-19) and precautions to be taken by transferring and receiving staff as well as place a facemask *or cloth face covering* on the resident during transfer *(as tolerated)*?

☐ For residents who need to leave the facility for care (e.g., dialysis), did the facility notify the transportation and receiving health care team of the resident's suspected or confirmed COVID-19 status?

2. Did staff provide appropriate resident care? ☐ Yes ☐ **No F880**

---

3. IPCP Standards, Policies and Procedures

☐ Did the facility establish a facility-wide IPCP including standards, policies, and procedures that are current and based on national standards for undiagnosed respiratory illness and COVID-19?

☐ Do the facility's policies or procedures include when to notify local/state public health officials if there are clusters of respiratory illness or cases of COVID-19 that are identified or suspected?

☐ Concerns must be corroborated as applicable including the review of pertinent policies/procedures as necessary.

3. Does the facility have a facility-wide IPCP including standards, policies, and procedures that are current and based on national standards for undiagnosed respiratory illness and COVID-19? ☐ Yes ☐ **No F880**

---

4. Infection Surveillance

☐ How many residents and staff in the facility have fever, respiratory signs/symptoms, or other signs/symptoms related to COVID-19?

☐ How many residents and staff have been diagnosed with COVID-19, and when was the first case confirmed?

☐ How has the facility established/implemented a surveillance plan, based on a facility assessment, for identifying (i.e., screening), tracking, monitoring and/or reporting of fever, respiratory illness, and/or other signs/symptoms of COVID-19, and immediately isolate anyone who is symptomatic?

☐ Does the plan include early detection, management of a potentially infectious, symptomatic resident that requires laboratory testing and/or Transmission-Based Precautions/PPE (the plan may include tracking this information in an infectious disease log)?

☐ Does the facility have a process for communicating diagnosis, treatment, and laboratory test results when transferring a resident to an acute care hospital or other healthcare provider; and obtaining pertinent notes such as discharge summary, lab results, current diagnoses, and infection or multidrug-resistant organism colonization status when residents are transferred back from acute care hospitals?

☐ Can appropriate staff (e.g., nursing and unit managers) identify/describe the communication protocol with local/state public health officials?

☐ Interview appropriate staff to determine if infection control concerns are identified, reported, and acted upon.

4. Did the facility provide appropriate infection surveillance? ☐ Yes ☐ **No F880**

---

5. Visitor Entry

☐ Review for compliance of:

- Screening processes and criteria (i.e., screening questions and assessment of illness);

- Restricting visitation based on federal or state guidance to ensure visitation does not lead to transmission of COVID-19*;* and
- Signage posted at facility entrances for screening and restrictions as well as a communication plan to alert visitors of new procedures/restrictions.

☐ For those permitted entry, are they instructed to frequently perform hand hygiene; limit their interactions with others in the facility and surfaces touched; restrict their visit to the resident's room or other location(s) designated by the facility*; maintain at least six feet from others in the facility;* and *wear a cloth face covering or facemask during the duration of their visit*? What is the facility's process for communicating this information?

5. Did the facility perform appropriate screening, restriction, and education of visitors? ☐ Yes ☐ **No F880**

---

6. Education, Monitoring, and Screening of Staff

☐ Is there evidence the facility has provided education to staff on COVID-19 (e.g., symptoms, how it is transmitted, screening criteria, work exclusions)?

☐ How does the facility convey updates on COVID-19 to all staff?

☐ Is the facility screening all staff at the beginning of their shift for fever and signs/symptoms of illness? Is the facility actively taking their temperature and documenting absence of illness (or signs/symptoms of COVID-19)?

☐ *Are non-essential staff permitted into the facility based on state or federal guidance (e.g., reopening recommendations include phase 1: non-essential staff limited; phase 2: limited numbers of non-essential staff allowed; phase 3: all non-essential staff allowed)?*

☐ If staff develop symptoms at work (as stated above), does the facility:

- Inform the facility's infection preventionist and include information on individuals, equipment, and locations the person came in contact with; and
- Follow current guidance about returning to work (e.g., local health department, CDC: https://www.cdc.gov/coronavirus/2019-ncov/healthcare-facilities/hcp-return-work.html).

6. Did the facility provide appropriate education, monitoring, and screening of staff? ☐ Yes ☐ **No F880**

---

7. Reporting to Residents, Representatives, and Families

Identify the mechanism(s) the facility is using to inform residents, their representatives, and families (e.g., newsletter, email, website, recorded voice message):

☐ Did the facility inform all residents, their representatives, and families by 5 PM the next calendar day following the occurrence of a single confirmed COVID-19 infection or of three or more residents or staff with new onset of respiratory symptoms that occurred within 72 hours of each other?

☐ Did the information include mitigating actions taken by the facility to prevent or reduce the risk of transmission, including if normal operations in the nursing home will be altered (e.g., restrictions to visitations or group activities)?

☐ Did the information include personally identifiable information?

☐ Is the facility providing cumulative updates to residents, their representatives, and families at least weekly or by 5 PM the next calendar day following the subsequent occurrence of either: each time a confirmed COVID-19 infection is identified, or whenever three or more residents or staff with new onset of respiratory symptoms occurs within 72 hours of each other?

☐ Interview a resident and a resident representative or family member to determine whether they are receiving timely notifications.

7. Did the facility inform residents, their representatives, and families of suspected or confirmed COVID-19 cases in the facility along with mitigating actions in a timely manner? ☐ Yes ☐ **No F885**

---

8. Reporting to the Centers for Disease Control and Prevention (CDC) – Performed Offsite by CMS. For consideration by CMS Federal Surveyors only.

☐ Review CDC data files provided to CMS to determine if the facility is reporting at least once a week.

☐ Review data files to determine if all data elements required in the National Healthcare Safety Network (NHSM) COVID-19 Module are completed.

8. Did the facility report at least once a week to CDC on all of the data elements required in the NHSN COVID-19 Module?
☐ Yes ☐ **No F884**

---

9. Emergency Preparedness – Staffing in Emergencies

☐ Policy development: Does the facility have a policy and procedure for ensuring staffing to meet the needs of the residents when needed during an emergency, such as COVID-19 outbreak?

☐ Policy implementation: In an emergency, did the facility implement its planned strategy for ensuring staffing to meet the needs of the residents? (N/A if an emergency staff was not needed).

9. Did the facility develop and implement policies and procedures for staffing strategies during an emergency?
☐ Yes ☐ **No E0024** ☐ N/A

---

10. Infection Preventionist (IP):

During interview with facility administration and Infection Preventionist(s), determine the following:

☐ *Did the facility designate one or more individual(s) as the infection preventionist(s) who are responsible for the facility's IPCP?*

☐ *Does the Infection Preventionist(s) work at least part-time at the facility?*

☐ *Has the Infection Preventionist(s) completed specialized training in infection prevention and control?*

☐ *Does the Infection Preventionist(s) participate in the quality assessment and assurance committee? The individual designated as the IP, or at least one of the individuals if there is more than one IP, must be a member of the facility's quality assessment and assurance committee and report to the committee on the IPCP on a regular basis.*

Note: If no to any of the question above, consider citing F882.

10. Is the facility in compliance with requirements set forth at 483.80(b)?
☐ Yes ☐ **No F882**

---

11. Staff and Resident Testing

Review the facility's testing documentation (e.g., logs of county level positivity rate, testing schedules, staff and resident records, other documentation). If possible, observe how the facility conducts testing, including the use of PPE and specimen collection. If such observation is not possible, interview an individual responsible for testing and inquire how testing is conducted (e.g., "what are the steps taken to conduct each test?").

☐ *Did the facility conduct testing of staff based on the county level positivity rate according to the recommended frequency?*

☐ *Based on observation or interview, did the facility conduct testing and specimen collection in a manner that is consistent with current standards of practice for conducting COVID-19 tests?*

☐ *Did the facility's documentation demonstrate the facility conducted testing of residents or staff with signs of symptoms of COVID-19 in a manner that is consistent with current standards of practice for conducting COVID-19 tests?*

☐ *Did the facility's documentation demonstrate the facility conducted testing of residents and staff based on the identification of an individual diagnosed with COVID-19 in the facility in a manner that is consistent with current standards of practice for conducting COVID-19 tests?*

☐ *Did the facility take actions to prevent the transmission of COVID-19 upon the identification of an individual with symptoms consistent with or who tests positive for COVID-19?*

☐ *Did the facility have procedures for addressing residents and staff that refuse testing or are unable to be tested**?***

☐ *If there was an issue related to testing supplies or processing tests, did the facility contact the state and local health departments for assistance?*

Note: If no to any of the question above, consider citing F886.

11. Is the facility in compliance with requirements set forth at 483.80(h)?

☐ Yes ☐ **No F886**

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	505400	A. BUILDING _____ B. WING _____	C 03/26/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ENUMCLAW HEALTH & REHAB CENTER	**2323 JENSEN STREET ENUMCLAW, WA 98022**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
F 000	INITIAL COMMENTS This report is the result of an unannounced Abbreviated Survey conducted off site at Enumclaw Health and Rehabilitation Center on 03/23/2020, with an onsite visit of 03/26/2020. A sample of 15 residents was selected from a census of 57. The sample included ten current residents and five discharged residents. On 03/27/2020, the facility was notified of an IJ related to Infection Control. The IJ was not removed before exit. The following were complaints investigated as part of this survey: #3699402 #3699510 #3699523 The survey was conducted by: Susan Lee Loewen MSN, BSN, RN, Investigator Lisa Foster, MN, RN, NH Surveyor The survey team is from: Department of Social & Health Services Aging & Long Term Support Administration Residential Care Services, Region 2, Unit F 20425 72nd Avenue South, Suite 400 Kent, Washington 98032-2388 Telephone: (253) 234-6000 Fax: (253) 395-5070 .	F 000		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE	TITLE	(X6) DATE
Electronically Signed		04/15/2020

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	505400	A. BUILDING _____ B. WING _____	C 03/26/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ENUMCLAW HEALTH & REHAB CENTER	**2323 JENSEN STREET ENUMCLAW, WA 98022**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
F 880 SS=K	Infection Prevention & Control CFR(s): 483.80(a)(1)(2)(4)(e)(f) §483.80 Infection Control The facility must establish and maintain an infection prevention and control program designed to provide a safe, sanitary and comfortable environment and to help prevent the development and transmission of communicable diseases and infections. §483.80(a) Infection prevention and control program. The facility must establish an infection prevention and control program (IPCP) that must include, at a minimum, the following elements: §483.80(a)(1) A system for preventing, identifying, reporting, investigating, and controlling infections and communicable diseases for all residents, staff, volunteers, visitors, and other individuals providing services under a contractual arrangement based upon the facility assessment conducted according to §483.70(e) and following accepted national standards; §483.80(a)(2) Written standards, policies, and procedures for the program, which must include, but are not limited to: (i) A system of surveillance designed to identify possible communicable diseases or infections before they can spread to other persons in the facility; (ii) When and to whom possible incidents of communicable disease or infections should be reported; (iii) Standard and transmission-based precautions to be followed to prevent spread of infections; (iv)When and how isolation should be used for a resident; including but not limited to:	F 880		5/19/20

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	505400	A. BUILDING _____ B. WING _____	C 03/26/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ENUMCLAW HEALTH & REHAB CENTER	2323 JENSEN STREET ENUMCLAW, WA 98022

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
F 880	Continued From page 2 (A) The type and duration of the isolation, depending upon the infectious agent or organism involved, and (B) A requirement that the isolation should be the least restrictive possible for the resident under the circumstances. (v) The circumstances under which the facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease; and (vi)The hand hygiene procedures to be followed by staff involved in direct resident contact. §483.80(a)(4) A system for recording incidents identified under the facility's IPCP and the corrective actions taken by the facility. §483.80(e) Linens. Personnel must handle, store, process, and transport linens so as to prevent the spread of infection. §483.80(f) Annual review. The facility will conduct an annual review of its IPCP and update their program, as necessary. This REQUIREMENT is not met as evidenced by: Based on observation, interviews and record reviews the facility failed to take appropriate actions related to a COVID-19 outbreak. These failed practices may have contributed to multiple residents and staff contracting COVID-19. As of 03/26/2020, based upon the facility's incomplete LTC (Long Term Care) Respiratory Surveillance Line List, and multiple staff interviews, 15 residents tested positive for Coronavirus disease (COVID-19) and 9 residents	F 880	Please see attached informal dispute resolution request. Preparation and/or execution of this plan of correction does not constitute admission or agreement by the provider of the truth of the facts alleged or conclusions set forth in the statement of deficiencies. The plan of correction is prepared and/or executed solely because it is required by the provision of federal	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	505400	A. BUILDING _____ B. WING _____	C 03/26/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ENUMCLAW HEALTH & REHAB CENTER	2323 JENSEN STREET ENUMCLAW, WA 98022

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
F 880	Continued From page 3 had pending lab results. Three residents who tested positive for COVID-19 remained at the local hospital. As of 04/02/2020 38 residents and 10 staff tested positive for COVID-19. Five residents expired. Additionally the facility failed to operationalize their infection prevention and control program to provide a safe, sanitary environment, and to help prevent the development and transmission of communicable diseases and infections, in particular COVID-19. These failed practices resulted in an immediate jeopardy on 03/27/2020. Findings included... On March 4th CMS (Center for Medicare & Medicaid Services) released a transmittal to nursing homes that directed nursing homes to monitor the CDC (Center for Disease Control) website which included a link to CDC. Upon clicking on the link it directs the facility to a Coronavirus Disease 2019 (COVID-19) Preparedness Checklist for Nursing Homes and other Long-Term Care Settings This checklist should be used as one tool in developing a comprehensive COVID-19 response plan. The checklist did not describe mandatory requirements or standards; rather, it highlights important areas to review to prepare for the possibility of residents with COVID-19. In general, when caring for residents with undiagnosed respiratory infection use Standard, Contact, and Droplet Precautions with eye protection unless the suspected diagnosis	F 880	and state law. Identified residents Resident #1, # 2 and # 4 no longer reside in the facility. Resident # 3, #5 and # 6 care plans have been update and continue in isolation. Resident #7: staff are wearing goggles when entering the room and are being cleaned in doorway prior to placing on isolation cart. Identification of others Residents at the facility who have been in contact with another resident or staff member with symptoms or became symptomatic are in isolation. systematic changes ED has been educated on having staff member screen staff or visitor at point of entry. Facility has limited access to the building and thermometer is placed at the entrance to facility. Staff have been educated to place residents in droplet precautions if they become symptomatic. Nurse Managers have been educated on the COVID-19 Tool Kit sent by DOH. Staff have been educated on donning and doffing isolation PPE and competencies have been completed. They have been educated to have N95 mask on during resident care. SDC has been educated on reporting 2 residents or staff with respiratory symptoms to Health Department. SDC is in contact with the DOH	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	505400	A. BUILDING _____ B. WING _____	C 03/26/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ENUMCLAW HEALTH & REHAB CENTER	**2323 JENSEN STREET ENUMCLAW, WA 98022**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
F 880	Continued From page 4 requires Airborne Precautions (e.g., tuberculosis). This includes restricting residents with respiratory infection to their rooms. If they leave the room, residents should wear a facemask (if tolerated) or use tissues to cover their mouth and nose. Continue to assess the need for Transmission-Based Precautions as more information about the resident's suspected diagnosis becomes available. Observations were conducted on 03/26/2020 from 1:41 PM until 2:46 PM. VISITOR ENTRY Review of the facility February 2020 Infection Prevention and Control Recommendations for Patients with Confirmed Coronavirus Disease (COVID-19) or Persons Under Investigation for COVID-19 policy, showed the procedure directed staff to manage visitor access and movement within the facility. The Centers of Disease Control (CDC) Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings recommended, "Limit points of entry to the facility." The back door was posted with the following signs; "No Admittance - Use front door only", "Attention: Due to recent outbreak of COVID-19 in our nation we are trying to minimize all-essential access to the center" and a second posting to those with questions, regarding the facility's management of Corono Virus, to call Staff C with a listed phone number.	F 880	routinely as needed and are sending LTC facility COVID-19 Updating Report form every 3 days and complete line listing every 7 days. DSHS is sent a weekly line listing with staff and resident on separated line listing per DSHS request. DNS/Designee has been educated to complete COVID-19 focused survey for nursing homes on a daily basis. Staff monitoring door for screening have been educated on surveillance results out of normal baseline and when not to allow persons into building. If staff are symptomatic they are turned away at the door, recommend to get tested for COVID-19, and added to line listing. Staff will report to ED/DNS findings daily. MONITORING Dns/Designee to complete the Daily COVID-19 Focus Survey audit daily x 4 weeks then 3 x week x 4 weeks then weekly x 4 weeks. SDC/Designee to review screening to validate completion SDC to complete random donning and doffing competencies including cleaning and drying of goggles. ED to validate point of entry that staff are checking results before allowing into the building including temperatures. Findings from audit to be brought to QAPI for further evaluation Person Responsible Executive Director	

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	505400	A. BUILDING _____ B. WING _____	C 03/26/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ENUMCLAW HEALTH & REHAB CENTER	**2323 JENSEN STREET ENUMCLAW, WA 98022**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
F 880	Continued From page 5	F 880		

The front door had one sign posted directing those with questions, regarding the facility's management of Corono Virus, to call Staff C with a listed phone number.

On 03/26/2020 Staff G, Housekeeping, was observed walking down the hallway, carrying a mask, looking for assistance as they were told to spray with disinfectant and bag the mask before going home. Administrative Staff assisted Staff G, who then exited the facility out the back door. Later on, during the onsite visit, Staff G was observed in the facility without wearing a protective facial mask. Staff G was not observed to have come into the facility by either the front or back entrance, nor observed to have been screened for symptoms of COVID-19. During an interview on 03/27/2020 at 1:04 PM, Staff D stated that she did not know how staff G re-entered the facility, but she re-educated Staff G on the process. According to Staff D, the facility doors are locked but staff have a code to unlock the door and enter the facility. When asked why Staff G returned, Staff D stated that Staff G went to get a Burrito or Taco out of the break room.

The Centers of Disease Control (CDC) Interim Infection Prevention and Control Recommendations for Patients with Suspected or Confirmed Coronavirus Disease 2019 (COVID-19) in Healthcare Settings recommended, "All visitors should be actively assessed for fever and respiratory symptoms upon entry to the facility. If fever or respiratory symptoms are present, visitor should not be allowed entry into the facility."

Upon entrance to the facility, on 03/26/2020 at

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	505400	A. BUILDING _____ B. WING _____	C 03/26/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ENUMCLAW HEALTH & REHAB CENTER	**2323 JENSEN STREET ENUMCLAW, WA 98022**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
F 880	Continued From page 6	F 880		

1:41 PM, the facility requested the surveyor to complete a health screening form at the reception desk, located in the foyer, directly to the right of the front entrance. Located at reception was a sign in sheet with visitors listed. During an interview with Staff A, the visitors listed included two plumbers on 03/25/2020 and a hospice staff member on 03/26/2020.

Staff A, Administrator, then escorted the surveyor, down the hallways, past ten resident rooms,and through resident care areas, to Nursing Station #2 located in the 500 unit the epicenter of the facility's COVID-19 outbreak, to be screened for the presence of a fever. The only thermometer available, at the nurse's station, was an oral thermometer, so the surveyor had to remove their face mask to be screened for the presence of a temperature. When questioned regarding the use of an oral thermometer, Staff A stated, "That's all we have."

INFECTION SURVEILLANCE
HealthCare Workers

A March 10, 2020 letter to Long-Term Care Facility Director, from WA (Washington) State DOH (Department of Health), instructed the facility to "Immediately notify the health department about anyone with COVID-19 or if you identify two or more residents or healthcare providers who develop respiratory infections within a week.

Review of the facility COVID-19 Timeline showed that on 03/17/2020 three staff (Staff H, I, J) were identified as symptomatic. The facility failed to notify the Department or DOH of healthcare workers with symptoms.

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	505400	A. BUILDING _____ B. WING _____	C 03/26/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ENUMCLAW HEALTH & REHAB CENTER	**2323 JENSEN STREET ENUMCLAW, WA 98022**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
F 880	Continued From page 7 According to the facility provided Timeline, on 03/20/2020 Staff K exhibited symptoms of a fever and cough. Review of the line listing provided by the facility on 03/25/2020 at 9:03 AM showed, Staff K was not entered on the line list. Further review of the facility Timeline showed on 03/23/2020 Resident L, M, B, D and N were symptomatic. Review of the line listing, provided by the facility on 03/25/2020 at 9:03 AM, showed the results of testing conducted were not noted for Staff L, M and N. Residents On 03/19/2020 at 4:01 PM the Department received an anonymous Report that: "Supposedly the facility is in lockdown yet they are admitting patients from St. Elizabeth Hospital in Enumclaw where the coronavirus has affected a patient." According to the facility Timeline, On 03/13/2020 Resident #14 and #15 were admitted to the facility. On 03/17/2020 Resident #13 was readmitted to the facility from St. Elizabeth Hospital. Staff B, interviewed on 03/23/2020 at 10:00 AM, stated that the facility stopped admitting residents on 03/20/2020 because residents exhibited symptoms of suspected COVID-19. On 03/20/2020 at 7:18 PM the Department received notification from the facility of seven Residents (#s 8, 9, 10, 11, 12, 13 & 14) who presented with acute fever and/or respiratory symptoms. According to the report, Per Medical Director, all symptomatic residents were placed on Droplet/Contact isolation and sent to the Emergency Department for COVID testing.	F 880		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	505400	A. BUILDING _____ B. WING _____	C 03/26/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ENUMCLAW HEALTH & REHAB CENTER	2323 JENSEN STREET ENUMCLAW, WA 98022

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
F 880	Continued From page 8 Review of the line listing showed Resident's #s 12, 13 & 14 first exhibited symptoms on 03/20/2020, but review of the resident's clinical records showed elevated temperatures and other reported symptoms were present on 03/19/2020. During an interview on 03/27/2020 at 1:04 PM Staff D stated that she and Staff B called the DOH on 03/22/2020 after they received a resident's COVID-19 positive test result. The DOH representative sent the facility the Long Term Care (LTC) Tool Kit to use and said if the facility had questions or needed help to call. Staff D stated that she had been emailing the line lists, but the facility had not called and requested assistance, and had not spoken with a DOH representative since 03/22/2020. During an interview on 03/23/2020 at 10:00 AM, Staff B stated that DOH called the facility back and said they wouldn't go out to the facility because there were only three COVID-19 positive residents of seven tested. Review of the documents provided by Staff C on 03/26/2020 included the LTC [Long Term Care] Tool Kit included "Aggressive Infection Prevention and Control Actions for Facilities with Suspected or Confirmed Cases of COVID-19, which directed the facility to "Treat all other residents in that same section or unit as if they have been exposed and implement Droplet and Contact Precautions with eye protection in the entire unit." Review of facility Infection Control [IC] documentation showed Resident #1 was in room 503, bed B on 03/21/2020. On 03/21/2020 Resident #2 was also in room 503, bed A. On	F 880		

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	505400	A. BUILDING _____ B. WING _____	C 03/26/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ENUMCLAW HEALTH & REHAB CENTER	**2323 JENSEN STREET ENUMCLAW, WA 98022**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
F 880	Continued From page 9	F 880		

03/22/2020 Resident #2 was symptomatic for COVID-19, and moved to room 203A on the 200 unit, which the facility dedicated to the care of COVID-19 positive residents. Resident #2 tested positive for COVID-19 on 03/26/2020. Resident #1 remained in room 503, and was not placed on precautions until Resident #1 exhibited symptoms on 03/24/2020. Resident #1 tested positive on 03/26/2020.

On 03/21/2020 Resident #3 and Resident #4 were roommates in room 522. On 03/22/2020 Resident #3 exhibited symptoms, was moved to the 200 unit and tested positive for COVID-19. On 03/26/2020 Resident #4 was not observed on precautions. During an interview on 03/27/2020 Staff B stated that Resident #4 was exhibiting symptoms and was "placed on isolation this morning."

On 03/21/2020 Resident #5 and Resident #6 were roommates in room 110. On 03/26/2020 Resident #5 was observed in room 501, on precautions, pending COVID-19 test results. On 03/27/2020 Resident #5's COVID-19 test results were positive. On 03/26/2020 Resident #6 was observed in room 110 still not on any isolation precautions.

During an interview on 03/27/2020 at 1:04 PM when asked why roommates of symptomatic residents were not placed on precautions until symptomatic, Staff D stated that they were told by corporate not to start the roommate on isolation, and continue with surveillance to conserve PPE [Personal Protective Equipment].

Corporate Nurse, Staff C, interviewed on 03/27/2020 at 1:45 PM, stated that roommates, of

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	505400	A. BUILDING _____ B. WING _____	C 03/26/2020

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
ENUMCLAW HEALTH & REHAB CENTER	**2323 JENSEN STREET ENUMCLAW, WA 98022**

(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE
F 880	Continued From page 10	F 880		

residents who were positive for the COVID-19 virus, were not placed on any isolation precautions unless the roommates presented with symptoms of COVID-19, to conserve PPE's.

On 03/26/2020 all staff were observed wearing masks. Review of documents "Covid-19 Timeline" provided by the facility showed that on 03/20/2020 all staff that had contact with positive residents were issued a facemask to be worn, and education was provided. In an email on 03/30/2020 at 3:11 PM, when asked when the facility implemented universal face masks were to be worn by all staff, Staff A replied, 03/24/2020.

STANDARD and TRANSMISSION-BASED PRECAUTIONS

On 03/26/2020 Resident #7's room was observed with posted precautions, and an infection control (IC) cart outside the room. Staff F, Lead Aide was observed to donn and doff Personal Protective Equipment (PPE) to respond to Resident #7's request for potato chips. Staff F was wearing a N95 mask, donned disposable gown and gloves but there was no eye protection in the IC cart. Staff D went down the hallway and retrieved goggles, which Staff F donned over N95 mask. Staff F entered the resident's room, provided the potato chips, and removed the gown and gloves prior to exiting the room. Outside the room, Staff F removed the goggles, and disinfected them. Staff D cued Staff F that the removal and cleaning of goggles should have been conducted before leaving the room.

Refer to WAC 388-97-1320(1)(a)(2)(a)(b)(c)

EXHIBIT C

Ohio, Court of Federal Claims No: 20–0225V
71. Shannon Pyers, Dresher, Pennsylvania, Court of Federal Claims No: 20–0231V
72. Lisa Macon, Englewood, New Jersey, Court of Federal Claims No: 20–0232V

[FR Doc. 2020–05525 Filed 3–16–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of declaration.

SUMMARY: The Secretary is issuing this Declaration pursuant to section 319F–3 of the Public Health Service Act to provide liability immunity for activities related to medical countermeasures against COVID–19.

DATES: The Declaration was effective as of February 4, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; Telephone: 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving ''willful misconduct'' as defined in the PREP Act. This Declaration is subject to amendment as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding Section 319F–3, which addresses liability immunity, and Section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d-6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food, Drug, and Cosmetic (FD&C) Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of ''Covered Countermeasures'' and ''qualified pandemic and epidemic products'' in Section 319F–3 of the Public Health Service Act (PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

COVID–19 is an acute respiratory disease caused by the SARS-CoV-2 betacoronavirus or a virus mutating therefrom. This virus is similar to other betacoronaviruses, such as Middle Eastern Respiratory Syndrome (MERS) and Severe Acute Respiratory Syndrome (SARS). Although the complete clinical picture regarding SARS-CoV-2 or a virus mutating therefrom is not fully understood, the virus has been known to cause severe respiratory illness and death in a subset of those people infected with such virus(es).

In December 2019, the novel coronavirus was detected in Wuhan City, Hubei Province, China. Today, over 101 countries, including the United States have reported multiple cases. Acknowledging that cases had been reported in five WHO regions in one month, on January 30, 2020, WHO declared the COVID–19 outbreak to be a Public Health Emergency of International Concern (PHEIC) following a second meeting of the Emergency Committee convened under the International Health Regulations (IHR).

To date, United States traveler-associated cases have been identified in a number of States and community-based transmission is suspected. On January 31, 2020, Secretary Azar declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, for the entire United States to aid in the nation's health care community response to the COVID–19 outbreak.[1] The outbreak remains a significant public health challenge that requires a sustained, coordinated proactive response by the Government in order to contain and mitigate the spread of COVID–19.[2]

Description of This Declaration by Section

Section I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a Declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may constitute such an emergency. This determination is separate and apart from the Declaration issued by the Secretary on January 31, 2020 under Section 319 of the PHS Act that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other Declarations or determinations made under other authorities of the Secretary. Accordingly in Section I of the Declaration, the Secretary determines that the spread of SARS-CoV-2 or a virus mutating therefrom and the resulting disease, COVID–19, constitutes a public health emergency for purposes of this Declaration under the PREP Act.

Section II. Factors Considered by the Secretary

In deciding whether and under what circumstances to issue a Declaration with respect to a Covered Countermeasure, the Secretary must consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the countermeasure. In Section II of the Declaration, the Secretary states that he has considered these factors.

Section III. Activities Covered by This Declaration Under the PREP Act's Liability Immunity

The Secretary must delineate the activities for which the PREP Act's liability immunity is in effect. These activities may include, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures

[1] *https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx.*

[2] CDC COVID–19 Summary; *https://www.cdc.gov/coronavirus/2019-ncov/summary.html,* accessed 27Feb2020,

(Recommended Activities). In Section III of the Declaration, the Secretary sets out the activities for which the immunity is in effect.

Section IV. Limited Immunity

The Secretary must also state that liability protections available under the PREP Act are in effect with respect to the Recommended Activities. These liability protections provide that, ''[s]ubject to other provisions of [the PREP Act], a covered person shall be immune from suit and liability under federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure if a Declaration has been issued with respect to such countermeasure.'' In Section IV of the Declaration, the Secretary states that liability protections are in effect with respect to the Recommended Activities.

Section V. Covered Persons

Section V of the Declaration describes Covered Persons, including Qualified Persons. The PREP Act defines Covered Persons to include, among others, the United States, and those that manufacturer, distribute, administer, prescribe or use Covered Countermeasures. This Declaration includes all persons and entities defined as Covered Persons under the PREP Act (PHS Act 317F–3(i)(2)) as well as others set out in paragraphs (3), (4), (6), (8)(A) and (8)(B).

The PREP Act's liability immunity applies to ''Covered Persons'' with respect to administration or use of a Covered Countermeasure. The term ''Covered Persons'' has a specific meaning and is defined in the PREP Act to include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States. The PREP Act further defines the terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' as described below.

A manufacturer includes a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

A distributor means a person or entity engaged in the distribution of drugs, biologics, or devices, including but not limited to: Manufacturers; re-packers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

A program planner means a state or local government, including an Indian tribe; a person employed by the state or local government; or other person who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure, including a person who establishes requirements, provides policy guidance, or supplies technical or scientific advice or assistance or provides a facility to administer or use a Covered Countermeasure in accordance with the Secretary's Declaration. Under this definition, a private sector employer or community group or other ''person'' can be a program planner when it carries out the described activities.

A qualified person means a licensed health professional or other individual authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the Covered Countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's Declaration. Under this definition, the Secretary can describe in the Declaration other qualified persons, such as volunteers, who are Covered Persons. Section V describes other qualified persons covered by this Declaration.

The PREP Act also defines the word ''person'' as used in the Act: A person includes an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, state, or local government agency or department.

Section VI. Covered Countermeasures

As noted above, Section III of the Declaration describes the activities (referred to as ''Recommended Activities'') for which liability immunity is in effect. Section VI of the Declaration identifies the Covered Countermeasures for which the Secretary has recommended such activities. The PREP Act states that a ''Covered Countermeasure'' must be a ''qualified pandemic or epidemic product,'' or a ''security countermeasure,'' as described immediately below; or a drug, biological product or device authorized for emergency use in accordance with Sections 564, 564A, or 564B of the FD&C Act.

A qualified pandemic or epidemic product means a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that is (i) manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product, or device; (iii) or a product or technology intended to enhance the use or effect of such a drug, biological product, or device.

A security countermeasure is a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that (i)(a) The Secretary determines to be a priority to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat by the Secretary of Homeland Security, or (b) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; and (ii) is determined by the Secretary of Health and Human Services to be a necessary countermeasure to protect public health.

To be a Covered Countermeasure, qualified pandemic or epidemic products or security countermeasures also must be approved or cleared under the FD&C Act; licensed under the PHS Act; or authorized for emergency use under Sections 564, 564A, or 564B of the FD&C Act.

A qualified pandemic or epidemic product also may be a Covered Countermeasure when it is subject to an exemption (that is, it is permitted to be used under an Investigational Drug Application or an Investigational Device Exemption) under the FD&C Act and is the object of research for possible use for diagnosis, mitigation, prevention, treatment, or cure, or to limit harm of a pandemic or epidemic or serious or life-threatening condition caused by such a drug or device.

A security countermeasure also may be a Covered Countermeasure if it may reasonably be determined to qualify for approval or licensing within 10 years after the Department's determination that procurement of the countermeasure is appropriate.

Section VI lists medical countermeasures against COVID–19 that

are Covered Countermeasures under this declaration.

Section VI also refers to the statutory definitions of Covered Countermeasures to make clear that these statutory definitions limit the scope of Covered Countermeasures. Specifically, the Declaration notes that Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

Section VII. Limitations on Distribution

The Secretary may specify that liability immunity is in effect only to Covered Countermeasures obtained through a particular means of distribution. The Declaration states that liability immunity is afforded to Covered Persons for Recommended Activities related to (a) present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements; or (b) activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasures following a Declaration of an emergency.

Section VII defines the terms ''Authority Having Jurisdiction'' and ''Declaration of an emergency.'' We have specified in the definition that Authorities having jurisdiction include federal, state, local, and tribal authorities and institutions or organizations acting on behalf of those governmental entities.

For governmental program planners only, liability immunity is afforded only to the extent they obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles. This last limitation on distribution is intended to deter program planners that are government entities from seizing privately held stockpiles of Covered Countermeasures. It does not apply to any other Covered Persons, including other program planners who are not government entities.

Section VIII. Category of Disease, Health Condition, or Threat

The Secretary must identify in the Declaration, for each Covered Countermeasure, the categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure. In Section VIII of the Declaration, the Secretary states that the disease threat for which he recommends administration or use of the Covered Countermeasures is COVID–19 caused by SARS-CoV-2 or a virus mutating therefrom.

Section IX. Administration of Covered Countermeasures

The PREP Act does not explicitly define the term ''administration'' but does assign the Secretary the responsibility to provide relevant conditions in the Declaration. In Section IX of the Declaration, the Secretary defines ''Administration of a Covered Countermeasure,'' as follows:

Administration of a Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.

The definition of ''administration'' extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a Declaration issued under the Act. Under the definition, these liability claims are precluded if they allege an injury caused by a countermeasure, or if the claims are due to manufacture, delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites.

Thus, it is the Secretary's interpretation that, when a Declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control. However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

Section X. Population

The Secretary must identify, for each Covered Countermeasure specified in a Declaration, the population or populations of individuals for which liability immunity is in effect with respect to administration or use of the countermeasure. Section X of the Declaration identifies which individuals should use the countermeasure or to whom the countermeasure should be administered—in short, those who should be vaccinated or take a drug or other countermeasure. Section X provides that the population includes ''any individual who uses or who is administered a Covered Countermeasure in accordance with the Declaration.''

It should be noted that under the PREP Act, liability protection extends beyond the Population specified in the Declaration. Specifically, liability immunity is afforded (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population, and (2) to program planners and qualified persons when the countermeasure is either used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population. Section X of the Declaration includes these statutory conditions in the Declaration for clarity.

Section XI. Geographic Area

The Secretary must identify, for each Covered Countermeasure specified in the Declaration, the geographic area or areas for which liability immunity is in effect, including, as appropriate, whether the Declaration applies only to

individuals physically present in the area or, in addition, applies to individuals who have a described connection to the area. Section XI of the Declaration provides that liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation. This could include claims related to administration or use in countries outside the U.S. It is possible that claims may arise in regard to administration or use of the Covered Countermeasures outside the U.S. that may be resolved under U.S. law.

In addition, the PREP Act specifies that liability immunity is afforded (1) to manufacturers and distributors without regard to whether the countermeasure is used by or administered to individuals in the geographic areas, and (2) to program planners and qualified persons when the countermeasure is either used or administered in the geographic areas or the program planner or qualified person reasonably could have believed the countermeasure was used or administered in the areas. Section XI of the Declaration includes these statutory conditions in the Declaration for clarity.

Section XII. Effective Time Period

The Secretary must identify, for each Covered Countermeasure, the period or periods during which liability immunity is in effect, designated by dates, milestones, or other description of events, including factors specified in the PREP Act. Section XII of the Declaration extends the effective period for different means of distribution of Covered Countermeasures through October 1, 2024.

Section XIII. Additional Time Period of Coverage

The Secretary must specify a date after the ending date of the effective time period of the Declaration that is reasonable for manufacturers to arrange for disposition of the Covered Countermeasure, including accepting returns of Covered Countermeasures, and for other Covered Persons to take appropriate actions to limit administration or use of the Covered Countermeasure. In addition, the PREP Act specifies that, for Covered Countermeasures that are subject to a Declaration at the time they are obtained for the Strategic National Stockpile (SNS) under 42 U.S.C. 247d-6b(a), the effective period of the Declaration extends through the time the countermeasure is used or administered. Liability immunity under the provisions of the PREP Act and the conditions of the Declaration continue during these additional time periods. Thus, liability immunity is afforded during the ''Effective Time Period,'' described under Section XII of the Declaration, plus the ''Additional Time Period'' described under Section XIII of the Declaration.

Section XIII of the Declaration provides for 12 months as the Additional Time Period of coverage after expiration of the Declaration. Section XIII also explains the extended coverage that applies to any product obtained for the SNS during the effective period of the Declaration.

Section XIV. Countermeasures Injury Compensation Program

Section 319F–4 of the PHS Act, 42 U.S.C. 247d-6e, authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to eligible individuals who sustain a serious physical injury or die as a direct result of the administration or use of a Covered Countermeasure. Compensation under the CICP for an injury directly caused by a Covered Countermeasure is based on the requirements set forth in this Declaration, the administrative rules for the Program, and the statute. To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires ''compelling, reliable, valid, medical and scientific evidence.'' The administrative rules for the Program further explain the necessary requirements for eligibility under the CICP. Please note that, by statute, requirements for compensation under the CICP may not align with the requirements for liability immunity provided under the PREP Act. Section XIV of the Declaration, ''Countermeasures Injury Compensation Program,'' explains the types of injury and standard of evidence needed to be considered for compensation under the CICP.

Further, the administrative rules for the CICP specify that if countermeasures are administered or used outside the United States, only otherwise eligible individuals at United States embassies, military installations abroad (such as military bases, ships, and camps) or at North Atlantic Treaty Organization (NATO) installations (subject to the NATO Status of Forces Agreement) where American servicemen and servicewomen are stationed may be considered for CICP benefits. Other individuals outside the United States may not be eligible for CICP benefits.

Section XV. Amendments

Section XV of the Declaration confirms that the Secretary may amend any portion of this Declaration through publication in the **Federal Register.**

Declaration

Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID–19.

I. Determination of Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that the spread of SARS-CoV–2 or a virus mutating therefrom and the resulting disease COVID–19 constitutes a public health emergency.

II. Factors Considered

42 U.S.C. 247d–6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d–6d(b)(1)

I recommend, under the conditions stated in this Declaration, the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures.

IV. Liability Immunity

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability immunity as prescribed in the PREP Act and conditions stated in this Declaration is in effect for the Recommended Activities described in Section III.

V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are ''manufacturers,'' ''distributors,'' ''program planners,'' ''qualified persons,'' and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

In addition, I have determined that the following additional persons are qualified persons: (a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and

volunteers, following a Declaration of an emergency; (b) any person

authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act; and (c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the

FD&C Act.

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS-CoV–2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures that are related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements; or

(b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency.

As used in this Declaration, the terms Authority Having Jurisdiction and Declaration of Emergency have the following meanings:

i. The Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.,* city, county, tribal, state, or federal boundary lines) or functional (*e.g.,* law enforcement, public health) range or sphere of authority.

ii. A Declaration of Emergency means any Declaration by any authorized local, regional, state, or federal official of an emergency specific to events that indicate an immediate need to administer and use the Covered Countermeasures, with the exception of a federal Declaration in support of an Emergency Use Authorization under Section 564 of the FD&C Act unless such Declaration specifies otherwise;

I have also determined that, for governmental program planners only, liability immunity is afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is COVID–19 caused by SARS-CoV–2 or a virus mutating therefrom.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals include any individual who uses or is administered the Covered Countermeasures in accordance with this Declaration.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered to this population, or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

Liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in any designated geographic area; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered in any designated geographic area, or the program planner or qualified person reasonably could have believed the recipient was in that geographic area.

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability immunity for Covered Countermeasures through means of distribution, as identified in Section VII(a) of this Declaration, other than in accordance with the public health and medical response of the Authority Having Jurisdiction and extends through October 1, 2024.

Liability immunity for Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with a Declaration and lasts through (1) the final day the emergency Declaration is in effect, or (2) October 1, 2024, whichever occurs first.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(B) and (C)

I have determined that an additional 12 months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the SNS during the effective period of this Declaration are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C 247d–6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available at the toll-free number 1–855–266–2427 or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

Amendments to this Declaration will be published in the **Federal Register**, as warranted.

Authority: 42 U.S.C. 247d–6d.

Dated: March 10, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–05484 Filed 3–12–20; 4:15 pm]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; PAR–18–423: NIDDK Multi-Center Clinical Study Implementation Planning Cooperative Agreements (U34) in Digestive Diseases.

Date: May 22, 2020.

Time: 11:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Dianne Camp, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7013, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 594–7682, *campd@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: March 10, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05361 Filed 3–16–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, Small Business: Cardiovascular Sciences, March 19, 2020 08:00 a.m. to March 20, 2020, 01:00 p.m., Embassy Suites Alexandria Old Town, 1900 Diagonal Road, Alexandria, VA 22314 which was published in the **Federal Register** on February 20, 2020, 85 FR 9791.

The meeting location is being held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, at 09:00 a.m. The meeting date remains the same. The meeting is closed to the public.

Dated: March 11, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05417 Filed 3–16–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, PAR 19–059: Global Noncommunicable Diseases and Injury Across the Lifespan (R21), March 23, 2020, 8:00 a.m. to 5:00 p.m., at the Hotel Palomar, 2121 P Street NW, Washington, DC 20037, which was published in the **Federal Register** on February 25, 2020, 85 FR 10708.

The meeting will be held at the National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892. The format of the meeting has been changed to a Video Assisted Meeting. The meeting date and time remain the same. The meeting is closed to the public.

Dated: March 11, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–05419 Filed 3–16–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Consortium for the Study of Chronic Pancreatitis, Diabetes, and Pancreatic Cancer Clinical Centers Special Emphasis Panel.

Date: April 2, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

EXHIBIT D

document entitled, ''Agency Information Collection Activities: Proposed Collection; Comment Request''. That notice invited public comments on five separate information collection requests, under Document Identifiers: CMS–10468, CMS–10418, CMS–10488, CMS–R–290, and CMS–10525. Through the publication of this document, we are withdrawing the portion of the notice requesting public comment on the information collection request titled, ''PACE Quality Data Monitoring and Reporting.'' Form number: CMS–10525 (OMB control number: 0938–1264).

DATES: The original comment period for the document that published on March 24, 2020, remains in effect and ends May 26, 2020.

SUPPLEMENTARY INFORMATION: In FR document, 2020–06077, published on March 24, 2020 (85 FR 16631), we are withdrawing item 6 ''PACE Quality Data Monitoring and Reporting'' which begins on page 16633.

Dated: April 9, 2020.

William N. Parham, III,

Director, Paperwork Reduction Staff, Office of Strategic Operations and Regulatory Affairs.

[FR Doc. 2020–07886 Filed 4–14–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Intergovernmental Reference Guide (IRG) OMB #0970–0209

AGENCY: Office of Child Support Enforcement; Administration for Children and Families; HHS

ACTION: Request for public comment.

SUMMARY: The Intergovernmental Reference Guide (IRG) is a centralized and automated repository of state and tribal profiles that contains high-level descriptions of each state and tribal child support enforcement (CSE) program. These profiles provide state, tribal, and foreign country CSE agencies with an effective and efficient method for updating and accessing information needed to process intergovernmental child support cases.

DATES: *Comments due within 30 days of publication.* The Office of Management and Budget (OMB) is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, Email: *OIRA_SUBMISSION@OMB.EOP.GOV,* Attn: Desk Officer for the Administration for Children and Families.

Copies of the proposed collection may be obtained by emailing *infocollection@acf.hhs.gov.* Alternatively, copies can also be obtained by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW, Washington, DC 20201, Attn: ACF Reports Clearance Officer. All requests, emailed or written, should be identified by the title of the information collection.

SUPPLEMENTARY INFORMATION:

Description: The Office of Child Support Enforcement (OCSE) is proposing to add a new section (Section O) with six questions pertaining to family violence in the state profile. This will help process intergovernmental cases with family violence and will help ensure the safety of children and families. OCSE is also proposing to delete Sections A–L (140 questions) from the tribal profile and create new sections (Sections A–D) with 11 questions regarding case processing. This will assist in the efficient processing of paternity and support obligations.

Respondents: State and tribal CSE agencies.

ANNUAL BURDEN ESTIMATES

Information collection instrument	Total number of respondents	Number of responses per respondent	Average burden hour per response	Annual burden hours
IRG: State Profile Guide (states and territories)	54	18	0.3	292
IRG: Tribal Profile Guide	62	18	0.3	335

Estimated Total Annual Burden Hours: 627.

Authority for the IRG information collection activities is: (1) 42 U.S.C. 652(a)(7), which requires the federal OCSE to provide technical assistance to state child support enforcement agencies to help them establish effective systems for collecting child and spousal support; (2) 42 U.S.C. 666(f), which requires states to enact the Uniform Interstate Family Support Act; (3) 45 CFR. 301.1, which defines an intergovernmental case to include cases between states and tribes; (4) 45 CFR. 303.7, which requires state CSE agencies to provide services in intergovernmental cases; and (5) 45 CFR. 309.120, which requires a tribal child support program to include intergovernmental procedures in its tribal IV–D plan.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2020–07885 Filed 4–14–20; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of amendment.

SUMMARY: The Secretary is issuing this amendment pursuant to section 319F–3 of the Public Health Service Act to extend liability immunity for activities related to medical countermeasures against COVID–19 authorized under the Coronavirus Aid, Relief, and Economic Security Act.

DATES: The amendment to the Declaration published on March 17, 2020 (85 FR 15198) was effective as of March 27, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue

SW, Washington, DC 20201; Telephone: 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving ''willful misconduct'' as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding Section 319F–3, which addresses liability immunity, and Section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively. The Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136 was enacted on March 27, 2020. The CARES Act amended section 319F–3(i)(1)(D) of the PHS Act, first added by the Families First Coronavirus Response Act, Public Law 116–127 on March 18, 2020. These amendments created a new category of covered countermeasures eligible for liability immunity under the PREP Act, namely, respiratory protective devices approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act.

On January 31, 2020, the Secretary declared a public health emergency, pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, for the entire United States to aid in the response of the nation's health care community to the COVID–19 outbreak. On March 10, 2020, the Secretary issued a Declaration under the PREP Act for medical countermeasures against COVID–19 (85 FR 15198 (March 17, 2020)). The Secretary is amending the March 10, 2020 Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act. This amendment is made in accordance with section 319F–3 of the PHS Act, which authorizes the Secretary to amend a PREP Act declaration at any time.

Description of This Amendment by Section

Section I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a Declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may constitute such an emergency. This determination is separate and apart from the Declaration issued by the Secretary on January 31, 2020 under section 319 of the PHS Act that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other Declarations or determinations made under other authorities of the Secretary. As amended by the CARES Act, to extend the Declaration to respiratory protective devices approved by NIOSH, the Secretary must also determine that a respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, is a priority for use during the public health emergency declared by the Secretary under section 319 of the PHS Act.

Accordingly, in Section I of the Declaration, the Secretary is amending his determination that the spread of SARS–CoV–2 or a virus mutating therefrom and the resulting disease, COVID–19, constitutes a public health emergency for purposes of this Declaration under the PREP Act to include the determination that the use of any respiratory protective devices approved by NIOSH under 42 CFR part 84, or any successor regulations, is a priority for use during the public health emergency declared by the Secretary on January 31, 2020 under section 319 of the PHS Act for the entire United States to aid in the nation's health care community response to the COVID–19 outbreak.

Section VI. Covered Countermeasures

Section VI of the Declaration identifies the Covered Countermeasures for which the Secretary has recommended such activities. As amended by the CARES Act, the PREP Act states that a ''Covered Countermeasure'' must be a ''qualified pandemic or epidemic product,'' a ''security countermeasure,'' a drug, biological product, or device authorized for emergency use in accordance with sections 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act, or a respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act. Accordingly, in Section VI of the Declaration, the Secretary is amending the list of medical countermeasures against COVID–19 that are covered countermeasures under the declaration to include covered countermeasures authorized by the CARES Act, namely respiratory protective devices approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act.

Section XII. Effective Time Period

The Secretary must identify, for each Covered Countermeasure, the period or periods during which liability immunity is in effect, designated by dates, milestones, or other description of events, including factors specified in the PREP Act. Accordingly, the Secretary is amending Section XII of the Declaration to specify the effective time period for covered countermeasures authorized by the CARES Act.

Amendments to Declaration

Amended Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID–19.

Sections I, VI and XII of the March 10, 2020, Declaration under the PREP Act for medical countermeasures against COVID–19 are amended pursuant to section 319F–3(b)(4) of the PHS Act as described below. All other Sections of the Declaration remain in effect as published at 85 FR 15198 (March 17, 2020).

1. Determination of Public Health Emergency, Section I: Delete in full and replace with:

I. Determination of Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that the spread of SARS–CoV–2 or a virus mutating therefrom and the resulting disease COVID–19 constitutes a public health emergency. I further determine that use of any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, is a priority for use during the public health emergency that I declared on January

31, 2020 under section 319 of the PHS Act for the entire United States to aid in the response of the nation's health care community to the COVID–19 outbreak.

2. Covered Countermeasures, Section VI, delete in full and replace with:

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act, or any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations.

3. Effective Time Period, Section XII, delete in full and replace with:

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability immunity for any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, through means of distribution, as identified in Section VII(a) of this Declaration, other than in accordance with the public health and medical response of the Authority Having Jurisdiction, begins on March 27, 2020 and extends through October 1, 2024.

Liability immunity for all other Covered Countermeasures identified in Section VI of this Declaration, through means of distribution, as identified in Section VII(a) of this Declaration, other than in accordance with the public health and medical response of the Authority Having Jurisdiction, begins February 4, 2020 and extends through October 1, 2024.

Liability immunity for all Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with an emergency declaration and lasts through (1) the final day the emergency Declaration is in effect, or (2) October 1, 2024, whichever occurs first.

Authority: 42 U.S.C. 247d–6d.

Dated: April 10, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–08040 Filed 4–13–20; 4:15 pm]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel: Mechanism for Time Sensitive Research Opportunities in Environmental Health Sciences.

Date: April 30, 2020.

Time: 11:00 a.m. to 1:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, National Institutes of Health, Keystone Building, 530 Davis Drive, Research Triangle Park, NC 27709 (Virtual Meeting).

Contact Person: Janice B Allen, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Science, P. O. Box 12233, MD EC–30/Room 3170 B, Research Triangle Park, NC 27709 919–541–7556.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: April 9, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–07917 Filed 4–14–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel RFA–RM–20–006: 4DN Organization and Function in Human Health and Disease, New Investigators (U01).

Date: May 14, 2020.

Time: 9:00 a.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Jessica Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–3717, *jessica.smith6@nih.gov*.

Name of Committee: Center for Scientific Review Special Emphasis Panel RFA–RM–20–005: 4DN Organization and Function in Human Health and Disease (U01).

Date: May 14–15, 2020.

Time: 1:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge II, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Jessica Smith, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (301) 402–3717, *jessica.smith6@nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844,

EXHIBIT E

services is a key component of the HRSA mission. HRSA's Maternal and Child Health Bureau (MCHB) provides funding to address some of the most urgent issues influencing the high rates of maternal mortality. Recent efforts to address persistent disparities in maternal, infant, and child health have employed a ''life course'' perspective and health equity lens focused on health promotion and disease prevention. The life course approach can be defined as analyzing people's lives within structural, social, and cultural contexts through a defined sequence of age categories that people are normally expected to pass through as they progress from birth to death. Health equity is defined as the attainment of the highest level of health for all people.

Achieving health equity for pregnant and postpartum women will require attention to barriers in access to quality health services and promotion of equal opportunities to seek the highest possible level of health and well-being. Achieving health equity also requires a focus on social determinants of health.

With this emphasis on improving maternal health across the life course and promoting optimal health for all mothers, HRSA is employing a multipronged strategy to address maternal mortality and severe maternal morbidity through the following suite of programs:

1. The State Maternal Health Innovation Program,
2. The Alliance for Innovation on Maternal Health Program,
3. The Alliance for Innovation on Maternal Health—Community Care Initiative,
4. The Rural Maternity and Obstetrics Management Strategies Program, and
5. The Supporting Maternal Health Innovation Program.

MCHB is conducting a portfolio-wide evaluation of HRSA-supported Maternal Health Programs with a primary focus on reducing maternal mortality. Through this evaluation, HRSA seeks to identify individual and/or collective strategies, interrelated activities, and common themes within and across the Maternal Health Programs that may be contributing to or driving improvements in key maternal health outcomes. HRSA seeks to ascertain which components should be elevated and replicated to the national level, as well as inform future investments to reduce rates of maternal mortality and severe maternal morbidity.

Need and Proposed Use of the Information: HRSA seeks to understand the impact of HRSA's investments into maternal health programs. These five HRSA maternal health programs represent a total of 12 state-based grantees and three grantees with the potential for national reach. In understanding the strategies that are most effective in reducing maternal morbidity and mortality, HRSA will be able to determine which program elements could be replicated and/or scaled up nationally.

Likely Respondents: Likely respondents are recipients of the cooperative agreements mentioned above (State Maternal Health Innovation Program, Alliance for Innovation on Maternal Health Program, Alliance for Innovation on Maternal Health—Community Care Initiative, Rural Maternity and Obstetrics Management Strategies Program, and Supporting Maternal Health Innovation Program) which include 11 state health agencies, 2 national organizations, and 2 academic organizations.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Instrument 1: Interview guide for grantee staff	75	1	75	1.00	75.0
Instrument 2: Interview guide for HRSA POs	7	1	7	1.50	10.5
Instrument 3: Partnership Survey	290	1	290	0.25	72.5
Instrument 4: Web-based data collection tool	15	1	15	0.50	7.5
Total	387		387		165.5

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–12308 Filed 6–5–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Second Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of amendment.

SUMMARY: The Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to clarify that Covered Countermeasures

under the Declaration include qualified pandemic and epidemic products that limit the harm COVID–19 might otherwise cause.

DATES: This amendment to the Declaration as published on March 17, 2020 (85 FR 15198) was effective as of February 4, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; Telephone: 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from, the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving ''willful misconduct'' as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, § 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively. Section 319F–3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, enacted on March 13, 2013, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

On January 31, 2020, the Secretary declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response of the nation's health care community to the COVID–19 outbreak. Pursuant to section 319 of the PHS Act, the Secretary renewed that Declaration on April 26, 2020. On March 10, 2020, the Secretary issued a Declaration under the PREP Act for medical countermeasures against COVID–19 (85 FR 15198, Mar. 17, 2020). On April 10, the Secretary amended the March 10, 2020 Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020).

The Secretary now amends the March 10, 2020, Declaration to clarify that covered countermeasures under the Declaration include qualified products that limit the harm COVID–19 might otherwise cause. 42 U.S.C. 247d–6d(i)(7)(A)(i)(II). This amendment is made in accordance with section 319F–3(b)(4) of the PHS Act, which authorizes the Secretary to amend a PREP Act Declaration at any time.

Description of This Amendment by Section

Section VI. Covered Countermeasures

Section VI of the Declaration identifies the Covered Countermeasures for which the Secretary has recommended activities under section III of the Declaration. The PREP Act, as amended, states that a ''Covered Countermeasure'' must be a ''qualified pandemic or epidemic product,'' a ''security countermeasure,'' a drug, biological product, or device authorized for emergency use in accordance with sections 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act, or a respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act.

As described in section VI of the preamble to the March 10, 2020 Declaration, the PREP Act further defines a ''qualified pandemic or epidemic product'' to mean a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that is (i) manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product, or device; or (iii) a product or technology intended to enhance the use or effect of such a drug, biological product, or device. A qualified pandemic or epidemic product must also be approved, cleared, licensed, or authorized for investigational or emergency use under the FD&C Act or PHS Act. The Coronavirus Aid, Relief, and Economic Security (CARES) Act section 3103, Public Law 116–136 (Mar. 27, 2020), amended the PREP Act to add respiratory protective devices to the list of covered countermeasures so long as they are NIOSH approved and determined by the Secretary to be a priority for use during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act. 85 FR 21012 (Apr. 15, 2020) (amending the Declaration effective March 27, 2020 to address this statutory change).

The Secretary intended section VI of the March 10, 2020 Declaration to include all qualified pandemic and epidemic products defined under the PREP Act and described in the preamble to the Declaration. But section VI of the March 10, 2020 Declaration identified Covered Countermeasures under the Declaration as ''any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.'' 85 FR 15202. That description omitted the phrase from the statutory definition that qualified pandemic and epidemic products may also include products that ''limit the harm such a pandemic or epidemic might otherwise cause.'' The Secretary intended to identify the full range of qualified countermeasures in the March 10, 2020 Declaration. The Secretary accordingly amends section VI of the Declaration to clarify that intent.

Qualified pandemic and epidemic products that limit the harm that COVID–19 might otherwise cause are those that would not have been manufactured, administered, used, designed, developed, modified, licensed, or procured but for the COVID–19 pandemic, even when the products are manufactured, administered, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure health threats or conditions other than COVID–19. For example, the COVID–19 pandemic has resulted in shortages of certain drugs and devices that the FDA has authorized. These drugs and devices may be used for COVID–19 and other health conditions. Those shortages are ''harm[s] [COVID–19] might otherwise cause.'' Filling those shortages caused by COVID–19 reduces the strain on the American healthcare system by mitigating the escalation of adverse

health conditions from COVID–19 and non-COVID–19 causes. And mitigating that escalation conserves limited healthcare resources—from personal protective equipment to healthcare providers—which are essential in the whole-of-Nation response to the COVID–19 pandemic.

Amendments to Declaration

Amended Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID–19.

Section VI of the March 10, 2020, Declaration under the PREP Act for medical countermeasures against COVID–19, as amended April 10, 2020, is further amended pursuant to section 319F–3(b)(4) of the PHS Act, as described below. All other sections of the Declaration remain in effect as published at 85 FR 15198 (Mar. 17, 2020) and amended at 85 FR 21012 (Apr. 15, 2020).

Covered Countermeasures, section VI, delete in full and replace with:

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are

(1) any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine, used

a. to treat, diagnose, cure, prevent, mitigate or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom, or

b. to limit the harm that COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom, might otherwise cause; or

(2) any device used in the administration of any such product, and all components and constituent materials of any such product.

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act, or a respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act.

Authority: 42 U.S.C. 247d–6d.

Dated: June 4, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–12465 Filed 6–4–20; 4:15 pm]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel; Addressing Racial Disparities in Maternal Mortality and Morbidity (R01 Clinical Trial Optional).

Date: July 29–30, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Gateway Plaza, 7201 Wisconsin Avenue, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Deborah Ismond, Ph.D., Scientific Review Officer, Division of Scientific Programs, NIMHD, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 402–1366, *ismonddr@mail.nih.gov.*

Dated: June 2, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–12335 Filed 6–5–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, NIAID Resource Related Research Projects (R24 Clinical Trial Not Allowed).

Date: June 30, 2020.

Time: 3:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G49, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Tara Capece, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health, 5601 Fishers Lane, Room 3G49, Rockville, MD 20852, 240–191–4281, *capecet2@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: June 2, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–12332 Filed 6–5–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

services is a key component of the HRSA mission. HRSA's Maternal and Child Health Bureau (MCHB) provides funding to address some of the most urgent issues influencing the high rates of maternal mortality. Recent efforts to address persistent disparities in maternal, infant, and child health have employed a ''life course'' perspective and health equity lens focused on health promotion and disease prevention. The life course approach can be defined as analyzing people's lives within structural, social, and cultural contexts through a defined sequence of age categories that people are normally expected to pass through as they progress from birth to death. Health equity is defined as the attainment of the highest level of health for all people.

Achieving health equity for pregnant and postpartum women will require attention to barriers in access to quality health services and promotion of equal opportunities to seek the highest possible level of health and well-being. Achieving health equity also requires a focus on social determinants of health.

With this emphasis on improving maternal health across the life course and promoting optimal health for all mothers, HRSA is employing a multipronged strategy to address maternal mortality and severe maternal morbidity through the following suite of programs:

1. The State Maternal Health Innovation Program,
2. The Alliance for Innovation on Maternal Health Program,
3. The Alliance for Innovation on Maternal Health—Community Care Initiative,
4. The Rural Maternity and Obstetrics Management Strategies Program, and
5. The Supporting Maternal Health Innovation Program.

MCHB is conducting a portfolio-wide evaluation of HRSA-supported Maternal Health Programs with a primary focus on reducing maternal mortality. Through this evaluation, HRSA seeks to identify individual and/or collective strategies, interrelated activities, and common themes within and across the Maternal Health Programs that may be contributing to or driving improvements in key maternal health outcomes. HRSA seeks to ascertain which components should be elevated and replicated to the national level, as well as inform future investments to reduce rates of maternal mortality and severe maternal morbidity.

Need and Proposed Use of the Information: HRSA seeks to understand the impact of HRSA's investments into maternal health programs. These five HRSA maternal health programs represent a total of 12 state-based grantees and three grantees with the potential for national reach. In understanding the strategies that are most effective in reducing maternal morbidity and mortality, HRSA will be able to determine which program elements could be replicated and/or scaled up nationally.

Likely Respondents: Likely respondents are recipients of the cooperative agreements mentioned above (State Maternal Health Innovation Program, Alliance for Innovation on Maternal Health Program, Alliance for Innovation on Maternal Health—Community Care Initiative, Rural Maternity and Obstetrics Management Strategies Program, and Supporting Maternal Health Innovation Program) which include 11 state health agencies, 2 national organizations, and 2 academic organizations.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
Instrument 1: Interview guide for grantee staff	75	1	75	1.00	75.0
Instrument 2: Interview guide for HRSA POs	7	1	7	1.50	10.5
Instrument 3: Partnership Survey	290	1	290	0.25	72.5
Instrument 4: Web-based data collection tool	15	1	15	0.50	7.5
Total	387		387		165.5

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2020–12308 Filed 6–5–20; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Second Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of amendment.

SUMMARY: The Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to clarify that Covered Countermeasures

under the Declaration include qualified pandemic and epidemic products that limit the harm COVID–19 might otherwise cause.

DATES: This amendment to the Declaration as published on March 17, 2020 (85 FR 15198) was effective as of February 4, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; Telephone: 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from, the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving ''willful misconduct'' as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, § 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively. Section 319F–3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, enacted on March 13, 2013, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

On January 31, 2020, the Secretary declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response of the nation's health care community to the COVID–19 outbreak. Pursuant to section 319 of the PHS Act, the Secretary renewed that Declaration on April 26, 2020. On March 10, 2020, the Secretary issued a Declaration under the PREP Act for medical countermeasures against COVID–19 (85 FR 15198, Mar. 17, 2020). On April 10, the Secretary amended the March 10, 2020 Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020).

The Secretary now amends the March 10, 2020, Declaration to clarify that covered countermeasures under the Declaration include qualified products that limit the harm COVID–19 might otherwise cause. 42 U.S.C. 247d–6d(i)(7)(A)(i)(II). This amendment is made in accordance with section 319F–3(b)(4) of the PHS Act, which authorizes the Secretary to amend a PREP Act Declaration at any time.

Description of This Amendment by Section

Section VI. Covered Countermeasures

Section VI of the Declaration identifies the Covered Countermeasures for which the Secretary has recommended activities under section III of the Declaration. The PREP Act, as amended, states that a ''Covered Countermeasure'' must be a ''qualified pandemic or epidemic product,'' a ''security countermeasure,'' a drug, biological product, or device authorized for emergency use in accordance with sections 564, 564A, or 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act, or a respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act.

As described in section VI of the preamble to the March 10, 2020 Declaration, the PREP Act further defines a ''qualified pandemic or epidemic product'' to mean a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that is (i) manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product, or device; or (iii) a product or technology intended to enhance the use or effect of such a drug, biological product, or device. A qualified pandemic or epidemic product must also be approved, cleared, licensed, or authorized for investigational or emergency use under the FD&C Act or PHS Act. The Coronavirus Aid, Relief, and Economic Security (CARES) Act section 3103, Public Law 116–136 (Mar. 27, 2020), amended the PREP Act to add respiratory protective devices to the list of covered countermeasures so long as they are NIOSH approved and determined by the Secretary to be a priority for use during a public health emergency declared by the Secretary under section 319 of the Public Health Service Act. 85 FR 21012 (Apr. 15, 2020) (amending the Declaration effective March 27, 2020 to address this statutory change).

The Secretary intended section VI of the March 10, 2020 Declaration to include all qualified pandemic and epidemic products defined under the PREP Act and described in the preamble to the Declaration. But section VI of the March 10, 2020 Declaration identified Covered Countermeasures under the Declaration as ''any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine, used to treat, diagnose, cure, prevent, or mitigate COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom, or any device used in the administration of any such product, and all components and constituent materials of any such product.'' 85 FR 15202. That description omitted the phrase from the statutory definition that qualified pandemic and epidemic products may also include products that ''limit the harm such a pandemic or epidemic might otherwise cause.'' The Secretary intended to identify the full range of qualified countermeasures in the March 10, 2020 Declaration. The Secretary accordingly amends section VI of the Declaration to clarify that intent.

Qualified pandemic and epidemic products that limit the harm that COVID–19 might otherwise cause are those that would not have been manufactured, administered, used, designed, developed, modified, licensed, or procured but for the COVID–19 pandemic, even when the products are manufactured, administered, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure health threats or conditions other than COVID–19. For example, the COVID–19 pandemic has resulted in shortages of certain drugs and devices that the FDA has authorized. These drugs and devices may be used for COVID–19 and other health conditions. Those shortages are ''harm[s] [COVID–19] might otherwise cause.'' Filling those shortages caused by COVID–19 reduces the strain on the American healthcare system by mitigating the escalation of adverse

health conditions from COVID–19 and non-COVID–19 causes. And mitigating that escalation conserves limited healthcare resources—from personal protective equipment to healthcare providers—which are essential in the whole-of-Nation response to the COVID–19 pandemic.

Amendments to Declaration

Amended Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID–19.

Section VI of the March 10, 2020, Declaration under the PREP Act for medical countermeasures against COVID–19, as amended April 10, 2020, is further amended pursuant to section 319F–3(b)(4) of the PHS Act, as described below. All other sections of the Declaration remain in effect as published at 85 FR 15198 (Mar. 17, 2020) and amended at 85 FR 21012 (Apr. 15, 2020).

Covered Countermeasures, section VI, delete in full and replace with:

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are

(1) any antiviral, any other drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine, used

a. to treat, diagnose, cure, prevent, mitigate or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom, or

b. to limit the harm that COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom, might otherwise cause; or

(2) any device used in the administration of any such product, and all components and constituent materials of any such product.

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act, or a respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act.

Authority: 42 U.S.C. 247d–6d.

Dated: June 4, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–12465 Filed 6–4–20; 4:15 pm]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Minority Health and Health Disparities; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Minority Health and Health Disparities Special Emphasis Panel; Addressing Racial Disparities in Maternal Mortality and Morbidity (R01 Clinical Trial Optional).

Date: July 29–30, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Gateway Plaza, 7201 Wisconsin Avenue, Bethesda, MD 20817 (Virtual Meeting).

Contact Person: Deborah Ismond, Ph.D., Scientific Review Officer, Division of Scientific Programs, NIMHD, National Institutes of Health, Gateway Building, 7201 Wisconsin Avenue, Bethesda, MD 20892, (301) 402–1366, *ismonddr@mail.nih.gov.*

Dated: June 2, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–12335 Filed 6–5–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy and Infectious Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, NIAID Resource Related Research Projects (R24 Clinical Trial Not Allowed).

Date: June 30, 2020.

Time: 3:00 p.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Allergy and Infectious Diseases, National Institutes of Health, 5601 Fishers Lane, Room 3G49, Rockville, MD 20892 (Virtual Meeting).

Contact Person: Tara Capece, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, National Institutes of Health, 5601 Fishers Lane, Room 3G49, Rockville, MD 20852, 240–191–4281, *capecet2@niaid.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: June 2, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–12332 Filed 6–5–20; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of General Medical Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which

EXHIBIT F

• Drawing the program link between outreach and education, promoting consumer understanding of health care coverage choices, and facilitating consumer selection/enrollment, which in turn support the overarching goal of improved access to quality care, including prevention services, envisioned under the Affordable Care Act.

The current members of the Panel as of February 28, 2020 are: E. Lorraine Bell, Chief Officer, Population Health, Catholic Charities USA; Nazleen Bharmal, Medical Director of Community Partnerships, Cleveland Clinic; Angie Boddie, Director of Health Programs, National Caucus and Center on Black Aging, Inc.; Julie Carter, Senior Federal Policy Associate, Medicare Rights Center; Scott Ferguson, Director of Care Transitions and Population Health, Mount Sinai St. Luke's Hospital; Leslie Fried, Senior Director, Center for Benefits Access, National Council on Aging; David Goldberg, President and CEO of Mon Health System; Jean-Venable Robertson Goode, Professor, Department of Pharmacotherapy and Outcomes Science, School of Pharmacy, Virginia Commonwealth University; Ted Henson, Director of Health Center Performance and Innovation, National Association of Community Health Centers; Joan Ilardo, Director of Research Initiatives, Michigan State University, College of Human Medicine; Cheri Lattimer, Executive Director, National Transitions of Care Coalition; Cori McMahon, Vice President, Tridiuum; Alan Meade, Director of Rehab Services, Holston Medical group; Michael Minor, National Director, H.O.P.E. HHS Partnership, National Baptist Convention USA, Incorporated; Jina Ragland, Associate State Director of Advocacy and Outreach, AARP Nebraska; Morgan Reed, Executive Director, Association for Competitive Technology; Margot Savoy, Chair, Department of Family and Community Medicine, Temple University Physicians; Congresswoman Allyson Schwartz, President and CEO, Better Medicare Alliance; and; Tia Whitaker, Statewide Director, Outreach and Enrollment, Pennsylvania Association of Community Health Centers.

II. Provisions of This Notice

In accordance with section 10(a) of the FACA, this notice announces a meeting of the APOE. The agenda for the September 23, 2020 meeting will include the following:

- Welcome and listening session with CMS leadership
- Recap of the previous (June 25, 2020) meeting
- CMS programs, initiatives, and priorities
- An opportunity for public comment
- Meeting summary, review of recommendations, and next steps

Individuals or organizations that wish to make a 5-minute oral presentation on an agenda topic should submit a written copy of the oral presentation to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice. The number of oral presentations may be limited by the time available. Individuals not wishing to make an oral presentation may submit written comments to the DFO at the address listed in the **ADDRESSES** section of this notice by the date listed in the **DATES** section of this notice.

III. Meeting Participation

The meeting is open to the public, but attendance is limited to registered participants. Persons wishing to attend this meeting must register at the website *https://www.eventbrite.com/e/apoe-september-23-2020-virtual-meeting-tickets-114295017474* or contact the DFO at the address or number listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice by the date specified in the **DATES** section of this notice. This meeting will be held virtually. Individuals who are not registered in advance will be unable to attend the meeting.

IV. Collection of Information

This document does not impose information collection requirements, that is, reporting, recordkeeping, or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35).

The Administrator of the Centers for Medicare & Medicaid Services (CMS), Seema Verma, having reviewed and approved this document, authorizes Lynette Wilson, who is the Federal Register Liaison, to electronically sign this document for purposes of publication in the **Federal Register**.

Authority: Sec. 1114(f) of the Social Security Act (42 U.S.C. 1314(f)), sec. 222 of the Public Health Service Act (42 U.S.C. 217a), and sec. 10(a) of Pub. L. 92–463 (5 U.S.C. App. 2, sec. 10(a) and 41 CFR part 102–3).

Dated: August 17, 2020.

Lynette Wilson,

Federal Register Liaison, Department of Health and Human Services.

[FR Doc. 2020–18535 Filed 8–21–20; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Third Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of amendment.

SUMMARY: The Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to add additional categories of Qualified Persons and amend the category of disease, health condition, or threat for which he recommends the administration or use of the Covered Countermeasures.

DATES: This amendment to the Declaration published on March 17, 2020 (85 FR 15198) is effective as of August 24, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; Telephone: 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving ''willful misconduct'' as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, § 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively. Section 319F–3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, enacted on March 13, 2013 and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27,

2020, to expand Covered Countermeasures under the PREP Act.

On January 31, 2020, the Secretary declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response of the nation's health care community to the COVID–19 outbreak. Pursuant to section 319 of the PHS Act, the Secretary renewed that declaration on April 26, 2020, and July 25, 2020. On March 10, 2020, the Secretary issued a Declaration under the PREP Act for medical countermeasures against COVID–19 (85 FR 15198, Mar. 17, 2020) (the Declaration). On April 10, the Secretary amended the Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020). On June 4, the Secretary amended the Declaration to clarify that covered countermeasures under the Declaration include qualified countermeasures that limit the harm COVID–19 might otherwise cause.

The Secretary now amends section V of the Declaration to identify as qualified persons covered under the PREP Act, and thus authorizes, certain State-licensed pharmacists to order and administer, and pharmacy interns (who are licensed or registered by their State board of pharmacy and acting under the supervision of a State-licensed pharmacist) to administer, any vaccine that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule (ACIP-recommended vaccines).[1]

The Secretary also amends section VIII of the Declaration to clarify that the category of disease, health condition, or threat for which he recommends the administration or use of the Covered Countermeasures includes not only COVID–19 caused by SARS–CoV–2 or a virus mutating therefrom, but also other diseases, health conditions, or threats that may have been caused by COVID–19, SARS–CoV–2, or a virus mutating therefrom, including the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of infectious diseases.

[1] The only vaccines that ACIP has recommended are authorized or approved by the Food and Drug Administration (FDA). PREP Act coverage here is limited to covered persons ordering and administering FDA-authorized or FDA-approved vaccines.

Description of This Amendment by Section

Section V. Covered Persons

Under the PREP Act and the Declaration, a ''qualified person'' is a ''covered person.'' Subject to certain limitations, a covered person is immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration or use of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure. ''Qualified person'' includes

(A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or

(B) ''a person within a category of persons so identified in a declaration by the Secretary'' under subsection (b) of the PREP Act.

42 U.S.C. 247d–6d(i)(8).[2]

By this amendment to the Declaration, the Secretary identifies an additional category of persons who are qualified persons under section 247d–6d(i)(8)(B).[3]

On May 8, 2020, CDC reported, ''The identified declines in routine pediatric vaccine ordering and doses administered might indicate that U.S. children and their communities face increased risks for outbreaks of vaccine-preventable diseases,'' and suggested that a decrease in rates of routine childhood vaccinations were due to changes in healthcare access, social distancing, and other COVID–19 mitigation strategies.[4] The report also stated that ''[p]arental concerns about potentially exposing their children to COVID–19 during well child visits might contribute to the declines observed.'' [5]

On July 10, 2020, CDC reported its findings of a May survey it conducted to assess the capacity of pediatric health care practices to provide immunization services to children during the COVID–19 pandemic. The survey, which was limited to practices participating in the Vaccines for Children program, found that, as of mid-May, 15 percent of Northeast pediatric practices were closed, 12.5 percent of Midwest practices were closed, 6.2 percent of practices in the South were closed, and 10 percent of practices in the West were closed. Most practices had reduced office hours for in-person visits. When asked whether their practices would likely be able to accommodate new patients for immunization services through August, 418 practices (21.3 percent) either responded that this was not likely or the practice was permanently closed or not resuming immunization services for all patients, and 380 (19.6 percent) responded that they were unsure. Urban practices and those in the Northeast were less likely to be able to accommodate new patients compared with rural practices and those in the South, Midwest, or West.[6]

In response to these troubling developments, CDC and the American Academy of Pediatrics have stressed, ''Well-child visits and vaccinations are essential services and help make sure children are protected.'' [7]

The Secretary re-emphasizes that important recommendation to parents and legal guardians here: If your child is due for a well-child visit, contact your pediatrician's or other primary-care provider's office and ask about ways that the office safely offers well-child visits and vaccinations.

Many medical offices are taking extra steps to make sure that well-child visits can occur safely during the COVID–19 pandemic, including:

- Scheduling sick visits and well-child visits during different times of the

[2] *See* Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act, 5–6 (May 19, 2020), *https://www.hhs.gov/sites/default/files/prep-act-advisory-opinion-hhs-ogc.pdf* (last visited Aug. 5, 2020).

[3] *See* Advisory Opinion 20–02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, 3–5 (May 19, 2020), *https://www.hhs.gov/sites/default/files/advisory-opinion-20-02-hhs-ogc-prep-act.pdf* (setting forth PREP Act's legal framework for identifying a ''qualified person'' and preemption of state law that is different from, or is in conflict with, that designation).

[4] Jeanne M. Santoli et al., *Effects of the COVID–19 Pandemic on Routine Pediatric Vaccine Ordering and Administration—United States, 2020,* 69 MMWR 591, 592 (2020), *https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6919e2-H.pdf.* (last visited July 15, 2020); *see also* Melissa Jenco, *AAP urges vaccination as rates drop due to COVID–19, AAP News* (May 8, 2020), *https://www.aappublications.org/news/2020/05/08/covid19vaccinations050820* (last visited July 15, 2020).

[5] Jeanne M. Santoli et al., *Effects of the COVID–19 Pandemic on Routine Pediatric Vaccine Ordering and Administration—United States, 2020,* 69 MMWR 591, 592 (2020), *https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6919e2-H.pdf* (last visited July 15, 2020).

[6] Tara M. Vogt, *Provision of Pediatric Immunization Services During the COVID–19 Pandemic: an Assessment of Capacity Among Pediatric Immunization Providers Participating in the Vaccines for Children Program—United States, May 2020,* 69 MMWR 859, 859–61, *https://www.cdc.gov/mmwr/volumes/69/wr/pdfs/mm6927a2-H.pdf* (last visited July 15, 2020).

[7] *Routine Vaccination During the COVID–19 Outbreak,* CDC, *https://www.cdc.gov/vaccines/parents/visit/vaccination-during-COVID-19.html* (last visited July 14, 2020).

day or days of the week, or at different locations.

- Asking patients to remain outside until it is time for their appointments to reduce the number of people in waiting rooms.
- Adhering to recommended social (physical) distancing and other infection-control practices, such as the use of masks.

The decrease in childhood-vaccination rates is a public health threat and a collateral harm caused by COVID–19. Together, the United States must turn to available medical professionals to limit the harm and public health threats that may result from decreased immunization rates. We must quickly do so to avoid preventable infections in children, additional strains on our healthcare system, and any further increase in avoidable adverse health consequences—particularly if such complications coincide with additional resurgence of COVID–19.

Together with pediatricians and other healthcare professionals, pharmacists are positioned to expand access to childhood vaccinations. Many States already allow pharmacists to administer vaccines to children of any age.[8] [9] Other States permit pharmacists to administer vaccines to children depending on the age—for example, 2, 3, 5, 6, 7, 9, 10, 11, or 12 years of age and older.[10] Few States restrict pharmacist-administered vaccinations to only adults.[11] Many States also allow properly trained individuals under the supervision of a trained pharmacist to administer those vaccines.[12]

Pharmacists are well positioned to increase access to vaccinations, particularly in certain areas or for certain populations that have too few pediatricians and other primary-care providers, or that are otherwise medically underserved.[13] As of 2018, nearly 90 percent of Americans lived within five miles of a community pharmacy.[14] Pharmacies often offer extended hours and added convenience. What is more, pharmacists are trusted healthcare professionals with established relationships with their patients. Pharmacists also have strong relationships with local medical providers and hospitals to refer patients as appropriate.

For example, pharmacists already play a significant role in annual influenza vaccination. In the early 2018–19 season, they administered the influenza vaccine to nearly a third of all adults who received the vaccine.[15] Given the potential danger of serious influenza and continuing COVID–19 outbreaks this autumn and the impact that such concurrent outbreaks may have on our population, our healthcare system, and our whole-of-nation response to the COVID–19 pandemic, we must quickly expand access to influenza vaccinations. Allowing more qualified pharmacists to administer the influenza vaccine to children will make vaccinations more accessible.

Therefore, the Secretary amends the Declaration to identify State-licensed pharmacists (and pharmacy interns acting under their supervision if the pharmacy intern is licensed or registered by his or her State board of pharmacy) as qualified persons under section 247d–6d(i)(8)(B) when the pharmacist orders and either the pharmacist or the supervised pharmacy intern administers vaccines to individuals ages three through 18 pursuant to the following requirements:

- The vaccine must be FDA-authorized or FDA-approved.
- The vaccination must be ordered and administered according to ACIP's standard immunization schedule.[16]
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training

[8] For purposes of this amendment, ''State'' shall have the same meaning ascribed to it in 42 U.S.C. 201(f). Under section 201(f), ''State'' includes the several States, the District of Columbia, Guam, the Commonwealth of Puerto Rico, the Northern Mariana Islands, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.

[9] *See, e.g.,* Ala. Code § 34–23–1(5), (21) (2020); Ala. Admin. Code r. 680–X–2–.14(1) (2000); Alaska Stat. Ann. § 08.80.168(a) (West 2020); Cal. Bus. & Prof. Code § 4052(a)(11) (West 2020); Colo. Code Regs. § 719–1:19.00.00 (West 2020); Ga. Code Ann. § 43–34–26.1 (West 2020); Idaho Code Ann. § 54–1704 (West 2020); Idaho Code Ann. § 37–201 (West 2020); Ind. Code Ann. § 25–26–13–31.2(a) (West 2020); Iowa Admin. Code § 657–39.10(6) (2020); La. Admin. Code tit. 46, Pt. LIII, § 521 (2020); Mich. Comp. Laws Ann. § 333.9204 (2020); Miss. Code Ann. § 73–21–73(a), (dd) (West 2000); MO 20 CSR 2220–6.040; MO 20 CSR 2220–6.050; Neb. Rev. Stat. Ann. §§ 38–2806, 38–2837 (West 2000); 175 Neb. Admin. Code. § 8.003.01A(3)(m)(4)(a) (2020); N.H. Rev. Stat. § 318:16–b (2020); Nev. Admin. Code § 639.2971 (2020); N.M. Stat. Ann. § 61–11–2(A), (G), (CC) (West 2020); Okla. Stat. Ann. tit. 59, § 353.30 (West 2020); Or. Rev. Stat. § 689.645 (West 2020); *https://www.oregon.gov/oha/PH/PREVENTIONWELLNESS/VACCINESIMMUNIZATION/IMMUNIZATIONPROVIDERRESOURCES/Pages/pharmacy.aspx#:~:text=Immunization%20Resources%20for%20Oregon%20Pharmacists,a%20patient%20of%20any%20age* (last visited Aug. 13, 2020); S.C. Code Ann. § 40–43–190 (2020); S.D. Codified Laws § 36–11–2, S.D. Codified Laws § 36–11–19.1; Tenn. Code Ann. § 63–10–204(1), 39(A) (West 2020); Tex. Occ. Code Ann. § 551.003(33) (2020); 22 Tex. Admin. Code § 295.15(e) (2020); Utah Code Ann. § 58–17b–102(1), (57) (West 2020); Utah Admin. Code R156–17b–621(5) (2020); Va. Code Ann. § 54.1–3408(I) (2020); Wash. Rev. Code Ann. § 18.64.011(1), (28) (West 2020); Wis. Stat. Ann. § 450.035 (West 2020). While these states allow pharmacists to administer vaccines to children of any age, some impose additional requirements. *See, e.g.,* Cal. Bus. & Prof. Code §§ 4052(a)(11), 4052.8 (permitting pharmacists to administer any vaccine listed on the routine immunization schedules recommended by the Advisory Committee on Immunization Practices to persons three years of age and older, but requiring the pharmacist to administer immunizations to persons under three years of age only pursuant to a protocol with a prescriber); Colo. Code Regs. § 719–1:19.00.00 (West 2020) (requiring that pharmacists administer vaccines and immunizations ''per authorization of a physician'').

[10] *See, e.g.,* Ariz. Rev. Stat. Ann. § 32–1974(B) (2020); Ark. Code Ann. § 17–92–101 (2020); D.C. Mun. Reg Tit. 17 sec. 6512.10 (2012); Haw. Rev. Stat. § 461–11.4 (West 2019); 225 Ill. Comp. Stat. Ann. 85/3(d) (West 2020); Kan. Stat. Ann. § 65–1635a (2020); Ky. Rev. Stat. Ann. § 315.010(22) (West 2020); Me. Rev. Stat. Ann. tit. 32, § 13831 (West 2020); Md. Code Ann., Health Occ. § 12–508 (2020); 247 Mass. Code Regs. 16.03 (2020); Minn. Stat. Ann. § 151.01 (West 2020); Mont. Code Ann. § 37–7–105 (West 2019); N.J. Stat. Ann. § 45:14–63 (West 2020); N.Y. Comp. Codes R. & Regs. tit. 8, § 63.9 (2020); N.C. Gen. Stat. Ann. § 90–85.15B (West 2020); N.D. Cent. Code Ann. § 43–15–01 (West 2020); Ohio Rev. Code Ann. § 4729.41 (West 2020); 63 Pa. Cons. Stat. § 390–9.2 (West 2020); P.R. Laws tit. 20, § 410c (2018); 5 R.I. Gen. Laws Ann. § 5–19.1–31 (West 2020); W.Va. Code Ann. § 30–5–7 (West 2020); Wyo Stat. Ann. § 33–24–157 (2020).

[11] *See, e.g.,* Conn. Gen. Stat. § 20–633(a) (West 2012); 24 Del. Code Ann. § 2502(23)(h) (West 2020); Fla. Stat. Ann. § 465.189(1) (West 2020); Vt. Admin. R. of Board of Pharm. § 10.35 (West 2020).

[12] *See, e.g.,* Or. Admin. R. 855–019–0270 (2020) (''[A]n intern who is appropriately trained and qualified in accordance with Section (3) of this rule may perform the same duties as a pharmacist, provided that the intern is supervised by an appropriately trained and qualified pharmacist.'').

[13] *See, e.g., Guidance for Pharmacists and Pharmacy Technicians in Community Pharmacies during the COVID–19 Response,* CDC, *https://www.cdc.gov/coronavirus/2019-ncov/hcp/pharmacies.html* (last updated June 28, 2020) (''As a vital part of the healthcare system, pharmacies play an important role in providing medicines, therapeutics, vaccines, and critical health services to the public.''); Kimberly McKeirnan & Gregory Sarchet, *Implementing Immunizing Pharmacy Technicians in a Federal Healthcare Facility,* 7 Pharmacy 1, 7 (2019), *https://www.mdpi.com/2226-4787/7/4/152/htm* (last visited Aug. 5, 2020) (HHS Indian Health Service study demonstrating ''the effective implementation of immunization-trained pharmacy technicians and the positive impact utilization of pharmacy support personnel can create'' on childhood vaccination rates in medically underserved populations).

[14] *Get to Know Your Pharmacist,* CDC, *https://www.cdc.gov/features/pharmacist-month/index.html* (last visited July 14, 2020).

[15] *Early-Season Flu Vaccination Coverage—United States, November 2018,* CDC, *https://www.cdc.gov/flu/fluvaxview/nifs-estimates-nov2018.htm* (last visited July 14, 2020).

[16] *See Immunization Schedules: For Health Care Providers,* CDC, *https://www.cdc.gov/vaccines/schedules/hcp/index.html* (last visited July 14, 2020). The immunization schedule recommends that certain vaccines be administered only to children of a certain age. For example, the second dose of both the measles, mumps, and rubella vaccine, as well as the varicella vaccine, should not be administered until a child is between four and six years old. *See Recommended Child and Adolescent Immunization Schedule for ages 18 years or younger, United States, 2020,* CDC (Jan. 29, 2020), *https://www.cdc.gov/vaccines/schedules/downloads/child/0-18yrs-child-combined-schedule.pdf* (last visited Aug. 5, 2020).

program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.[17]

- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.[18]
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.[19]
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.[20]
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine.[21]
- The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregivers accompanying the children of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.[22]

These requirements are consistent with those in many States that permit licensed pharmacists to order and administer vaccines to children and permit licensed or registered pharmacy interns acting under their supervision to administer vaccines to children.[23]

Administering vaccinations to children age three and older is less complicated and requires less training and resources than administering vaccinations to younger children. That is because ACIP generally recommends administering intramuscular injections in the deltoid muscle for individuals age three and older.[24] For individuals less than three years of age, ACIP generally recommends administering intramuscular injections in the anterolateral aspect of the thigh muscle.[25] Administering injections in the thigh muscle often presents additional complexities and requires additional training and resources including additional personnel to safely position the child while another healthcare professional injects the vaccine.[26]

Moreover, as of 2018, 40% of three-year-olds were enrolled in preprimary programs (*i.e.* preschool or kindergarten programs).[27] Preprimary programs are beginning in the coming weeks or months, so the Secretary has concluded that it is particularly important for individuals ages three through 18 to receive ACIP-recommended vaccines according to ACIP's standard immunization schedule. All States require children to be vaccinated against certain communicable diseases as a condition of school attendance. These laws often apply to both public and private schools with identical immunization and exemption provisions.[28] As nurseries, preschools, kindergartens, and schools reopen, increased access to childhood vaccinations is essential to ensuring children can return.

Notwithstanding any State or local scope-of-practice legal requirements, (1) qualified licensed pharmacists are identified as qualified persons to order and administer ACIP-recommended vaccines and (2) qualified State-licensed or registered pharmacy interns are identified as qualified persons to administer the ACIP-recommended vaccines ordered by their supervising qualified licensed pharmacist.[29]

Both the PREP Act and the June 4, 2020 Second Amendment to the Declaration define ''covered countermeasures'' to include qualified pandemic and epidemic products that ''limit the harm such pandemic or epidemic might otherwise cause.'' [30] The troubling decrease in ACIP-recommended childhood vaccinations and the resulting increased risk of associated diseases, adverse health conditions, and other threats are categories of harms otherwise caused by

[17] *Cf., e.g.,* Cal. Bus. & Prof. Code § 4052.8; 3 Colo. Code Regs. § 719–1:19.00.00; 856 Ind. Admin. Code 4–1–1; 46 La. Admin. Code tit. 46Part LIII, § 521; Nev. Admin. Code § 639.2973; 22 Tex. Admin. Code § 295.15(c).

[18] *Cf., e.g.,* Ark. Admin. Code § 070.00.9–09–00–0002; 3 Colo. Code Regs. § 719–1:19.00.00; Nev. Admin. Code § 639.2973; N.H. Rev. Stat. § 318:16–d; Ohio Rev. Code Ann. § 4729.41(B); Or. Admin. R. 855–019–0270 (2020); S.C. Code Ann. §§ 40–43–190(B)(1), (4); Utah Admin. Code r. 156R–17b–621(5); Vt. Admin. Code 20–4–1400:10.35.

[19] *Cf., e.g.,* Ariz. Admin. Code § R4–23–411(D(3); Conn. Gen. Stat. § 20–633(b); D.C. Mun. Regs. tit. 17, § 6512.3; 856 Ind. Admin. Code 4–1–1(c); Iowa Admin. Code r. 657–39.10(2)(A); Kan. Stat. Ann. § 65–1635a(a); La. Admin. Code tit. 46 Part LIII, § 521(D); Me. Rev. Stat. Ann. tit. 32, § 13832; Md. Code Ann., Health Occ. § 12–508(b)(2)(ii); Mont. Code Ann. § 37–7–101(24)(b); N.J. Admin. Code § 13:39–4.21(b)(2); N.D. Cent. Code Ann. § 43–15–31.5; Or. Admin. R. 855–019–0270 (2020); 63 Pa. Stat. Ann. § 390–9.2;(a)(2) 216 R.I. Code R. § 40–15–1.11; S.C. Code Ann. §§ 40–43–190(B)(4); S.D. Admin. R. 20:51:28:02; W. Va. Code St. R. § 15–12–4; Wyo. Admin. Code 059.0001.16 § 7.

[20] *Cf., e.g.,* AR ADC § 070.00.9–09–00–0002; 3 Colo. Code Regs. § 719–1:19.00.00; N.J. Stat. Ann. § 13:39–4.21; S.C. Code Ann. §§ 40–43–190(B)(1), (5); 22 Tex. Admin. Code § 295.15(c); Utah Admin. Code r. 156–17b–621(5); 59–0001–16 Wyo. Code R. § 7.

[21] *Cf., e.g.,* Ala. Admin. Code. r. 680–X–2.14; Ariz. Admin. Code § R4–23–411(E); AR ADC § 070.00.9–09–00–0002; Cal. Code Regs. tit. 16, § 1746.4; Conn. Gen. Stat. § 20–633(b); 225 Ill. Comp. Stat. Ann. 85/3(d)(4); Kan. Stat. Ann. § 65–1635a(a); Mont. Admin. R. 24.174.503; Nev. Rev. Stat. Ann. § 454.213(s); N.H. Rev. Stat. § 318:16–d; N.J. Stat. Ann. § 45:14–63; N.Y. Comp. Codes R. & Regs. tit. 8, § 63.9; N.D. Cent. Code Ann. § 43–15–31.5; Or. Admin. r. 855–019–0280; 216–40; R.I. Code R. § 15–1.11; S.C. Code Ann. §§ 40–43–190(B)(1), (5); S.D. Admin. R. 20:51:28:04; Tenn. Code Ann. § 53–10–211; 22 Tex. Admin. Code § 295.15(c); 04–230 Vt. Code R. § 10.35; Va. Code Ann. § 54.1–3408; Wis. Stat. Ann. § 450.035.

[22] *See, e.g.,* Letter from Kathleen E. Toomey, M.D., M.P.H., Comm'r and State Health Officer, Ga. Dep't of Pub. Health, *available at https://www.gpha.org/immunization/* (last visited July 15, 2020).

[23] *See, e.g.,* AL ST § 34–23–53; 12 AAC 52.992; Cal. Bus. & Prof. Code § 4052; Cal. Bus. & Prof. Code § 4052.8(b); 3 Colo. Code Regs. § 719–1:19.00.00; Ga. Code Ann., § 43–34–26.1; 856 IAC 4–1–1; Iowa Code § 39.10(2)(a); N.M. Admin. Code 16.19.26; Okla. Admin. Code 535:10–11–5; Code 1976 § 40–43–190 (South Carolina).

[24] Vaccine Recommendations and Guidelines of the ACIP, *https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html* (last visited July 29, 2020).

[25] *Id.*

[26] *Id.;* Nicole E. Omecene, *et al., Implementation of pharmacist-administered pediatric vaccines in the United States: major barriers and potential solutions for the outpatient setting, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6594428/* (last visited July 29, 2020).

[27] Preschool and Kindergarten Enrollment, *https://nces.ed.gov/programs/coe/indicator_cfa.asp* (last visited July 29, 2020).

[28] State School Immunization Requirements and Vaccine Exemption Laws, *https://www.cdc.gov/phlp/docs/school-vaccinations.pdf,* (last visited July 29, 2020).

[29] Nothing herein shall affect federal law requirements in 42 CFR part 455, subpart E regarding screening and enrollment of Medicare and Medicaid providers. Moreover, nothing herein shall preempt State laws that permit additional individuals to administer vaccines that ACIP recommends to persons age 18 or younger according to ACIP's standard immunization schedule. For example, Idaho permits pharmacy technicians who meet certain requirements to administer vaccines under the supervision of an immunizing pharmacist. Such technicians can still administer vaccines to the extent they would have been able to absent publication of this amendment. Moreover, pharmacists and pharmacy interns may still order or administer vaccines to individuals ages two or younger to the extent authorized under State law.

[30] 42 U.S.C. 247d–d6(i)(7)(A); 85 FR 35–100, 35–102.

COVID–19 as set forth in Sections VI and VIII of this Declaration.[31] Hence, such vaccinations are ''covered countermeasures'' under the PREP Act and the June 4, 2020 Second Amendment to the Declaration.

Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa-10 *et seq.* are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such covered countermeasures.

Section VIII. Category of Disease, Health Condition, or Threat

As discussed, the troubling decrease in ACIP-recommended childhood vaccinations and the resulting increased risk of associated diseases, adverse health conditions, and other threats are categories of harms otherwise caused by COVID–19. The Secretary therefore amends section VIII, which describes the category of disease, health condition, or threat for which he recommends the administration or use of the Covered Countermeasures, to clarify that the category of disease, health condition, or threat for which he recommends the administration or use of the Covered Countermeasures is not only COVID–19 caused by SARS–CoV–2 or a virus mutating therefrom, but also other diseases, health conditions, or threats that may have been caused by COVID–19, SARS–CoV–2, or a virus mutating therefrom, including the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of infectious diseases.

Amendments to Declaration

Amended Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID–19.

Sections V and VIII of the March 10, 2020 Declaration under the PREP Act for medical countermeasures against COVID–19, as amended April 10, 2020 and June 4, 2020, are further amended pursuant to section 319F–3(b)(4) of the PHS Act as described below. All other sections of the Declaration remain in effect as published at 85 FR 15198 (Mar. 17, 2020) and amended at 85 FR 21012 (Apr. 15, 2020) and 85 FR 35100 (June 8, 2020).

1. Covered Persons, section V, delete in full and replace with:

V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are ''manufacturers,'' ''distributors,'' ''program planners,'' ''qualified persons,'' and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

In addition, I have determined that the following additional persons are qualified persons: (a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an emergency; (b) any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act; (c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act; and (d) a State-licensed pharmacist who orders and administers, and pharmacy interns who administer (if the pharmacy intern acts under the supervision of such pharmacist and the pharmacy intern is licensed or registered by his or her State board of pharmacy), vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule.

Such State-licensed pharmacists and the State-licensed or registered interns under their supervision are qualified persons only if the following requirements are met:

- The vaccine must be FDA-authorized or FDA-approved.
- The vaccination must be ordered and administered according to ACIP's standard immunization schedule.
- The licensed pharmacist must complete a practical training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE). This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.
- The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation.
- The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period.
- The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine.
- The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary-care provider and refer patients as appropriate.

Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa–10 *et seq.* are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other

[31] Jeanne M. Santoli et al., *Effects of the COVID–19 Pandemic on Routine Pediatric Vaccine Ordering and Administration—United States, 2020,* 69 MMWR No. 19, at 591–93 (May 15, 2020), *https://www.cdc.gov/mmwr/volumes/69/wr/mm6919e2.htm;* Cristi A. Bramer et al., *Decline in Child Vaccination Coverage During the COVID–19 Pandemic—Michigan Care Improvement Registry, May 2016–May 2020,* 69 MMWR No. 20, at 630–31 (May 22, 2020), *https://www.cdc.gov/mmwr/volumes/69/wr/mm6920e1.htm.*

terms and conditions of the Declaration apply to such covered countermeasures.

2. Category of Disease, Health Condition, or Threat, section VIII, delete in full and replace with:

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is not only COVID–19 caused by SARS-CoV–2 or a virus mutating therefrom, but also other diseases, health conditions, or threats that may have been caused by COVID–19, SARS-CoV–2, or a virus mutating therefrom, including the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of infectious diseases.

Authority: 42 U.S.C. 247d–6d.

Dated: August 19, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–18542 Filed 8–20–20; 4:15 pm]

BILLING CODE 4150–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Meeting of the Tick-Borne Disease Working Group

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: As required by the Federal Advisory Committee Act, the Department of Health and Human Services (HHS) is hereby giving notice that the Tick-Borne Disease Working Group (TBDWG) will hold a virtual meeting. The meeting will be open to the public. For this meeting, the TBDWG will review the draft 2020 report to the HHS Secretary and Congress and review and approve graphics and images for the report. The 2020 report will address ongoing tick-borne disease research, including research related to causes, prevention, treatment, surveillance, diagnosis, diagnostics, and interventions for individuals with tick-borne diseases; advances made pursuant to such research; federal activities related to tick-borne diseases; and gaps in tick-borne disease research.

DATES: The meeting will be held online via webcast on September 15, 2020 and September 22, 2020 from 9:00 a.m. to 2:30 p.m. ET both days (times are tentative and subject to change). The confirmed times and agenda items for the meeting will be posted on the TBDWG web page at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-9-15/index.html* when this information becomes available.

FOR FURTHER INFORMATION CONTACT: James Berger, Designated Federal Officer for the TBDWG; Office of Infectious Disease and HIV/AIDS Policy, Office of the Assistant Secretary for Health, Department of Health and Human Services, Mary E. Switzer Building, 330 C Street SW, Suite L600, Washington, DC, 20024. *Email: tickbornedisease@hhs.gov; Phone:* 202–795–7608.

SUPPLEMENTARY INFORMATION: The registration link will be posted on the website at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-9-15/index.html* when it becomes available. After registering, you will receive an email confirmation with a personalized link to access the webcast on September 15, 2020 and September 22, 2020

The public will have an opportunity to present their views to the TBDWG orally during the meeting's public comment session or by submitting a written public comment. Comments should be pertinent to the meeting discussion. Persons who wish to provide verbal or written public comment should review instructions at *https://www.hhs.gov/ash/advisory-committees/tickbornedisease/meetings/2020-9-15/index.html* and respond by midnight September 4, 2020 ET. Verbal comments will be limited to three minutes each to accommodate as many speakers as possible during the 30 minute session. Written public comments will be accessible to the public on the TBDWG web page prior to the meeting.

Background and Authority: The Tick-Borne Disease Working Group was established on August 10, 2017, in accordance with Section 2062 of the 21st Century Cures Act, and the Federal Advisory Committee Act, 5 U.S.C. App., as amended, to provide expertise and review federal efforts related to all tick-borne diseases, to help ensure interagency coordination and minimize overlap, and to examine research priorities. The TBDWG is required to submit a report to the HHS Secretary and Congress on their findings and any recommendations for the federal response to tick-borne disease every two years.

Dated: August 12, 2020.

James J. Berger,

Designated Federal Officer, Tick-Borne Disease Working Group, Office of Infectious Disease and HIV/AIDS Policy.

[FR Doc. 2020–18519 Filed 8–21–20; 8:45 am]

BILLING CODE 4150–28–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel RFA–DK–20–503 Limited Competition: TEDDY Data Coordinating Center.

Date: October 7, 2020.

Time: 3:00 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892, (Telephone Conference Call).

Contact Person: Dianne Camp, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, Room 7013, 6707 Democracy Boulevard, Bethesda, MD 20892–2542, (301) 5947682, *campd@extra.niddk.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: August 18, 2020.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2020–18438 Filed 8–21–20; 8:45 am]

BILLING CODE 4140–01–P

EXHIBIT G

and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lubna Merchant, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 4418, Silver Spring, MD 20993–0002, 301–796–5162, or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Best Practices in Developing Proprietary Names for Human Prescription Drug Products.'' This guidance describes best practices to help minimize proprietary name-related medication errors and otherwise avoid adoption of proprietary names that contribute to violations of the FD&C Act and its implementing regulations. This guidance also describes the framework FDA uses in evaluating proprietary names that sponsors could use before submitting names for FDA review if they wish.

FDA has long recognized the importance of proprietary name confusion as a potential cause of medication errors and has addressed this issue repeatedly in recent decades. Our focus has been to develop and communicate to sponsors a systematic, standardized, and transparent approach to proprietary name evaluation within the product development, review, and approval process.

In the **Federal Register** of May 29, 2014 (79 FR 30852), FDA announced the availability of a draft guidance entitled ''Best Practices in Developing Proprietary Names for Drugs.'' The guidance announced in this notice finalizes the draft guidance issued in May 2014. The Agency has carefully reviewed and considered the comments it received in developing this final version of the guidance.

FDA received several comments on the guidance and revised the guidance in response to these comments. The revisions include (a) adding a note in the section discussing the United States Adopted Name (USAN) stating that FDA will no longer object to the use of two-letter USAN stems in names for products that do not share any association with the stem in question; (b) streamlining the name simulation study section based on the feedback received; (c) providing clarifications to the section that discusses medical abbreviations, modifiers, and computational methods; (d) separating the content pertaining to nonprescription proprietary names and issuing separate guidance to address the name development process for nonprescription drugs; (e) revising the misbranding discussion for greater clarity and included information on one possible study methodology that sponsors may consider to test proposed names for misbranding concerns; and (f) adding certain definitions and specific criteria for prescreening proprietary name candidates and updating definitions in the glossary and clarified terminology where needed. FDA also revised the document throughout to ensure consistency in terminology, clarified section headings, and reordered information for clarity where applicable.

Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of a draft guidance entitled ''Best Practices in Developing Proprietary Names for Human Nonprescription Drug Products.'' That draft guidance is issued in response to industry stakeholders' requests to specifically address the approaches for naming of human nonprescription drug products. The draft guidance is being issued to provide greater clarity on the considerations applicable to nonprescription drug products.

The guidance announced in this notice is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Best Practices in Developing Proprietary Names for Human Prescription Drug Products.'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. Therefore, clearance by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521) is not required for this guidance. The previously approved collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001, and the collections of information in 21 CFR part 601 have been approved under OMB control number 0910–0338.

III. Electronic Access

Persons with access to the internet may obtain the document at *https://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,* or *https://www.regulations.gov.*

Dated: December 4, 2020.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2020–27058 Filed 12–8–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Fourth Amendment to the Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19 and Republication of the Declaration

ACTION: Notice of Amendment and Republished Declaration.

SUMMARY: The Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to amend his March 10, 2020 Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19.

DATES: The amendments to the Declaration are applicable as of February 4, 2020, except as otherwise specified in Section XII.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue

SW, Washington, DC 20201; Telephone: 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. 247d–6d et. seq., authorizes the Secretary of Health and Human Services (the Secretary) to issue a declaration to provide liability protections to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from, the manufacture, distribution, administration, or use of certain medical countermeasures (Covered Countermeasures), except for claims involving ''willful misconduct,'' as defined in the PREP Act. Such declarations are subject to amendment as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding Section 319F–3, which addresses liability immunity, and Section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively. Section 319F–3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, enacted on March 13, 2013, and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

On January 31, 2020, the Secretary declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response to the Coronavirus Disease 2019 (COVID–19) outbreak, which subsequently became a global pandemic. Pursuant to section 319 of the PHS Act, the Secretary renewed that declaration on April 21, 2020, July 23, 2020, and October 2, 2020. On March 10, 2020, the Secretary issued a declaration under the PREP Act for medical countermeasures against COVID–19.[1] On April 10, the Secretary amended the Declaration to extend liability protections to Covered Countermeasures authorized under the CARES Act.[2] On June 4, the Secretary amended the Declaration to clarify that Covered Countermeasures under the Declaration include qualified pandemic and epidemic products that limit the harm that COVID–19 might otherwise cause.[3] On August 19, the Secretary amended the Declaration to add additional categories of Qualified Persons and to amend the category of disease, health condition, or threat for which he recommends the administration or use of Covered Countermeasures.[4]

The Secretary now further amends the Declaration pursuant to section 319F–3 of the Public Health Service Act. This Fourth Amendment to the Declaration:

(a) Clarifies that the Declaration must be construed in accordance with the Department of Health and Human Services (HHS) Office of the General Counsel (OGC) Advisory Opinions on the Public Readiness and Emergency Preparedness Act and the Declaration (Advisory Opinions).[5] The Declaration incorporates the Advisory Opinions for that purpose.

(b) Incorporates authorizations that the HHS Office of the Assistant Secretary for Health (OASH) has issued as an Authority Having Jurisdiction.[6]

(c) Adds an additional category of Qualified Persons under Section V of the Declaration and 42 U.S.C. 247d–6d(i)(8)(B), *i.e.,* healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are permitted to practice.[7]

(d) Modifies and clarifies the training requirements for certain licensed pharmacists and pharmacy interns to administer certain routine childhood or COVID–19 vaccinations.

(e) Makes explicit that Section VI covers all qualified pandemic and epidemic products under the PREP Act.

(f) Adds a third method of distribution under Section VII of the Declaration and 42 U.S.C. 247d–6d(a)(5) that would provide liability protections for, among other things, additional private-distribution channels.

(g) Makes explicit in Section IX that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and this Declaration's liability protections.

(h) Makes explicit in Section XI that there are substantial federal legal and policy issues, and substantial federal legal and policy interests, in having a unified, whole-of-nation response to the COVID–19 pandemic among federal, state, local, and private-sector entities. The world is facing an unprecedented pandemic. To effectively respond, there must be a more consistent pathway for Covered Persons to manufacture, distribute, administer or use Covered Countermeasures across the nation and the world.

[1] 85 FR 15198 (Mar. 17, 2020).

[2] 85 FR 21012 (Apr. 15, 2020).

[3] 85 FR 35100 (June 8, 2020).

[4] 85 FR 52136 (Aug. 24, 2020).

[5] *See, e.g.,* Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act, Apr. 17, 2020, as Modified on May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf* (last visited Dec. 1, 2020); Advisory Opinion 20–02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf* (last visited Dec. 1, 2020); Advisory Opinion 20–03 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO3.1.2_Updated_FINAL_SIGNED_10.23.20.pdf* (last visited Dec. 1, 2020); Advisory Opinion 20–04 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO%204.2_Updated_FINAL_SIGNED_10.23.20.pdf* (last visited Dec. 1, 2020).

[6] *See, e.g.,* Guidance for Licensed Pharmacists, COVID–19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf* (last visited Dec. 1, 2020); Guidance for PREP Act Coverage for COVID–19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities, OASH, Aug. 31, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-coverage-for-screening-in-congregate-settings.pdf* (last visited Dec. 1, 2020); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Dec. 1, 2020); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf* (last visited Dec. 1, 2020); PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, Oct. 29, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf* (last visited Dec. 1, 2020) (collectively, OASH PREP Act Authorizations).

[7] ''Telehealth, telemedicine, and related terms generally refer to the exchange of medical information from one site to another through electronic communication to improve a patient's health.'' Medicare Telemedicine Health Care Provider Fact Sheet, Mar. 17, 2020, available at *https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet* (last visited on Dec. 2, 2020). For the Declaration and the Fourth Amendment, the term ''telehealth'' includes telehealth, telemedicine, and related terms as described by the Centers for Medicare & Medicaid (CMS).

(i) Revises the effective time period of the Declaration in light of the amendments to the Declaration.[8]

The Secretary republishes the Declaration, as amended, in full. Unless otherwise noted, all statutory citations are to the U.S. Code.

Description of This Amendment

Declaration

The Declaration has fifteen sections describing PREP Act coverage for medical countermeasures against COVID–19. OGC has issued Advisory Opinions interpreting the PREP Act and reflecting the Secretary's interpretation of the Declaration.[9] The Secretary now amends the Declaration to clarify that the Declaration must be construed in accordance with the Advisory Opinions. The Secretary expressly incorporates the Advisory Opinions for that purpose.

Section V. Covered Persons

Section V of the Declaration describes Covered Persons, including additional qualified persons identified by the Secretary, as required under the PREP Act. The Secretary amends Section V to specify an additional category of qualified persons. Specifically, healthcare personnel who are permitted to order and administer a Covered Countermeasure through telehealth in a state may do so for patients in another state so long as the healthcare personnel comply with the legal requirements of the state in which the healthcare personnel are permitted to order and administer the Covered Countermeasure by means of telehealth.

Telehealth is widely recognized as a valuable tool to promote public health during this pandemic. According to the Centers for Disease Control and Prevention (CDC),

Telehealth services can facilitate public health mitigation strategies during this pandemic by increasing social distancing. These services can be a safer option for [healthcare personnel (HCP)] and patients by reducing potential infectious exposures. They can reduce the strain on healthcare systems by minimizing the surge of patient demand on facilities and reduce the use of [personal protective equipment (PPE)] by healthcare providers.

Maintaining continuity of care to the extent possible can avoid additional negative consequences from delayed preventive, chronic, or routine care. Remote access to healthcare services may increase participation for those who are medically or socially vulnerable or who do not have ready access to providers. Remote access can also help preserve the patient-provider relationship at times when an in-person visit is not practical or feasible. Telehealth services can be used to:

- Screen patients who may have symptoms of COVID–19 and refer as appropriate
- Provide low-risk urgent care for non-COVID–19 conditions, identify those persons who may need additional medical consultation or assessment, and refer as appropriate
- Access primary care providers and specialists, including mental and behavioral health, for chronic health conditions and medication management
- Provide coaching and support for patients managing chronic health conditions, including weight management and nutrition counseling
- Participate in physical therapy, occupational therapy, and other modalities as a hybrid approach to in-person care for optimal health
- Monitor clinical signs of certain chronic medical conditions (*e.g.,* blood pressure, blood glucose, other remote assessments)
- Engage in case management for patients who have difficulty accessing care (*e.g.,* those who live in very rural settings, older adults, those with limited mobility)
- Follow up with patients after hospitalization
- Deliver advance care planning and counseling to patients and caregivers to document preferences if a life-threatening event or medical crisis occurs
- Provide non-emergent care to residents in long-term care facilities
- Provide education and training for HCP through peer-to-peer professional medical consultations (inpatient or outpatient) that are not locally available, particularly in rural areas.[10]

Similarly, CMS has stressed the importance of telehealth during this pandemic:

Telehealth, telemedicine, and related terms generally refer to the exchange of medical information from one site to another through electronic communication to improve a patient's health. Innovative uses of this kind of technology in the provision of healthcare is increasing. And with the emergence of the virus causing the disease COVID–19, there is an urgency to expand the use of technology to help people who need routine care, and keep vulnerable beneficiaries and beneficiaries with mild symptoms in their homes while maintaining access to the care they need. Limiting community spread of the virus, as well as limiting the exposure to other patients and staff members will slow viral spread.[11]

Accordingly, CMS and other HHS components has substantially expanded the scope of services paid under Medicare when furnished using telehealth technologies during this pandemic.

Other HHS components have also taken steps to expand the use of telehealth during the pandemic.[12]

Moreover, to expand the use of telehealth during this pandemic, the Office for Civil Rights (OCR) at HHS is exercising enforcement discretion and will not impose penalties for noncompliance with the regulatory requirements under the Health Insurance Portability and Accountability Act (HIPAA) Rules against covered healthcare providers that serve patients through everyday communications technologies during the COVID–19 nationwide public health emergency.[13] This exercise of discretion

[8] In addition, the Fourth Amendment makes certain non-substantive changes. Those should not be interpreted to change any substantive provisions.

[9] *See, e.g.,* Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act, Apr. 17, 2020, as Modified on May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf* (last visited Dec. 1, 2020); Advisory Opinion 20–02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf* (last visited Dec. 1, 2020); Advisory Opinion 20–03 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO3.1.2_Updated_FINAL_SIGNED_10.23.20.pdf* (last visited Dec. 1, 2020); Advisory Opinion 20–04 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO%204.2_Updated_FINAL_SIGNED_10.23.20.pdf* (last visited Dec. 1, 2020).

[10] Using Telehealth to Expand Access to Essential Health Services during the COVID–19 Pandemic, CDC, updated June 10, 2020, available at *https://www.cdc.gov/coronavirus/2019-ncov/hcp/telehealth.html* (last visited Dec. 1, 2020).

[11] Medicare Telemedicine Health Care Provider Fact Sheet, Mar. 17, 2020, available at *https://www.cms.gov/newsroom/fact-sheets/medicare-telemedicine-health-care-provider-fact-sheet* (last visited Dec. 1, 2020).

[12] *See, e.g.,* Trump Administration Drives Telehealth Services in Medicaid and Medicare, CMS, Oct. 14, 2020, available at *https://www.cms.gov/newsroom/press-releases/trump-administration-drives-telehealth-services-medicaid-and-medicare* (last visited Dec. 1, 2020); Secretary Azar Announces Historic Expansion of Telehealth Access to Combat COVID–19, Mar. 17, 2020, available at *https://www.hhs.gov/about/news/2020/03/17/secretary-azar-announces-historic-expansion-of-telehealth-access-to-combat-covid-19.html* (last visited Nov. 30, 2020); OIG Policy Statement Regarding Physicians and Other Practitioners That Reduce or Waive Amounts Owed by Federal Health Care Program Beneficiaries for Telehealth Services During the 2019 Novel Coronavirus (COVID–19) Outbreak, Mar. 17, 2020, available at *https://oig.hhs.gov/fraud/docs/alertsandbulletins/2020/policy-telehealth-2020.pdf* (last visited Nov. 30, 2020).

[13] OCR Announces Notification of Enforcement Discretion for Telehealth Remote Communications During the COVID–19 Nationwide Public Health Emergency, Mar. 17, 2020, available at *https://www.hhs.gov/about/news/2020/03/17/ocr-announces-notification-of-enforcement-discretion-for-telehealth-remote-communications-during-the-covid-19.html* (last visited Dec. 1, 2020). The PREP Act does not provide immunity against federal enforcement actions brought by the federal government. We refer to this exercise of

applies to widely available communications apps, such as FaceTime or Skype, when used in good faith for any telehealth treatment or diagnostic purpose, regardless of whether the telehealth service is directly related to COVID–19.[14]

Many states have authorized out-of-state healthcare personnel to deliver telehealth services to in-state patients, either generally or in the context of COVID–19.[15]

To help maximize the utility of telehealth, the Secretary declares that the term ''qualified person'' under 42 U.S.C. 247d–6d(i)(8)(B) includes healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are permitted to practice. When ordering and administering Covered Countermeasures through telehealth to patients in a state where the healthcare personnel are not already permitted to do so, the healthcare personnel must comply with all requirements for ordering and administering Covered Countermeasures to patients through telehealth in the state where the healthcare personnel are licensed or otherwise permitted to practice. Any state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures through telehealth is preempted.[16] Nothing in this Declaration shall preempt state laws that permit additional persons to deliver telehealth services.

The Secretary also amends Section V to include several examples of Covered Persons who are Qualified Persons, because they are authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures. Those examples include certain pharmacists, pharmacy interns, and pharmacy technicians who order or administer certain COVID–19 tests and certain vaccines.[17] These examples are not an exclusive or exhaustive list of persons who are qualified persons identified by the Secretary in Section V.

The Secretary also amends Section V to make explicit that the requirement in that section for certain qualified persons to have a current certificate in basic cardiopulmonary resuscitation is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the Accreditation Council for Pharmacy Education (ACPE), or the Accreditation Council for Continuing Medical Education.

The Secretary also amends Section V's training requirements for licensed pharmacists to order and administer certain childhood or COVID–19 vaccines. To order and administer vaccines, the licensed pharmacist must have completed the immunization training that the licensing State requires in order for pharmacists to administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines.

Other than the basic cardiopulmonary resuscitation requirement and the practical training program requirement, this Amendment does not change the requirements for a pharmacist, pharmacy intern, or pharmacy technician to be a ''qualified person'' under 42 U.S.C. 247d–6d(i)(8)(B) who can order or administer childhood or COVID–19 vaccines pursuant to the Declaration.

Section VI. Covered Countermeasures

The Secretary amends Section VI to make explicit that Section VI covers all qualified pandemic and epidemic products under the PREP Act.

enforcement discretion as another example of the Department's desire to support the expanded use of telehealth during this pandemic.

[14] *Id.*

[15] *See, e.g.,* 2020 Alaska Laws Ch. 10 (S.B. 241) Sec. 7 (healthcare provider can perform telehealth if, among other things, ''the health care provider is licensed, permitted, or certified to provide healthcare services in another jurisdiction and is in good standing in the jurisdiction that issued the license, permit, or certification''); CT Exec. Order No. 7G, Sec. 5(b), Mar. 19, 2020, available at *https://portal.ct.gov/-/media/Office-of-the-Governor/Executive-Orders/Lamont-Executive-Orders/Executive-Order-No-7G.pdf* (last visited Dec. 1, 2020) (''Subsection (a)(12)'s requirements for the licensure, certification or registration of telehealth providers shall be suspended for such telehealth providers that are Medicaid enrolled providers or in-network providers for commercial fully insured health insurance providing telehealth services to patients''); Fl. Emerg. Order, DOH No. 20–002, *In Re: Suspension of Statutes, Rules, and Orders, Made Necessary by COVID–19,* Mar. 16, 2020, available at *http://www.flhealthsource.gov/pdf/emergencyorder-20-002.pdf?inf_contact_key=c1be7c474d297aa416752a23d269 4901680f8914173f9191b1c0223e68310bb1* (last visited Dec. 1, 2020) (''For purposes of preparing for, responding to, and mitigating any effect of COVID–19, health care professionals not licensed in this state may provide health care services to a patient licensed in this state using telehealth, notwithstanding the requirements of section 456.47(4)(a) through (c), (h), and (i), Florida Statutes . . . . This exemption shall apply only to the following out of state health care professionals holding a valid, clear, and unrestricted license in another state or territory in the United States who are not currently under investigation or prosecution in any disciplinary proceeding in any of the states in which they hold a license: physicians, osteopathic physicians, physician assistants, and advanced practice registered nurses.''); IA Emer. Dec., Sec. 39 (Nov. 10, 2020), available at *https://governor.iowa.gov/sites/default/files/documents/Public%20Health%20Proclamation%20-%202020.11.10.pdf* (last visited Dec. 1, 2020) (temporarily suspending any statute or rule defining a doctor or medical staff as ''requiring all doctors and medical staff be licensed to practice in this state, to the extent that individual is licensed to practice in another state''); NH Emer. Order # 15 Pursuant to Exec. Order 2020–4, Sec. 1, Mar. 23, 2020, available at *https://www.governor.nh.gov/sites/g/files/ehbemt336/files/documents/emergency-order-15.pdf* (last visited Dec. 1, 2020) (''any out-of-state medical provider whose profession is licensed within this State shall be allowed to perform any medically necessary service as if the medical provider were licensed to perform such service within the state of New Hampshire subject to,'' among other things, the medical provider being ''licensed and in good standing in another United States jurisdiction'').

[16] Advisory Opinion 20–02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf* (last visited Dec. 1, 2020).

[17] *See, e.g.,* Guidance for Licensed Pharmacists, COVID–19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf* (last visited Dec. 1, 2020); Guidance for PREP Act Coverage for COVID–19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities, OASH, Aug. 31, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-coverage-for-screening-in-congregate-settings.pdf* (last visited Dec. 1, 2020); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Dec. 1, 2020); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf* (last visited Dec. 1, 2020); PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, Oct. 29, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf* (last visited Dec. 1, 2020).

Section VII. Limitations on Distribution

The Secretary may specify that liability protections are in effect only for Covered Countermeasures obtained through a particular means of distribution. The Declaration previously stated that liability immunity is afforded to Covered Persons only for Recommended Activities related to (a) present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements; or (b) activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasures following a declaration of an emergency.

COVID–19 is an unprecedented global challenge that requires a whole-of-nation response that utilizes federal-, state-, and local- distribution channels as well as private-distribution channels. Given the broad scale of this pandemic, the Secretary amends the Declaration to extend PREP Act coverage to additional private-distribution channels, as set forth below.

The amended Section VII adds that PREP Act liability protections also extend to Covered Persons for Recommended Activities that are related to any Covered Countermeasure that is:

(a) Licensed, approved, cleared, or authorized by the Food and Drug Administration (FDA) (or that is permitted to be used under an Investigational New Drug Application or an Investigational Device Exemption) under the Federal Food, Drug, and Cosmetic (FD&C) Act or Public Health Service (PHS) Act to treat, diagnose, cure, prevent, mitigate or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom; or

(b) a respiratory protective device approved by the National Institute for Occupational Safety and Health (NIOSH) under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act to prevent, mitigate, or limit the harm from, COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom.

To qualify for this third distribution channel (but not necessarily to qualify for the other distribution channels), a Covered Person must manufacture, test, develop, distribute, administer, or use the Covered Countermeasure pursuant to the FDA licensure, approval, clearance, or authorization (or pursuant to an Investigational New Drug Application or Investigational Device Exemption), or the NIOSH approval.

This third distribution channel may extend PREP Act coverage when there is no federal agreement or authorization in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a declaration of an emergency. For example, a manufacturer, distributor, program planner, or qualified person engages in manufacturing, testing, development, distribution, administration, or use of a COVID–19 test pursuant to an FDA Emergency Use Authorization for that COVID–19 test. If the Covered Person satisfies all other requirements of the PREP Act and Declaration, there will be PREP Act coverage even if there is no federal agreement to cover those activities and those activities are not part of the authorized activity of an Authority Having Jurisdiction.

Section IX. Administration of Covered Countermeasures

The Secretary amends Section IX to make explicit that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and this Declaration's liability protections.

Section XI. Geographic Area

The Secretary makes explicit in Section XI that there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc.* v. *Darue Eng'g. & Mf'g.,* 545 U.S. 308 (2005), in having a unified, whole-of-nation response to the COVID–19 pandemic among federal, state, local, and private-sector entities. The world is facing an unprecedented global pandemic. To effectively respond, there must be a more consistent pathway for Covered Persons to manufacture, distribute, administer or use Covered Countermeasures across the nation and the world. Thus, there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc.* v. *Darue Eng'g. & Mf'g.,* 545 U.S. 308 (2005), in having a uniform interpretation of the PREP Act. Under the PREP Act, the sole exception to the immunity from suit and liability of covered persons is an exclusive Federal cause of action against a Covered Person for death or serious physical injury proximately caused by willful misconduct by such Covered Person. In all other cases, an injured party's exclusive remedy is an administrative remedy under section 319F–4 of the PHS Act. Through the PREP Act, Congress delegated to me the authority to strike the appropriate Federal-state balance with respect to particular Covered Countermeasures through PREP Act declarations.

Section XII. Effective Time Period

The Secretary amends Section XII to provide that liability protections for all Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction, as identified in Section VII(b) of this Declaration, begins with a ''Declaration of Emergency,'' as defined in Section VII (except that, with respect to qualified persons who order or administer a routine childhood vaccination that ACIP recommends to persons ages three through 18 according to ACIP's standard immunization schedule, PREP Act coverage began on August 24, 2020), and lasts through (a) the final day the Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first. This change is to conform the text of the Declaration to the Third Amendment.[18]

The Secretary also amends Section XII to provide that liability protections for all Covered Countermeasures identified in Section VII(c) of this Declaration begins on the date of this amended Declaration and lasts through (a) the final day the Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first. Because the Secretary is adding Section VII(c) to the Declaration in this Amendment, Section XII provides that Section VII(c) is effective as of the date this amended Declaration is published.

Additional Amendments

The Secretary also makes other, non-substantive amendments.

Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Medical Countermeasures Against COVID–19

To the extent any term previously in the Declaration, including its amendments, is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling. This Declaration must be construed in accordance with the Advisory Opinions

[18] *See* 85 FR 52136 (Aug. 24, 2020).

of the Office of the General Counsel (Advisory Opinions). I incorporate those Advisory Opinions as part of this Declaration.[19] This Declaration is a ''requirement'' under the PREP Act.

I. Determination of Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that the spread of SARS–CoV–2 or a virus mutating therefrom and the resulting disease COVID–19 constitutes a public health emergency. I further determine that use of any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, is a priority for use during the public health emergency that I declared on January 31, 2020 under section 319 of the PHS Act for the entire United States to aid in the response of the nation's healthcare community to the COVID–19 outbreak.

II. Factors Considered

42 U.S.C. 247d–6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d–6d(b)(1)

I recommend, under the conditions stated in this Declaration, the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures.

IV. Liability Protections

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability protections as prescribed in the PREP Act and conditions stated in this Declaration are in effect for the Recommended Activities described in Section III.

V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability protections under this Declaration are ''manufacturers,'' ''distributors,'' ''program planners,'' and ''qualified persons,'' as those terms are defined in the PREP Act; their officials, agents, and employees; and the United States.

In addition, I have determined that the following additional persons are qualified persons:

(a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of Emergency, as that term is defined in Section VII of this Declaration; [20]

(b) any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act;

(c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act;

(d) a State-licensed pharmacist who orders and administers, and pharmacy interns who administer (if the pharmacy intern acts under the supervision of such pharmacist and the pharmacy intern is licensed or registered by his or her State board of pharmacy), [21] (1) vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule or (2) FDA-authorized or FDA-licensed COVID–19 vaccines to persons ages three or older. Such State-licensed pharmacists and the State-licensed or registered interns under their supervision are qualified persons only if the following requirements are met:

i. The vaccine must be authorized, approved, or licensed by the FDA;

ii. In the case of a COVID–19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID–19 vaccine recommendation(s).

iii. In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule;

iv. The licensed pharmacist must have completed the immunization training that the licensing State requires in order for pharmacists to order and administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation

[19] *See, e.g.,* Advisory Opinion on the Public Readiness and Emergency Preparedness Act and the March 10, 2020 Declaration under the Act, Apr. 17, 2020, as Modified on May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf* (last visited Dec. 1, 2020); Advisory Opinion 20–02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf* (last visited Dec. 1, 2020); Advisory Opinion 20–03 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO3.1.2_Updated_FINAL_SIGNED_10.23.20.pdf* (last visited Dec. 1, 2020); Advisory Opinion 20–04 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, Oct. 22, 2020, as Modified on Oct. 23, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/AO%204.2_Updated_FINAL_SIGNED_10.23.20.pdf* (last visited Dec. 1, 2020). This is not to suggest that other PREP Act declarations should be construed in a manner contrary to the interpretation provided in the Advisory Opinions.

[20] *See, e.g.,* Guidance for Licensed Pharmacists, COVID–19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf* (last visited Dec. 1, 2020); Guidance for PREP Act Coverage for COVID–19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities, OASH, Aug. 31, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-coverage-for-screening-in-congregate-settings.pdf* (last visited Dec. 1, 2020); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Dec. 1, 2020); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf* (last visited Dec. 1, 2020); PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, Oct. 29, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf* (last visited Dec. 1, 2020) (collectively, OASH PREP Act Authorizations). Nothing herein shall suggest that, for purposes of the Declaration, the foregoing are the only persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction.

[21] Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, ''State-licensed or registered intern'' (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but need not, take the form of a license from, or registration with, the State board of pharmacy. *See* Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020 at 2, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Dec. 1, 2020).

Council for Pharmacy Education (ACPE) to order and administer vaccines. Such a training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

v. The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

vi. The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation; [22]

vii. The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period;

viii. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine; and

ix. The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate.

x. The licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID–19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID–19 vaccine(s).

(e) Healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are licensed or otherwise permitted to practice. When ordering and administering Covered Countermeasures by means of telehealth to patients in a state where the healthcare personnel are not already permitted to practice, the healthcare personnel must comply with all requirements for ordering and administering Covered Countermeasures to patients by means of telehealth in the state where the healthcare personnel are permitted to practice. Any state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures by means of telehealth is preempted.[23] Nothing in this Declaration shall preempt state laws that permit additional persons to deliver telehealth services.

Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered Countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa–10 *et seq.* are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such Covered Countermeasures.

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are:

(a) Any antiviral, any drug, any biologic, any diagnostic, any other device, any respiratory protective device, or any vaccine manufactured, used, designed, developed, modified, licensed, or procured:

i. To diagnose, mitigate, prevent, treat, or cure COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom; or

ii. to limit the harm that COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom, might otherwise cause;

(b) a product manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by a product described in paragraph (a) above;

(c) a product or technology intended to enhance the use or effect of a product described in paragraph (a) or (b) above; or

(d) any device used in the administration of any such product, and all components and constituent materials of any such product.

To be a Covered Countermeasure under the Declaration, a product must also meet 42 U.S.C. 247d–6d(i)(1)'s definition of ''Covered Countermeasure.''

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability protections are afforded to Covered Persons only for Recommended Activities involving:

(a) Covered Countermeasures that are related to present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements;

(b) Covered Countermeasures that are related to activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of Emergency; or

(c) Covered Countermeasures that are:

i. Licensed, approved, cleared, or authorized by the FDA (or that are permitted to be used under an Investigational New Drug Application or an Investigational Device Exemption) under the FD&C Act or PHS Act to treat, diagnose, cure, prevent, mitigate, or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom; or

[22] This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase ''current certificate in basic cardiopulmonary resuscitation,'' when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. *See* Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Dec. 1, 2020); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/sites/default/files/prep-act-guidance.pdf* (last visited Dec. 1, 2020).

[23] *See, e.g.,* Advisory Opinion 20–02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf* (last visited Dec. 1, 2020).

ii. a respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, that the Secretary determines to be a priority for use during a public health emergency declared under section 319 of the PHS Act to prevent, mitigate, or limit the harm from COVID–19, or the transmission of SARS–CoV–2 or a virus mutating therefrom.

To qualify for this third distribution channel, a Covered Person must manufacture, test, develop, distribute, administer, or use the Covered Countermeasure pursuant to the FDA licensure, approval, clearance, or authorization (or pursuant to an Investigational New Drug Application or Investigational Device Exemption), or the NIOSH approval.

As used in this Declaration, the terms ''Authority Having Jurisdiction'' and ''Declaration of Emergency'' have the following meanings:

(a) The Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.,* city, county, tribal, state, or federal boundary lines) or functional (*e.g.,* law enforcement, public health) range or sphere of authority.

(b) A Declaration of Emergency means any declaration by any authorized local, regional, state, or federal official of an emergency specific to events that indicate an immediate need to administer and use the Covered Countermeasures, with the exception of a federal declaration in support of an Emergency Use Authorization under Section 564 of the FD&C Act unless such declaration specifies otherwise.

I have also determined that, for governmental program planners only, liability protections are afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (a) donation; (b) commercial sale; (c) deployment of Covered Countermeasures from federal stockpiles; or (d) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is not only COVID–19 caused by SARS–CoV–2, or a virus mutating therefrom, but also other diseases, health conditions, or threats that may have been caused by COVID–19, SARS–CoV–2, or a virus mutating therefrom, including the decrease in the rate of childhood immunizations, which will lead to an increase in the rate of infectious diseases.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for the purpose of distributing and dispensing countermeasures.

Where there are limited Covered Countermeasures, *not* administering a Covered Countermeasure to one individual in order to administer it to another individual can constitute ''relating to . . . the administration to . . . an individual'' under 42 U.S.C. 247d–6d. For example, consider a situation where there is only one dose [24] of a COVID–19 vaccine, and a person in a vulnerable population and a person in a less vulnerable population both request it from a healthcare professional. In that situation, the healthcare professional administers the one dose to the person who is more vulnerable to COVID–19. In that circumstance, the failure to administer the COVID–19 vaccine to the person in a less-vulnerable population ''relat[es] to . . . the administration to'' the person in a vulnerable population. The person in the vulnerable population was able to receive the vaccine only because it was not administered to the person in the less-vulnerable population. Prioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority's directive, can fall within the PREP Act and this Declaration's liability protections.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals to whom the liability protections of this Declaration extend include any individual who uses or is administered the Covered Countermeasures in accordance with this Declaration.

Liability protections are afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability protections are afforded to program planners and qualified persons when the countermeasure is used by or administered to this population, or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

Liability protections are afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability protections are afforded to manufacturers and distributors without regard to whether the Covered Countermeasure is used by or administered in any designated geographic area; liability protections are afforded to program planners and qualified persons when the countermeasure is used by or administered in any designated geographic area, or the program planner or qualified person reasonably could have believed the recipient was in that geographic area.

COVID–19 is a global challenge that requires a whole-of-nation response. There are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc.* v. *Darue Eng'g. & Mf'g.,* 545 U.S. 308 (2005), in having a unified, whole-of-nation response to the COVID–19 pandemic among federal, state, local, and private-sector entities. The world is facing an unprecedented pandemic. To effectively respond, there must be a more consistent pathway for Covered Persons to manufacture, distribute, administer or use Covered Countermeasures across the nation and the world. Thus, there are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc.* v. *Darue Eng'g. & Mf'g.,* 545 U.S. 308 (2005), in having a uniform interpretation of the PREP Act. Under the PREP Act, the sole exception to the immunity from suit and liability of covered persons under the PREP Act is an exclusive Federal cause of action against a covered person for death or serious physical injury proximately caused by willful misconduct by such covered person. In all other cases, an injured party's exclusive remedy is an administrative

[24] For simplicity, this example assumes a patient only requires one dose of the vaccine.

remedy under section 319F–4 of the PHS Act. Through the PREP Act, Congress delegated to me the authority to strike the appropriate Federal-state balance with respect to particular Covered Countermeasures through PREP Act declarations.[25]

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability protections for any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, through the means of distribution identified in Section VII(a) of this Declaration, begin on March 27, 2020 and extend through October 1, 2024.

Liability protections for all other Covered Countermeasures identified in Section VI of this Declaration, through means of distribution identified in Section VII(a) of this Declaration, begin on February 4, 2020 and extend through October 1, 2024.

Liability protections for all Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction, as identified in Section VII(b) of this Declaration, begin with a Declaration of Emergency as that term is defined in Section VII (except that, with respect to qualified persons who order or administer a routine childhood vaccination that ACIP recommends to persons ages three through 18 according to ACIP's standard immunization schedule, liability protections began on August 24, 2020), and last through (a) the final day the Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first.

Liability protections for all Covered Countermeasures identified in Section VII(c) of this Declaration begin on the date of this amended Declaration and last through (a) the final day the Declaration of Emergency is in effect, or (b) October 1, 2024, whichever occurs first.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(B) and (C)

I have determined that an additional 12 months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the SNS during the effective period of this Declaration are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C 247d–6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available at the toll-free number 1–855–266–2427 or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

Amendments to this Declaration will be published in the **Federal Register**, as warranted.

Authority: 42 U.S.C. 247d–6d.

Dated: December 3, 2020.

Alex M. Azar II,

Secretary of Health and Human Services.

[FR Doc. 2020–26977 Filed 12–8–20; 8:45 am]

BILLING CODE 4150–37–P

[25] 42 U.S.C. 247d–6d(b)(7) provides that ''[n]o court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection.''

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Notice of Declaration Under the Public Readiness and Emergency Preparedness Act for Countermeasures Against Marburgvirus and/or Marburg Disease

SUMMARY: The Secretary is issuing this Declaration pursuant to section 319F–3 of the Public Health Service Act to provide limited immunity for activities related to countermeasures against marburgvirus and/or Marburg disease.

DATES: The Declaration is effective as of November 25, 2020.

FOR FURTHER INFORMATION CONTACT: Robert P. Kadlec, MD, MTM&H, MS, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; Telephone: 202–205–2882.

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving ''willful misconduct'' as defined in the PREP Act. This Declaration is subject to amendment as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding Section 319F–3, which addresses liability immunity, and Section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food, Drug, and Cosmetic (FD&C) Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of ''Covered Countermeasures'' and ''qualified pandemic and epidemic products'' in Section 319F–3 of the Public Health Service Act (PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these

EXHIBIT H

Agenda: To review and evaluate grant applications.

For Further Information Contact: Jaya Raman, Ph.D., Scientific Review Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway, Mailstop S107–8, Atlanta, Georgia 30341, Telephone (770) 488–6511, *JRaman@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–02164 Filed 2–1–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended, and the Determination of the Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, CDC, pursuant to Public Law 92–463. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP)—SIP21–003, Evaluating Alternative Delivery Models for Arthritis-Appropriate Evidence-Based Physical Activity and Self-Management Interventions.

Date: April 29, 2021.

Time: 11:00 a.m.–6:00 p.m., EDT.

Place: Teleconference.

Agenda: To review and evaluate grant applications.

For Further Information Contact: Jaya Raman, Ph.D., Scientific Review Officer, National Center for Chronic Disease Prevention and Health Promotion, CDC, 4770 Buford Highway, Mailstop S107–8, Atlanta, Georgia 30341, Telephone (770) 488–6511, *JRaman@cdc.gov.*

The Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry.

Kalwant Smagh,

Director, Strategic Business Initiatives Unit, Office of the Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2021–02160 Filed 2–1–21; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Fifth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of amendment.

SUMMARY: The Acting Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID–19 vaccines that are covered countermeasures under section VI of this Declaration.

DATES: This amendment to the Declaration is effective as of February 2, 2021.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; Telephone: 202–260–0365; *paige.ezernack@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving ''willful misconduct'' as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, section 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively. Section 319F–3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, enacted on March 13, 2013 and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27, 2020, to expand Countermeasures under the PREP Act.

On January 31, 2020, former Secretary Alex M. Azar II declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response of the nation's health care community to the COVID–19 outbreak. Pursuant to section 319 of the PHS Act, the Secretary renewed that declaration effective on April 26, 2020, July 25, 2020, October 23, 2020, and January 21, 2121.

On March 10, 2020, former Secretary Azar issued a Declaration under the PREP Act for medical countermeasures against COVID–19 (85 FR 15198, Mar. 17, 2020) (the Declaration). On April 10, the former Secretary amended the Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020). On June 4, the former Secretary amended the Declaration to clarify that covered countermeasures under the Declaration include qualified countermeasures that limit the harm COVID–19 might otherwise cause. (85 FR 35100, June 8, 2020) On August 19, the former Secretary amended the declaration to add additional categories of Qualified Persons and amend the category of disease, health condition, or threat for which he recommended the administration or use of the Covered Countermeasures. (85 FR 51236, August 24, 2020). On December 3, 2020, the former Secretary amended the declaration to incorporate Advisory Opinions of the General Counsel interpreting the PREP Act and the

Secretary's Declaration and authorizations issued by the Department's Office of the Assistant Secretary for Health as an Authority Having Jurisdiction to respond; added an additional category of qualified persons under Section V of the Declaration; made explicit that the Declaration covers all qualified pandemic and epidemic products as defined under the PREP Act; added a third method of distribution to provide liability protections for, among other things, private distribution channels; made explicit that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and the Declaration's liability protections; made explicit that there are substantive Federal legal and policy issues and interests in having a unified whole-of-nation response to the COVID–19 pandemic among Federal, state, local, and private-sector entities; revised the effective time period of the Declaration; and republished the declaration in full. (85 FR 79190 December 9, 2020).

The Acting Secretary now amends section V of the Declaration to add additional categories of qualified persons covered under the PREP Act, and thus authorizes:

(f) Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State as of the effective date of this amendment, or as authorized under section V(d) of this Declaration, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held, in association with a COVID–19 vaccination effort by a federal, State, local, Tribal, or territorial authority or by an institution in the State in which the COVID–19 vaccine covered countermeasure is administered, so long as the license or certification of the healthcare professional has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, subject to:

(i) Documentation of completion of the Centers for Disease Control and Prevention COVID–19 (CDC) Vaccine Training Modules [1] and, for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and administration of the particular COVID–19 vaccine(s) to be administered; and

(g) Any physician, advanced practice registered nurse, registered nurse, or practical nurse who has held an active license or certification to prescribe, dispense, or administer vaccines under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a federal, State, local, tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline, or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, subject to (i) documentation of completion of the Centers for Disease Control and Prevention COVID–19 Vaccine Training Modules and (ii) documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and administration of the particular COVID–19 vaccine(s) to be administered.

Description of This Amendment by Section

Section V. Covered Persons

Under the PREP Act and the Declaration, a ''qualified person'' is a ''covered person.'' Subject to certain limitations, a covered person is immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration or use of a covered countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure. ''Qualified person'' includes (A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) ''a person within a category of persons so identified in a declaration by the Secretary'' under subsection (b) of the PREP Act. 42 U.S.C. 247d–6d(i)(8).

By this amendment to the Declaration, the Acting Secretary identifies two additional categories of persons who are qualified persons under section 247d–6d(i)(8)(B), allowing healthcare providers who are licensed in a State to prescribe, dispense, and/or administer COVID–19 vaccines in any State or jurisdiction where the PREP Act applies, and allowing physicians, registered nurses, and practical nurses whose licenses expired within the past five years to prescribe, dispense, and/or administer COVID–19 vaccines in any State.

The Acting Secretary has determined that there is an urgent need to expand the pool of available COVID–19 vaccinators in order to respond effectively to the pandemic. As vaccine supply is made more widely available over the coming months, health care system capacity and the vaccination workforce are likely to become increasingly strained throughout the Nation. Permitting Physicians, registered nurses, and practical nurses who have recently expired licenses also significantly expands the vaccination workforce. There are approximately 160,000 inactive physicians and 350,000 inactive registered nurses and practical nurses in the United States.

These healthcare professionals can safely administer COVID–19 vaccines because they all have training in performing injections and observing for side effects and will be required to document completion of the Centers for Disease Control and Prevention (CDC) COVID–19 Vaccine Training Modules.

Including these healthcare professionals as Qualified Persons under this amended Declaration achieves two purposes. First, the healthcare professionals will be afforded liability protections in accordance with the PREP Act and the terms of this amended Declaration. Second, any State law that would otherwise prohibit the healthcare professionals who are a ''qualified person'' from prescribing, dispensing, or administering COVID–19 vaccines is preempted. On May 19, 2020, the Office of the General Counsel issued an advisory opinion concluding that, because licensed pharmacists are

[1] *See* COVID–19 Vaccine Training Modules, available at *https://www.cdc.gov/vaccines/covid-19/training.html.*

''qualified persons'' under this declaration, the PREP Act preempts state law that would otherwise prohibit such pharmacists from ordering and administering authorized COVID–19 diagnostic tests.[2] The opinion relied in part on the fact that the Congressional delegation of authority to the Secretary under the PREP Act to specify a class of persons, beyond those who are authorized to administer a covered countermeasure under State law, as ''qualified persons'' would be rendered a nullity in the absence of such preemption. This opinion is incorporated by reference into this declaration. Based on the reasoning set forth in the May 19, 2020 advisory opinion, any State law that would otherwise prohibit a member of any of the classes of ''qualified persons'' specified in this declaration from administering a covered countermeasure is likewise preempted. In accordance with section 319F–3(i)(8)(A) of the Public Health Service Act, a State remains free to expand the universe of individuals authorized to administer covered countermeasures within its jurisdiction under State law.

The plain language of the PREP Act makes clear that there is complete preemption of state law as described above. Furthermore, preemption of State law is justified to respond to the nation-wide public health emergency caused by COVID–19 as it will enable States to quickly expand the vaccination workforce with additional qualified healthcare professionals where State or local requirements might otherwise inhibit or delay allowing these healthcare professionals to participate in the COVID–19 vaccination program.

Amendments to Declaration

Amended Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID–19.

Section V of the March 10, 2020 Declaration under the PREP Act for medical countermeasures against COVID–19, as amended April 10, 2020, June 4, 2020, and August 19, 2020 and amended and republished on December 3, 2020 is further amended pursuant to section 319F–3(b)(4) of the PHS Act as described below. All other sections of the Declaration remain in effect as republished at 85 FR 79190 (December 9, 2020).

1. Covered Persons, section V, delete in full and replace with:

V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are ''manufacturers,'' ''distributors,'' ''program planners,'' ''qualified persons,'' and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States. ''Order'' as used herein and in guidance issued by the Office of the Assistant Secretary for Health [3] means a provider medication order, which includes prescribing of vaccines, or a laboratory order, which includes prescribing laboratory orders, if required. In addition, I have determined that the following additional persons are qualified persons:

(a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an Emergency, as that term is defined in Section VII of this Declaration; [4]

(b) Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act;

(c) Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act;

(d) A State-licensed pharmacist who orders and administers, and pharmacy interns who administer (if the pharmacy intern acts under the supervision of such pharmacist and the pharmacy intern is licensed or registered by his or her State board of pharmacy),[5] (1) vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule or (2) FDA authorized or FDA licensed COVID –19 vaccines to persons ages three or older. Such State-licensed pharmacists and the State-licensed or registered interns under their supervision are qualified persons only if the following requirements are met:

i. The vaccine must be authorized, approved, or licensed by the FDA;

ii. In the case of a COVID–19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID–19 vaccine recommendation(s).

[2] Department of Health and Human Services General Counsel Advisory Opinion on the Public Readiness and Emergency Preparedness Act, May 19, 2020, available at: *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf/* (last visited Jan. 24, 2021). *See also,* Department of Justice Office of Legal Counsel Advisory Opinion for Robert P. Charrow, General Counsel of the Department of Health and Human Services, January 12, 2020, available at: *https://www.justice.gov/sites/default/files/opinions/attachments/2021/01/19/2021-01-19-prep-act-preemption.pdf* (last visited Jan. 24, 2021).

[3] *See* Guidance for Licensed Pharmacists, COVID–19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf* (last visited Jan. 24, 2021); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021).

[4] *See, e.g.,* Guidance for Licensed Pharmacists, COVID–19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for COVID–19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities, OASH, Aug. 31, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-coverage-for-screening-in-congregate-settings.pdf* (last visited Jan. 24, 2021); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021); PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, Oct. 29, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf* (last visited Jan. 24, 2021) (collectively, OASH PREP Act Authorizations). Nothing herein shall suggest that, for purposes of the Declaration, the foregoing are the only persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction.

[5] Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, ''State-licensed or registered intern'' (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but need not, take the form of a license from, or registration with, the State board of pharmacy. *See* Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020 at 2, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021).

iii. In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule;

iv. The licensed pharmacist must have completed the immunization training that the licensing State requires in order for pharmacists to order and administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. Such a training program must include hands on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

v. The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

vi. The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation; [6]

vii. The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period;

viii. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine;

ix. The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate; and

x. The licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID–19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID–19 vaccine(s).

(e) Healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are licensed or otherwise permitted to practice. When ordering and administering Covered Countermeasures by means of telehealth to patients in a state where the healthcare personnel are not already permitted to practice, the healthcare personnel must comply with all requirements for ordering and administering Covered Countermeasures to patients by means of telehealth in the state where the healthcare personnel are permitted to practice. Any state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures by means of telehealth is preempted.[7] Nothing in this Declaration shall preempt state laws that permit additional persons to deliver telehealth services.

(f) Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State as of the effective date of this amendment, or as authorized under the section V(d) of this Declaration, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held, in association with a COVID–19 vaccination effort by a federal, State, local Tribal or territorial authority or by an institution in the State in which the COVID–19 vaccine covered countermeasure is administered, so long as the license or certification of the healthcare professional has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, subject to: (i) Documentation of completion of the Centers for Disease Control and Prevention COVID–19 (CDC) Vaccine Training Modules [8] and, for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and administration of the particular COVID–19 vaccine(s) to be administered; and

(g) Any physician, advanced practice registered nurse, registered nurse, or practical nurse who has held an active license or certification to prescribe, dispense, or administer vaccines under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a federal, State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector

[6] This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase ''current certificate in basic cardiopulmonary resuscitation,'' when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. *See* Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021).

[7] *See, e.g.,* Advisory Opinion 20–02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf* (last visited Jan. 24, 2021).

[8] *See* COVID–19 Vaccine Training Modules, available at *https://www2.cdc.gov/vaccines/ed/covid19/index.asp* (last visited Jan. 23, 2021) *https://www.cdc.gov/vaccines/covid-19/training.html.*

General, subject to (i) documentation of completion of the Centers for Disease Control and Prevention COVID–19 Vaccine Training Modules and (ii) documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and administration of the particular COVID–19 vaccine(s) to be administered.

Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa–10 *et seq.* are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such covered countermeasures.

2. Effective Time Period, section XII, add to the end of the section:

Liability protections for Qualified Persons under sections V(f) and V(d) of the declaration begin on January 28, 2021, and last through October 1, 2024.

Authority: 42 U.S.C. 247d–6d.

Norris Cochran,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2021–02174 Filed 1–29–21; 4:15 pm]

BILLING CODE 4150–37–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 701–TA–663–664 and 731–TA–1555–1556 (Preliminary)]

Granular Polytetrafluoroethylene (PTFE) Resin From India and Russia; Institution of Anti-Dumping and Countervailing Duty Investigations and Scheduling of Preliminary Phase Investigations

AGENCY: United States International Trade Commission.

ACTION: Notice.

SUMMARY: The Commission hereby gives notice of the institution of investigations and commencement of preliminary phase antidumping and countervailing duty investigation Nos. 701–TA–663–664 and 731–TA–1555–1556 (Preliminary) pursuant to the Tariff Act of 1930 (''the Act'') to determine whether there is a reasonable indication that an industry in the United States is materially injured or threatened with material injury, or the establishment of an industry in the United States is materially retarded, by reason of imports of granular polytetrafluoroethylene (PTFE) resin from India and Russia, provided for in subheading 3904.61.00 of the Harmonized Tariff Schedule of the United States, that are alleged to be sold in the United States at less than fair value and alleged to be subsidized by the Governments of India and Russia. Unless the Department of Commerce (''Commerce'') extends the time for initiation, the Commission must reach a preliminary determination in antidumping and countervailing duty investigations in 45 days, or in this case by March 15, 2021. The Commission's views must be transmitted to Commerce within five business days thereafter, or by March 22, 2021.

DATES: January 27, 2021.

FOR FURTHER INFORMATION CONTACT: Keysha Martinez ((202) 205–2136), Office of Investigations, U.S. International Trade Commission, 500 E Street SW, Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*https://www.usitc.gov*). The public record for these investigations may be viewed on the Commission's electronic docket (EDIS) at *https://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—These investigations are being instituted, pursuant to sections 703(a) and 733(a) of the Tariff Act of 1930 (19 U.S.C. 1671b(a) and 1673b(a)), in response to a petition filed on January 27, 2021, by Daikin America, Inc., Orangeburg, New York.

For further information concerning the conduct of these investigations and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A and B (19 CFR part 201), and part 207, subparts A and B (19 CFR part 207).

Participation in the investigations and public service list.—Persons (other than petitioners) wishing to participate in the investigations as parties must file an entry of appearance with the Secretary to the Commission, as provided in §§ 201.11 and 207.10 of the Commission's rules, not later than seven days after publication of this notice in the **Federal Register**. Industrial users and (if the merchandise under investigation is sold at the retail level) representative consumer organizations have the right to appear as parties in Commission antidumping duty and countervailing duty investigations. The Secretary will prepare a public service list containing the names and addresses of all persons, or their representatives, who are parties to these investigations upon the expiration of the period for filing entries of appearance.

Limited disclosure of business proprietary information (BPI) under an administrative protective order (APO) and BPI service list.—Pursuant to § 207.7(a) of the Commission's rules, the Secretary will make BPI gathered in these investigations available to authorized applicants representing interested parties (as defined in 19 U.S.C. 1677(9)) who are parties to the investigations under the APO issued in the investigations, provided that the application is made not later than seven days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive BPI under the APO.

Conference.— In light of the restrictions on access to the Commission building due to the COVID–19 pandemic, the Commission is conducting the staff conference through video conferencing on February 17, 2021. Requests to appear at the conference should be emailed to *preliminaryconferences@usitc.gov* (DO NOT FILE ON EDIS) on or before February 12, 2021. Please provide an email address for each conference participant in the email. Information on conference procedures will be provided separately and guidance on joining the video conference will be available on the Commission's Daily Calendar. A nonparty who has testimony that may aid the Commission's deliberations may request permission to participate by submitting a short statement.

Please note the Secretary's Office will accept only electronic filings during this time. Filings must be made through the Commission's Electronic Document Information System (EDIS, *https://edis.usitc.gov*). No in-person paper-based filings or paper copies of any electronic filings will be accepted until further notice.

Written submissions.—As provided in §§ 201.8 and 207.15 of the Commission's rules, any person may submit to the Commission on or before February 22, 2021, a written brief containing information and arguments pertinent to the subject matter of the investigations. Parties shall file written

EXHIBIT I

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]—Continued

Activity; 21 CFR part	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	22,000	1	22,000	1	22,000
Total					592,276

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] One-time burden.

TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

Activity; 21 CFR part	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Acquisition of tracked devices and final distributor data—821.30(a) and (b)	22,000	1	22,000	1	22,000
Multiple distributor data and distributor tracking records—821.30(c)(2) and (d)	1,100	1	1,100	1	1,100
Total					23,100

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate for this information collection has not changed since the last OMB approval.

Dated: February 9, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–03017 Filed 2–12–21; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Sixth Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of amendment.

SUMMARY: The Acting Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer covered countermeasures under section VI of this Declaration.

DATES: This amendment to the Declaration is effective as of February 16, 2021.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health andHuman Services, 200 Independence Avenue SW, Washington, DC 20201; 202–260–0365, *paige.ezernack@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving ''willful misconduct'' as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, section 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively. Section 319F–3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, enacted on March 13, 2013 and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27, 2020, to expand Countermeasures under the PREP Act.

On January 31, 2020, former Secretary, Alex M. Azar II, declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response of the nation's health care community to the COVID–19 outbreak. Pursuant to section 319 of the PHS Act, the Secretary renewed that declaration effective on April 26, 2020, July 25, 2020, October 23, 2020, and January 21, 2021.

On March 10, 2020, former Secretary Azar issued a Declaration under the PREP Act for medical countermeasures against COVID–19 (85 FR 15198, Mar. 17, 2020) (the Declaration). On April 10, the former Secretary amended the Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020). On June 4, the former Secretary amended the Declaration to clarify that covered countermeasures under the Declaration include qualified countermeasures that limit the harm COVID–19 might otherwise cause. (85 FR 35100, June 8, 2020). On August 19, the former Secretary amended the declaration to add additional categories of Qualified Persons and amend the category of disease, health condition, or threat for which he recommended the administration or use of the Covered Countermeasures. (85 FR 52136, August 24, 2020). On December 3, 2020, the former Secretary amended the declaration to incorporate Advisory Opinions of the General Counsel interpreting the PREP Act and the Secretary's Declaration and

authorizations issued by the Department's Office of the Assistant Secretary for Health as an Authority Having Jurisdiction to respond; added an additional category of qualified persons under Section V of the Declaration; made explicit that the Declaration covers all qualified pandemic and epidemic products as defined under the PREP Act; added a third method of distribution to provide liability protections for, among other things, private distribution channels; made explicit that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and the Declaration's liability protections; made explicit that there are substantive federal legal and policy issues and interests in having a unified whole-of-nation response to the COVID–19 pandemic among federal, state, local, and private-sector entities; revised the effective time period of the Declaration; and republished the declaration in full. (85 FR 79190 December 9, 2020). On January 28, 2021, the Acting Secretary amended the Declaration to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID–19 vaccines that are covered countermeasures under the Declaration (86 FR 7872, February 2, 2021).

The Acting Secretary now amends section V of the Declaration to add a new subsection (h) to add an additional category of qualified persons covered under the PREP Act, and thus authorizes:

(h) Any Federal government employee, contractor, or volunteer who prescribes, administers, delivers, distributes or dispenses a Covered Countermeasure. Such Federal government employees, contractors, or volunteers are qualified persons if the following requirement is met: The executive department or agency by or for which the Federal employee, contractor, or volunteer is employed, contracts, or volunteers has authorized or could authorize that employee, contractor, or volunteer to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of the duties or responsibilities of that employee, contractor, or volunteer, even if those authorized duties or responsibilities ordinarily would not extend to members of the public or otherwise would be more limited in scope than the activities such employees, contractors, or volunteers are authorized to carry out under this declaration.

Description of This Amendment by Section

Section V. Covered Persons

Under the PREP Act and the Declaration, a ''qualified person'' is a ''covered person.'' Subject to certain limitations, a covered person is immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration or use of a covered countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure. ''Qualified person'' includes (A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) ''a person within a category of persons so identified in a declaration by the Secretary'' under subsection (b) of the PREP Act. 42 U.S.C. 247d–6d(i)(8)

By this amendment to the Declaration, the Acting Secretary identifies an additional category of persons who are qualified persons under section 247d–6d(i)(8)(B): Federal employees, contractors and volunteers authorized by their Department or agency to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of their duties or responsibilities.

The Acting Secretary has determined that there is an urgent need to expand the pool of available COVID–19 vaccinators in order to respond effectively to the pandemic. As vaccine supply is made more widely available over the coming months, health care system capacity and the vaccination workforce are likely to become increasingly strained throughout the Nation. The United States is deploying federal personnel, contractors and volunteers to assist in the national COVID–19 vaccination program. While the United States is a covered person under the PREP Act and the Declaration, this amendment clarifies that federal employees, contractors and volunteers are also qualified persons authorized by the Secretary to prescribe, dispense, or administer covered countermeasures, consistent with the terms and conditions of the Declaration.

As qualified persons, these employees, contractors and volunteers will be afforded liability protections in accordance with the PREP Act and the terms of this amended Declaration in addition to the protection that is afforded to the United States as a covered person. Second, to the extent that any State law that would otherwise prohibit the employees, contractors, or volunteers who are a ''qualified person'' from prescribing, dispensing, or administering COVID–19 vaccines or other Covered Countermeasures, such law is preempted. On May 19, 2020, the Office of the General Counsel issued an advisory opinion concluding that, because licensed pharmacists are ''qualified persons'' under this declaration, the PREP Act preempts state law that would otherwise prohibit such pharmacists from ordering and administering authorized COVID–19 diagnostic tests.[1] The opinion relied in part on the fact that the Congressional delegation of authority to the Secretary under the PREP Act to specify a class of persons, beyond those who are authorized to administer a covered countermeasure under State law, as ''qualified persons'' would be rendered a nullity in the absence of such preemption. This opinion is incorporated by reference into this declaration. Based on the reasoning set forth in the May 19, 2020 advisory opinion, any State law that would otherwise prohibit a member of any of the classes of ''qualified persons'' specified in this declaration from administering a covered countermeasure is likewise preempted. In accordance with section 319F–3(i)(8)(A) of the Public Health Service Act, a State remains free to expand the universe of individuals authorized to administer covered countermeasures within its jurisdiction under State law.

The plain language of the PREP Act makes clear that there is preemption of state law as described above. Furthermore, preemption of State law is justified to respond to the nation-wide public health emergency caused by COVID–19 as it will enable States to quickly expand the vaccination workforce with additional qualified healthcare professionals where State or local requirements might otherwise inhibit or delay allowing these healthcare professionals to participate in the COVID–19 vaccination program.

[1] Department of Health and Human Services General Counsel Advisory Opinion on the Public Readiness and Emergency Preparedness Act, May 19, 2020, available at: *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf/* (last visited Jan. 24, 2021). *See also,* Department of Justice Office of Legal Counsel Advisory Opinion for Robert P. Charrow, General Counsel of the Department of Health and Human Services, January 12, 2020, available at: *https://www.justice.gov/sites/default/files/opinions/attachments/2021/01/19/2021-01-19-prep-act-preemption.pdf* (last visited Jan. 24, 2021).

Amendments to Declaration

Amended Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID–19.

Section V of the March 10, 2020 Declaration under the PREP Act for medical countermeasures against COVID–19, as amended April 10, 2020, June 4, 2020, August 19, 2020, as amended and republished on December 3, 2020, and as amended on February 2, 2021, is further amended pursuant to section 319F–3(b)(4) of the PHS Act as described below. All other sections of the Declaration remain in effect as republished at 85 FR 79190 (December 9, 2020).

1. Covered Persons, section V, delete in full and replace with:

V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are ''manufacturers,'' ''distributors,'' ''program planners,'' ''qualified persons,'' and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States. ''Order'' as used herein and in guidance issued by the Office of the Assistant Secretary for Health [2] means a provider medication order, which includes prescribing of vaccines, or a laboratory order, which includes prescribing laboratory orders, if required. In addition, I have determined that the following additional persons are qualified persons:

(a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an Emergency, as that term is defined in Section VII of this Declaration; [3]

(b) Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act;

(c) Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act;

(d) A State-licensed pharmacist who orders and administers, and pharmacy interns who administer (if the pharmacy intern acts under the supervision of such pharmacist and the pharmacy intern is licensed or registered by his or her State board of pharmacy),[4] (1) vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule or (2) FDA authorized or FDA licensed COVID –19 vaccines to persons ages three or older. Such State-licensed pharmacists and the State-licensed or registered interns under their supervision are qualified persons only if the following requirements are met:

i. The vaccine must be authorized, approved, or licensed by the FDA;

ii. In the case of a COVID–19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID–19 vaccine recommendation(s).

iii. In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule;

iv. The licensed pharmacist must have completed the immunization training that the licensing State requires in order for pharmacists to order and administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. Such a training program must include hands on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

v. The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

vi. The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation; [5]

[2] *See* Guidance for Licensed Pharmacists, COVID–19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf* (last visited Jan. 24, 2021); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021).

[3] *See, e.g.,* Guidance for Licensed Pharmacists, COVID–19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for COVID–19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities, OASH, Aug. 31, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-coverage-for-screening-in-congregate-settings.pdf* (last visited Jan. 24, 2021); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021); PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, Oct. 29, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf* (last visited Jan. 24, 2021) (collectively, OASH PREP Act Authorizations). Nothing herein shall suggest that, for purposes of the Declaration, the foregoing are the only persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction.

[4] Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, ''State-licensed or registered intern'' (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but need not, take the form of a license from, or registration with, the State board of pharmacy. *See* Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020 at 2, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021).

[5] This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase ''current certificate in basic cardiopulmonary resuscitation,'' when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. *See* Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://*

vii. The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period;

viii. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine;

ix. The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate; and

x. The licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID–19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID–19 vaccine(s).

(e) Healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are licensed or otherwise permitted to practice. When ordering and administering Covered Countermeasures by means of telehealth to patients in a state where the healthcare personnel are not already permitted to practice, the healthcare personnel must comply with all requirements for ordering and administering Covered Countermeasures to patients by means of telehealth in the state where the healthcare personnel are permitted to practice. Any state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures by means of telehealth is preempted.[6] Nothing in this Declaration shall preempt state laws that permit additional persons to deliver telehealth services.

(f) Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State as of the effective date of this amendment, or as authorized under the section V(d) of this Declaration, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held, in association with a COVID–19 vaccination effort by a federal, State, local Tribal or territorial authority or by an institution in the State in which the COVID–19 vaccine covered countermeasure is administered, so long as the license or certification of the healthcare professional has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, subject to: (i) Documentation of completion of the Centers for Disease Control and Prevention COVID–19 (CDC) Vaccine Training Modules[7] and, for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and administration of the particular COVID–19 vaccine(s) to be administered; and

(g) Any physician, advanced practice registered nurse, registered nurse, or practical nurse who has held an active license or certification to prescribe, dispense, or administer vaccines under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a federal, State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, subject to (i) documentation of completion of the Centers for Disease Control and Prevention COVID–19 Vaccine Training Modules and (ii) documentation of an observation period by a currently practicing healthcare professional adequately experienced in vaccination who confirms competency of the healthcare provider in preparation and administration of the particular COVID–19 vaccine(s) to be administered.

(h) Any Federal government employee, contractor, or volunteer who prescribes, administers, delivers, distributes or dispenses a Covered Countermeasure. Such Federal government employees, contractors, or volunteers are qualified persons if the following requirement is met: The executive department or agency by or for which the Federal employee, contractor, or volunteer is employed, contracts, or volunteers has authorized or could authorize that employee, contractor, or volunteer to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of the duties or responsibilities of that employee, contractor, or volunteer, even if those authorized duties or responsibilities ordinarily would not extend to members of the public or otherwise would be more limited ien scope than the activities such employees, contractors, or volunteers are authorized to carry out under this declaration.

Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa–10 *et seq.* are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such covered countermeasures.

www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf (last visited Jan. 24, 2021).

[6] *See, e.g.,*Advisory Opinion 20–02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf* (last visited Jan. 24, 2021).

[7] *See* COVID–19 Vaccine Training Modules, available at *https://www.cdc.gov/vaccines/covid-19/training.html.*

2. Effective Time Period, Section XII, Add to the End of the Section:

Liability protections for Qualified Persons under sections V(f) and V(d) of the declaration begin on February 8, 2021 and last through October 1, 2024.

Authority: 42 U.S.C. 247d–6d.

Norris Cochran,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2021–03106 Filed 2–11–21; 4:15 pm]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The invention listed below is owned by an agency of the U.S. Government and is available for licensing to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Peter Soukas, J.D., 301–594–8730; *peter.soukas@nih.gov.* Licensing information and copies of the patent applications listed below may be obtained by communicating with the indicated licensing contact at the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD, 20852; tel. 301–496–2644. A signed Confidential Disclosure Agreement will be required to receive copies of unpublished patent applications.

SUPPLEMENTARY INFORMATION: Technology description follows.

Epstein-Barr Virus Antibody That Blocks Fusion And Neutralizes Virus Infection of B Cells

Description of Technology

Epstein-Barr virus (EBV) is the most common cause of infectious mononucleosis and is associated with nearly 200,000 cancers and 140,000 deaths each year. EBV-associated cancers include Hodgkin's lymphoma, non-Hodgkin's lymphoma, Burkitt B cell lymphoma, and EBV post-transplant lymphoproliferative disease. The latent reservoir for EBV in the body is the B lymphocyte. Thus, blocking B cell infection is important for reducing EBV-related disease.

EBV can infect both B cells and epithelial cells; however, the method of entry differs between these two cell types. To initiate B cell infection, EBV glycoprotein 350 (gp350) binds to compliment receptor 2 (CR2; also known as CD21), followed by binding of glycoprotein 42 (gp42) to HLA class II molecules, which triggers fusion of EBV with the B cell, allowing virus entry into the cell. Fusion also requires the EBV proteins gH/gL, which are found complexed with gp42 as a heterotrimer, and gB. Infection of epithelial cells is initiated by the binding of the EBV protein BMRF2 to cellular integrins, followed by binding of gH/gL to ephrin receptor A2 and integrins, which triggers fusion by EBV gB.

Monoclonal antibodies that specifically bind EBV gp42 are described by this invention. The gp42-specific antibodies are capable of neutralizing EBV infection and inhibiting fusion of EBV with B cells. The monoclonal antibodies can be used for the treatment or prophylaxis of EBV infection, prevention of EBV-associated disease or infection in immunocompromised subjects, diagnosis of EBV infection, and detection of EBV in a biological sample.

This technology is available for licensing for commercial development in accordance with 35 U.S.C. 209 and 37 CFR part 404, as well as for further development and evaluation under a research collaboration.

Potential Commercial Applications

- Viral diagnostics
- Viral therapeutics
- Viral prophylaxis
- Vaccine research

Competitive Advantages

- Ease of manufacture
- Strongly neutralizing antibodies
- Alternative to EBV vaccines

Development Stage

- In vivo data assessment (animal)

Inventors: Jeffrey Cohen (NIAID), Wei Bu (NIAID), Nathan Board (NIAID), Kennichi Dowdell (NIAID).

Intellectual Property: HHS Reference No. E–020–2020–0—U.S. Provisional Application No. 62/979,070, filed February 20, 2020.

Licensing Contact: Peter Soukas, J.D., 301–594–8730; *peter.soukas@nih.gov.*

Collaborative Research Opportunity: The National Institute of Allergy and Infectious Diseases is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize for development of a vaccine for respiratory or other infections. For collaboration opportunities, please contact Peter Soukas, J.D., 301–594–8730; *peter.soukas@nih.gov.*

Dated: January 28, 2021.

Surekha Vathyam,

Deputy Director, Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases.

[FR Doc. 2021–03045 Filed 2–12–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; Renal RC2 Applications.

Date: March 19, 2021.

Time: 3:30 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Two Democracy Plaza, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Ryan G. Morris, Ph.D., Scientific Review Officer, Review Branch, Division of Extramural Activities, NIDDK, National Institutes of Health, 6707 Democracy Boulevard, Room 7015, Bethesda, MD 20892–2542, 301–594–4721, *ryan.morris@nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

EXHIBIT J

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Submission to OMB for Review and Approval; Public Comment Request; Voluntary Partner Surveys To Implement Executive Order 12862 in the Health Resources and Services Administration

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, HRSA submitted an Information Collection Request (ICR) to the Office of Management and Budget (OMB) for review and approval. Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. OMB may act on HRSA's ICR only after the 30 day comment period for this notice has closed.

DATES: Comments on this ICR should be received no later than April 15, 2021.

ADDRESSES: Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function.

FOR FURTHER INFORMATION CONTACT: To request a copy of the clearance requests submitted to OMB for review, email Lisa Wright-Solomon, the HRSA Information Collection Clearance Officer at *paperwork@hrsa.gov* or call (301) 443–1984.

SUPPLEMENTARY INFORMATION:

Information Collection Request Title: Voluntary Partner Surveys to Implement Executive Order 12862 in the Health Resources and Services Administration, OMB No. 0915–0212—Extension.

Abstract: In response to Executive Order 12862, HRSA is proposing to conduct voluntary customer surveys of its partners to assess strengths and weaknesses in program services and processes. HRSA partners are typically state or local governments, health care facilities, health care consortia, health care providers, and researchers. HRSA is requesting continued approval of a generic clearance from OMB to conduct the partner surveys.

Partner surveys to be conducted by HRSA might include, for example, mail, electronic, and/or telephone surveys of grantees to determine satisfaction with grant processes or technical assistance provided by a contractor, or in-class or virtual evaluation forms completed by providers who receive training from HRSA grantees to measure satisfaction with the training experience. Results of these surveys will be used to plan and redirect resources and efforts as needed to improve services and processes.

Focus groups may also be used to gain partner input that will inform the design of mail, electronic and/or telephone surveys. Focus groups, in-class evaluation forms, mail surveys, electronic surveys, and telephone surveys are expected to be the preferred data collection methods for this information collection.

A generic approval allows HRSA to conduct a limited number of partner surveys without a full-scale OMB review of each survey. If this generic information collection request receives continued approval, information on each individual partner survey will not be published in the **Federal Register**.

A 60-day notice published in the **Federal Register** on December 15, 2020, vol. 85, No. 241; pp. 81210–11. There were no public comments.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

TOTAL ESTIMATED ANNUALIZED BURDEN—HOURS

Form name	Number of respondents	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
In-class evaluations	40,000	1	40,000	.05	2,000
Mail/Telephone surveys	12,000	1	12,000	.25	3,000
Focus groups	250	1	250	1.50	375
Total	52,250	.....	52,250	.....	5,375

HRSA specifically requests comments on (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Maria G. Button,

Director, Executive Secretariat.

[FR Doc. 2021–05349 Filed 3–15–21; 8:45 am]

BILLING CODE 4165–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Seventh Amendment to Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID–19

ACTION: Notice of amendment.

SUMMARY: The Acting Secretary issues this amendment pursuant to section 319F–3 of the Public Health Service Act to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer covered countermeasures under section VI of this Declaration.

DATES: This amendment to the Declaration is effective as of March 11, 2021.

FOR FURTHER INFORMATION CONTACT: L. Paige Ezernack, Office of the Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW, Washington, DC 20201; 202–260–0365, *paige.ezernack@hhs.gov.*

SUPPLEMENTARY INFORMATION: The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the manufacture, distribution, administration, or use of medical countermeasures (Covered Countermeasures), except for claims involving ''willful misconduct'' as defined in the PREP Act. Under the PREP Act, a Declaration may be amended as circumstances warrant.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, section 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified at 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively. Section 319F–3 of the PHS Act has been amended by the Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, enacted on March 13, 2013 and the Coronavirus Aid, Relief, and Economic Security (CARES) Act, Public Law 116–136, enacted on March 27, 2020, to expand Covered Countermeasures under the PREP Act.

On January 31, 2020, the former Secretary, Alex M. Azar II, declared a public health emergency pursuant to section 319 of the PHS Act, 42 U.S.C. 247d, effective January 27, 2020, for the entire United States to aid in the response of the nation's health care community to the COVID–19 outbreak. Pursuant to section 319 of the PHS Act, the Secretary renewed that declaration effective on April 26, 2020, July 25, 2020, October 23, 2020, and January 21, 2021.

On March 10, 2020, former Secretary Azar issued a Declaration under the PREP Act for medical countermeasures against COVID–19 (85 FR 15198, Mar. 17, 2020) (the Declaration). On April 10, the former Secretary amended the Declaration under the PREP Act to extend liability immunity to covered countermeasures authorized under the CARES Act (85 FR 21012, Apr. 15, 2020). On June 4, the former Secretary amended the Declaration to clarify that covered countermeasures under the Declaration include qualified countermeasures that limit the harm COVID–19 might otherwise cause. (85 FR 35100, June 8, 2020). On August 19, the former Secretary amended the declaration to add additional categories of Qualified Persons and amend the category of disease, health condition, or threat for which he recommended the administration or use of the Covered Countermeasures. (85 FR 52136, August 24, 2020). On December 3, 2020, the former Secretary amended the declaration to incorporate Advisory Opinions of the General Counsel interpreting the PREP Act and the Secretary's Declaration and authorizations issued by the Department's Office of the Assistant Secretary for Health as an Authority Having Jurisdiction to respond; added an additional category of qualified persons under Section V of the Declaration; made explicit that the Declaration covers all qualified pandemic and epidemic products as defined under the PREP Act; added a third method of distribution to provide liability protections for, among other things, private distribution channels; made explicit that there can be situations where not administering a covered countermeasure to a particular individual can fall within the PREP Act and the Declaration's liability protections; made explicit that there are substantive Federal legal and policy issues and interests in having a unified whole-of-nation response to the COVID–19 pandemic among Federal, state, local, and private-sector entities; revised the effective time period of the Declaration; and republished the declaration in full. (85 FR 79190, December 9, 2020). On February 2, 2021, the Acting Secretary Norris Cochran amended the Declaration to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID–19 vaccines that are covered countermeasures under the Declaration (86 FR 7872, February 2, 2021). On February 16, 2021, the Acting Secretary amended the Declaration to add additional categories of Qualified Persons authorized to prescribe, dispense, and administer COVID–19 vaccines that are covered countermeasures under the Declaration (86 FR 9516, February 16, 2021) and on February 22, 2021, the Department filed a notice of correction to the February 2 and February 16 notices correcting effective dates stated in the Declaration, and correcting the description of qualified persons added by the February 16, 2021 amendment. (86 FR 10588, February 22, 2021).

The Acting Secretary now amends section V of the Declaration to revise subsection (f) to clarify that observers should be experienced in administering intramuscular injections; delete subsection (g), change the prior subsection (h) to subsection (g) and add a new subsection (h) to add additional categories of qualified persons covered under the PREP Act, and thus authorizes: (h) The following healthcare professionals and students in a healthcare profession training program subject to the requirements of this paragraph:

1. Any midwife, paramedic, advanced or intermediate emergency medical technician (EMT), physician assistant, respiratory therapist, dentist, podiatrist, optometrist or veterinarian licensed or certified to practice under the law of any state who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered;

2. Any physician, advanced practice registered nurse, registered nurse, practical nurse, pharmacist, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, respiratory therapist, dentist, physician assistant, podiatrist, optometrist, or veterinarian who has held an active license or certification under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is

administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General;

3. Any medical, nursing, pharmacy, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, physician assistant, respiratory therapy, dental, podiatry, optometry or veterinary student with appropriate training in administering vaccines as determined by his or her school or training program and supervision by a currently practicing healthcare professional experienced in administering intramuscular injections who administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered;

Subject to the following requirements:

i. The vaccine must be authorized, approved, or licensed by the FDA;

ii. Vaccination must be ordered and administered according to ACIP's COVID–19 vaccine recommendation(s);

iii. The healthcare professionals and students must have documentation of completion of the Centers for Disease Control and Prevention COVID–19 Vaccine Training Modules and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID–19 vaccines;

iv. The healthcare professionals and students must have documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering intramuscular injections is in their ordinary scope of practice, who confirms competency of the healthcare provider or student in preparation and administration of the COVID–19 vaccine(s) to be administered and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID–19 vaccines;

v. The healthcare professionals and students must have a current certificate in basic cardiopulmonary resuscitation; [1]

vi. The healthcare professionals and students must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine; and

vii. The healthcare professionals and students comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID–19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID–19 vaccine(s).

Description of This Amendment by Section

Section V. Covered Persons

Under the PREP Act and the Declaration, a ''qualified person'' is a ''covered person.'' Subject to certain limitations, a covered person is immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration or use of a covered countermeasure if a declaration under the PREP Act has been issued with respect to such countermeasure. ''Qualified person'' includes (A) a licensed health professional or other individual who is authorized to prescribe, administer, or dispense such countermeasures under the law of the State in which the countermeasure was prescribed, administered, or dispensed; or (B) ''a person within a category of persons so identified in a declaration by the Secretary'' under subsection (b) of the PREP Act. 42 U.S.C. 247d–6d(i)(8).

By this amendment to the Declaration, the Acting Secretary identifies an additional categories of persons who are qualified persons under section 247d–6d(i)(8)(B): licensed healthcare professionals who may not ordinarily prescribe, dispense or administer vaccines, additional healthcare providers with recently expired licenses, and students in a healthcare profession training program, subject to appropriate training, supervision, and other specified requirements. The Acting Secretary anticipates that significantly more vaccines will be available to the public in the spring and summer of 2021, and wants to ensure that states have the greatest flexibility in mobilizing the workforce they will need to engage in the largest vaccination effort in our Nation's history. This amendment thus expands the pool of vaccinators to individuals who have or can obtain training and the capability to administer vaccines even if prescribing, dispensing and administering vaccines is not within the scope of their license or usual responsibilities, allowing States, Territories, local areas and Tribes to use these individuals in their vaccination programs.

The Acting Secretary has determined that there is an urgent need to expand the pool of available COVID–19 vaccinators in order to respond effectively to the pandemic. As vaccine supply is made more widely available over the coming months, health care system capacity and the vaccination workforce are likely to become increasingly strained throughout the Nation.

As qualified persons, these healthcare professionals and students in healthcare profession training programs will be afforded liability protections in accordance with the PREP Act and the terms of this amended Declaration. Second, to the extent that any State law that would otherwise prohibit the healthcare professionals and students in healthcare profession training programs who are a ''qualified person'' from prescribing, dispensing, or administering COVID–19 vaccines or other Covered Countermeasures, such law is preempted. On May 19, 2020, the Office of the General Counsel issued an advisory opinion concluding that, because licensed pharmacists are

[1] This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase ''current certificate in basic cardiopulmonary resuscitation,'' when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. *See* Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021).

''qualified persons'' under this declaration, the PREP Act preempts state law that would otherwise prohibit such pharmacists from ordering and administering authorized COVID–19 diagnostic tests.[2] The opinion relied in part on the fact that the Congressional delegation of authority to the Secretary under the PREP Act to specify a class of persons, beyond those who are authorized to administer a covered countermeasure under State law, as ''qualified persons'' would be rendered a nullity in the absence of such preemption. This opinion is incorporated by reference into this declaration. Based on the reasoning set forth in the May 19, 2020 advisory opinion, any State law that would otherwise prohibit a member of any of the classes of ''qualified persons'' specified in this declaration from administering a covered countermeasure is likewise preempted. In accordance with section 319F–3(i)(8)(A) of the Public Health Service Act, a State remains free to expand the universe of individuals authorized to administer covered countermeasures within its jurisdiction under State law.

The plain language of the PREP Act makes clear that there is preemption of state law as described above. Furthermore, preemption of State law is justified to respond to the nation-wide public health emergency caused by COVID–19 as it will enable States to quickly expand the vaccination workforce with additional qualified healthcare professionals where State or local requirements might otherwise inhibit or delay allowing these healthcare professionals to participate in the COVID–19 vaccination program.

Amendments to Declaration

Amended Declaration for Public Readiness and Emergency Preparedness Act Coverage for medical countermeasures against COVID–19.

Section V of the March 10, 2020 Declaration under the PREP Act for medical countermeasures against COVID–19, as amended April 10, 2020, June 4, 2020, August 19, 2020, as amended and republished on December 3, 2020, and as amended on February 2, 2021, is further amended pursuant to section 319F–3(b)(4) of the PHS Act as described below. All other sections of the Declaration remain in effect as republished at 85 FR 79190 (December 9, 2020).

1. Covered Persons, section V, delete in full and replace with:

V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are ''manufacturers,'' ''distributors,'' ''program planners,'' ''qualified persons,'' and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States. ''Order'' as used herein and in guidance issued by the Office of the Assistant Secretary for Health [3] means a provider medication order, which includes prescribing of vaccines, or a laboratory order, which includes prescribing laboratory orders, if required. In addition, I have determined that the following additional persons are qualified persons:

(a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in Section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an Emergency, as that term is defined in Section VII of this Declaration; [4]

(b) Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with Section 564 of the FD&C Act;

(c) Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act;

(d) A State-licensed pharmacist who orders and administers, and pharmacy interns who administer (if the pharmacy intern acts under the supervision of such pharmacist and the pharmacy intern is licensed or registered by his or her State board of pharmacy),[5] (1) vaccines that the Advisory Committee on Immunization Practices (ACIP) recommends to persons ages three through 18 according to ACIP's standard immunization schedule or (2) FDA authorized or FDA licensed COVID–19 vaccines to persons ages three or older. Such State-licensed pharmacists and the State-licensed or registered interns under their supervision are qualified persons only if the following requirements are met:

i. The vaccine must be authorized, approved, or licensed by the FDA;

ii. In the case of a COVID–19 vaccine, the vaccination must be ordered and administered according to ACIP's COVID–19 vaccine recommendation(s);

[2] Department of Health and Human Services General Counsel Advisory Opinion on the Public Readiness and Emergency Preparedness Act, May 19, 2020, available at: *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-advisory-opinion-hhs-ogc.pdf/* (last visited Jan. 24, 2021). *See also,* Department of Justice Office of Legal Counsel Advisory Opinion for Robert P. Charrow, General Counsel of the Department of Health and Human Services, January 12, 2021, available at: *https://www.justice.gov/sites/default/files/opinions/attachments/2021/01/19/2021-01-19-prep-act-preemption.pdf* (last visited Jan. 24, 2021).

[3] *See* Guidance for Licensed Pharmacists, COVID–19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf* (last visited Jan. 24, 2021); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021).

[4] *See, e.g.,* Guidance for Licensed Pharmacists, COVID–19 Testing, and Immunity Under the PREP Act, OASH, Apr. 8, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for COVID–19 Screening Tests at Nursing Homes, Assisted-Living Facilities, Long-Term-Care Facilities, and other Congregate Facilities, OASH, Aug. 31, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/prep-act-coverage-for-screening-in-congregate-settings.pdf* (last visited Jan. 24, 2021); Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021); PREP Act Authorization for Pharmacies Distributing and Administering Certain Covered Countermeasures, Oct. 29, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-authorization-pharmacies-administering-covered-countermeasures.pdf* (last visited Jan. 24, 2021) (collectively, OASH PREP Act Authorizations). Nothing herein shall suggest that, for purposes of the Declaration, the foregoing are the only persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction.

[5] Some states do not require pharmacy interns to be licensed or registered by the state board of pharmacy. As used herein, ''State-licensed or registered intern'' (or equivalent phrases) refers to pharmacy interns authorized by the state or board of pharmacy in the state in which the practical pharmacy internship occurs. The authorization can, but need not, take the form of a license from, or registration with, the State board of pharmacy. *See* Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020 at 2, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021).

iii. In the case of a childhood vaccine, the vaccination must be ordered and administered according to ACIP's standard immunization schedule;

iv. The licensed pharmacist must have completed the immunization training that the licensing State requires for pharmacists to order and administer vaccines. If the State does not specify training requirements for the licensed pharmacist to order and administer vaccines, the licensed pharmacist must complete a vaccination training program of at least 20 hours that is approved by the Accreditation Council for Pharmacy Education (ACPE) to order and administer vaccines. Such a training program must include hands on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

v. The licensed or registered pharmacy intern must complete a practical training program that is approved by the ACPE. This training program must include hands-on injection technique, clinical evaluation of indications and contraindications of vaccines, and the recognition and treatment of emergency reactions to vaccines;

vi. The licensed pharmacist and licensed or registered pharmacy intern must have a current certificate in basic cardiopulmonary resuscitation; [6]

vii. The licensed pharmacist must complete a minimum of two hours of ACPE-approved, immunization-related continuing pharmacy education during each State licensing period;

viii. The licensed pharmacist must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine;

ix. The licensed pharmacist must inform his or her childhood-vaccination patients and the adult caregiver accompanying the child of the importance of a well-child visit with a pediatrician or other licensed primary care provider and refer patients as appropriate; and

x. The licensed pharmacist and the licensed or registered pharmacy intern must comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID–19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID–19 vaccine(s).

(e) Healthcare personnel using telehealth to order or administer Covered Countermeasures for patients in a state other than the state where the healthcare personnel are licensed or otherwise permitted to practice. When ordering and administering Covered Countermeasures by means of telehealth to patients in a state where the healthcare personnel are not already permitted to practice, the healthcare personnel must comply with all requirements for ordering and administering Covered Countermeasures to patients by means of telehealth in the state where the healthcare personnel are permitted to practice. Any state law that prohibits or effectively prohibits such a qualified person from ordering and administering Covered Countermeasures by means of telehealth is preempted.[7] Nothing in this Declaration shall preempt state laws that permit additional persons to deliver telehealth services;

(f) Any healthcare professional or other individual who holds an active license or certification permitting the person to prescribe, dispense, or administer vaccines under the law of any State as of the effective date of this amendment, or as authorized under the section V(d) of this Declaration, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies, other than the State in which the license or certification is held, in association with a COVID–19 vaccination effort by a federal, State, local Tribal or territorial authority or by an institution in the State in which the COVID–19 vaccine covered countermeasure is administered, so long as the license or certification of the healthcare professional has not been suspended or restricted by any licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General, subject to: (i) Documentation of completion of the Centers for Disease Control and Prevention COVID–19 (CDC) Vaccine Training Modules [8] and, for healthcare providers who are not currently practicing, documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering intramuscular injections is in their ordinary scope of practice, who confirms competency of the healthcare provider in preparation and administration of the COVID–19 vaccine(s) to be administered;

(g) Any member of a uniformed service (including members of the National Guard in a Title 32 duty status) (hereafter in this paragraph ''service member'') or Federal government, employee, contractor, or volunteer who prescribes, administers, delivers, distributes or dispenses a Covered Countermeasure. Such Federal government service members, employees, contractors, or volunteers are qualified persons if the following requirement is met: the executive department or agency by or for which the Federal service member, employee, contractor, or volunteer is employed, contracts, or volunteers has authorized or could authorize that service member, employee, contractor, or volunteer to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure as any part of the duties or responsibilities of that service member, employee, contractor, or volunteer, even if those authorized duties or responsibilities ordinarily would not extend to members of the

[6] This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase ''current certificate in basic cardiopulmonary resuscitation,'' when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. *See* Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021).

[7] *See, e.g.,* Advisory Opinion 20–02 on the Public Readiness and Emergency Preparedness Act and the Secretary's Declaration under the Act, May 19, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/advisory-opinion-20-02-hhs-ogc-prep-act.pdf* (last visited Jan. 24, 2021).

[8] *See* COVID–19 Vaccine Training Modules, available at *https://www.cdc.gov/vaccines/covid-19/training.html.*

public or otherwise would be more limited in scope than the activities such service member, employees, contractors, or volunteers are authorized to carry out under this declaration; and

(h) The following healthcare professionals and students in a healthcare profession training program subject to the requirements of this paragraph:

1. Any midwife, paramedic, advanced or intermediate emergency medical technician (EMT), physician assistant, respiratory therapist, dentist, podiatrist, optometrist or veterinarian licensed or certified to practice under the law of any state who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered;

2. Any physician, advanced practice registered nurse, registered nurse, practical nurse, pharmacist, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, respiratory therapist, dentist, physician assistant, podiatrist, optometrist, or veterinarian who has held an active license or certification under the law of any State within the last five years, which is inactive, expired or lapsed, who prescribes, dispenses, or administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered, so long as the license or certification was active and in good standing prior to the date it went inactive, expired or lapsed and was not revoked by the licensing authority, surrendered while under suspension, discipline or investigation by a licensing authority or surrendered following an arrest, and the individual is not on the List of Excluded Individuals/Entities maintained by the Office of Inspector General;

3. Any medical, nursing, pharmacy, pharmacy intern, midwife, paramedic, advanced or intermediate EMT, physician assistant, respiratory therapy, dental, podiatry, optometry or veterinary student with appropriate training in administering vaccines as determined by his or her school or training program and supervision by a currently practicing healthcare professional experienced in administering intramuscular injections who administers COVID–19 vaccines that are Covered Countermeasures under section VI of this Declaration in any jurisdiction where the PREP Act applies in association with a COVID–19 vaccination effort by a State, local, Tribal or territorial authority or by an institution in which the COVID–19 vaccine covered countermeasure is administered;

Subject to the following requirements:

i. The vaccine must be authorized, approved, or licensed by the FDA;

ii. Vaccination must be ordered and administered according to ACIP's COVID–19 vaccine recommendation(s);

iii. The healthcare professionals and students must have documentation of completion of the Centers for Disease Control and Prevention COVID–19 Vaccine Training Modules and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID–19 vaccines;

iv. The healthcare professionals and students must have documentation of an observation period by a currently practicing healthcare professional experienced in administering intramuscular injections, and for whom administering vaccinations is in their ordinary scope of practice, who confirms competency of the healthcare provider or student in preparation and administration of the COVID–19 vaccine(s) to be administered and, if applicable, such additional training as may be required by the State, territory, locality, or Tribal area in which they are prescribing, dispensing, or administering COVID–19 vaccines;

v. The healthcare professionals and students must have a current certificate in basic cardiopulmonary resuscitation; [9]

vi. The healthcare professionals and students must comply with recordkeeping and reporting requirements of the jurisdiction in which he or she administers vaccines, including informing the patient's primary-care provider when available, submitting the required immunization information to the State or local immunization information system (vaccine registry), complying with requirements with respect to reporting adverse events, and complying with requirements whereby the person administering a vaccine must review the vaccine registry or other vaccination records prior to administering a vaccine; and

vii. The healthcare professionals and students comply with any applicable requirements (or conditions of use) as set forth in the Centers for Disease Control and Prevention (CDC) COVID–19 vaccination provider agreement and any other federal requirements that apply to the administration of COVID–19 vaccine(s).

Nothing in this Declaration shall be construed to affect the National Vaccine Injury Compensation Program, including an injured party's ability to obtain compensation under that program. Covered countermeasures that are subject to the National Vaccine Injury Compensation Program authorized under 42 U.S.C. 300aa–10 *et seq.* are covered under this Declaration for the purposes of liability immunity and injury compensation only to the extent that injury compensation is not provided under that Program. All other terms and conditions of the Declaration apply to such covered countermeasures.

2. Effective Time Period, section XII, delete in full and replace with:

Liability protections for any respiratory protective device approved by NIOSH under 42 CFR part 84, or any successor regulations, through the means of distribution identified in Section VII(a) of this Declaration, begin on March 27, 2020 and extend through October l, 2024.

Liability protections for all other Covered Countermeasures identified in Section VI of this Declaration, through means of distribution identified in Section VII(a) of this Declaration, begin on February 4, 2020 and extend through October l, 2024.

Liability protections for all Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction, as

[9] This requirement is satisfied by, among other things, a certification in basic cardiopulmonary resuscitation by an online program that has received accreditation from the American Nurses Credentialing Center, the ACPE, or the Accreditation Council for Continuing Medical Education. The phrase ''current certificate in basic cardiopulmonary resuscitation,'' when used in the September 3, 2020 or October 20, 2020 OASH authorizations, shall be interpreted the same way. *See* Guidance for Licensed Pharmacists and Pharmacy Interns Regarding COVID–19 Vaccines and Immunity under the PREP Act, OASH, Sept. 3, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//licensed-pharmacists-and-pharmacy-interns-regarding-covid-19-vaccines-immunity.pdf* (last visited Jan. 24, 2021); Guidance for PREP Act Coverage for Qualified Pharmacy Technicians and State-Authorized Pharmacy Interns for Childhood Vaccines, COVID–19 Vaccines, and COVID–19 Testing, OASH, Oct. 20, 2020, available at *https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents//prep-act-guidance.pdf* (last visited Jan. 24, 2021).

identified in Section VII(b) of this Declaration, begin with a Declaration of Emergency as that term is defined in Section VII (except that, with respect to qualified persons who order or administer a routine childhood vaccination that ACIP recommends to persons ages three through 18 according to ACIP's standard immunization schedule, liability protections began on August 24, 2020), and last through (a) the final day the Declaration of Emergency is in effect, or (b) October l, 2024, whichever occurs first.

Liability protections for all Covered Countermeasures identified in Section VII(c) of this Declaration begin on December 9, 2020 and last through (a) the final day the Declaration of Emergency is in effect, or (b) October l, 2024, whichever occurs first.

Liability protections for Qualified Persons under section V(f) of the declaration begin on February 2, 2021, and last through October 1, 2024.

Liability protections for Qualified Persons under section V(g) of the declaration begin on February 16, 2021, and last through October 1, 2024.

Liability protections for Qualified Persons who are physicians, advanced practice registered nurses, registered nurses, or practical nurses under section V(h) of the declaration begins on February 2, 2021 and last through October 1, 2024, with additional conditions effective as of March 11, 2021 and liability protections for all other Qualified persons under section V(h) begins on March 11, 2021 and last through October 1, 2024.

Authority: 42 U.S.C. 247d–6d.

Norris Cochran,

Acting Secretary, Department of Health and Human Services.

[FR Doc. 2021–05401 Filed 3–11–21; 4:15 pm]

BILLING CODE 4150–37–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Dental & Craniofacial Research; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE OF DENTAL & CRANIOFACIAL RESEARCH, including consideration of personnel qualifications and performance, and the competence of individual investigators, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Board of Scientific Counselors, National Institute of Dental and Craniofacial Research.

Date: May 18–19, 2021.

Time: 9:00 a.m. to 4:15 p.m.

Agenda: To review and evaluate personnel qualifications and performance, and competence of individual investigators.

Place: National Institutes of Health, 6701 Democracy Blvd., Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Alicia J. Dombroski, Ph.D., Director, Division of Extramural Activities, Natl Inst of Dental and Craniofacial Research, National Institutes of Health, Bethesda, MD 20892.

(Catalogue of Federal Domestic Assistance Program No. 93.121, Oral Diseases and Disorders Research, National Institutes of Health, HHS)

Dated: March 10, 2021.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2021–05351 Filed 3–15–21; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0046]

Agency Information Collection Activities; Extension, Without Change, of a Currently Approved Collection: Interagency Alien Witness and Informant Record

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.,* the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until May 17, 2021.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0046 in the body of the letter, the agency name and Docket ID USCIS–2006–0062. Submit comments via the Federal eRulemaking Portal website at *https://www.regulations.gov* under e-Docket ID number USCIS–2006–0062. USCIS is limiting communications for this Notice as a result of USCIS' COVID–19 response actions.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Samantha Deshommes, Chief, telephone number (240) 721–3000 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS website at *https://www.uscis.gov,* or call the USCIS Contact Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments

You may access the information collection instrument with instructions or additional information by visiting the Federal eRulemaking Portal site at: *https://www.regulations.gov* and entering USCIS–2006–0062 in the search box. All submissions will be posted, without change, to the Federal eRulemaking Portal at *https://www.regulations.gov,* and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *https://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

EXHIBIT K

DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

The General Counsel
Washington, D.C. 20201

August 14, 2020

Thomas Barker
Foley Hoag LLP
1717 K Street, N.W.
Washington, DC 20006-5350

Dear Mr. Barker: Tom,

Thank you for your July 20, 2020 letter seeking confirmation that senior living communities are "covered persons" under the Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d, (the PREP Act) when performing certain functions during this declared emergency.

For the reasons set forth below, we conclude that senior living communities are "covered persons" under the PREP Act when they provide a facility to administer or use a covered countermeasure in accordance with the Secretary's March 10, 2020 Declaration under the PREP Act. *See* 85 Fed. Reg. 15,198 (March 17, 2020) (Declaration).[1]

Under the PREP Act and the Declaration, "covered persons," when used with respect to the administration or use of a covered countermeasure, "include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees." *Id.* at 151,199; *see also* 42 U.S.C. § 247d-6d(i)(2). The statute defines "program planner" as a

> State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b).

42 U.S.C. § 247d-6d(i)(6).

[1] This letter addresses only whether senior living communities can be "covered persons." To receive PREP Act immunity, the covered person must satisfy other requirements of the PREP Act and the Secretary's declaration under the Act.

The Declaration incorporates this definition, and its preamble explains that a program planner can be a "private sector employer or community group" that "carries out the described activities." 85 Fed. Reg. at 15,201. Thus, a senior living community meets the definition of a "program planner" to the extent that it supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including by "provid[ing] a facility to administer or use a Covered Countermeasure in accordance with" the Declaration.

This letter sets forth the current views of the Office of the General Counsel.[2] It is not a final agency action or a final order. Nor does it bind HHS or the federal courts. It does not have the force or effect of law.[3]

Sincerely yours,

Robert P. Charrow
General Counsel

[2] *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647-48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 ("The head of an executive department . . . may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]").

[3] It is possible that a senior living community could also be a "qualified person." Under the PREP Act, "qualified person" includes a "person within a category of persons so identified in" a PREP Act declaration. 42 U.S.C. § 247d-6d(i)(8). The Declaration defined "qualified person" to include "[a]ny person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction...to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors, and volunteers." 85 Fed. Reg. at 15,201-15,202. To the extent a senior living community were so authorized, it could be a qualified person.

EXHIBIT L

ADVISORY OPINION 21-01 ON THE PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT SCOPE OF PREEMPTION PROVISION JANUARY 8, 2021

Following the issuance by the Secretary on December 3, 2020, of the Fourth Amendment to his Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19, we have received questions as to whether the PREP Act applies where a covered person declined to use a covered countermeasure when it arguably ought to have been used.[1] *See* 85 Fed. Reg. 79,190 (Dec. 9, 2020). These inquiries were stimulated, as we understand, by a spate of recent lawsuits, most involving nursing homes and other healthcare facilities, where patients or their estates allege that patients contracted COVID-19 because the facility, among other things, failed to provide its staff with personal protective equipment ("PPE"), failed to teach the staff how to properly use that equipment, or failed to ensure that its staff used the PPE that it had been given. This Advisory Opinion addresses these questions in the context of our administration of the PREP Act and the Secretary's PREP Act Declaration, as amended.

I. Analysis

There has been a growing number of suits related to the use or non-use of covered countermeasures against COVID-19, including PPE. These cases tend to be filed in state courts alleging a variety of state law-based torts. In this "jurisprudential Kabuki dance" (*Maine Public Utilities Com'n v. F.E.R.C.*, 625 F.3d 754, 758 (D.C. Cir. 2010)), defendants file removal petitions and plaintiffs respond with remand motions. To resolve the remand motions, courts first assess whether the doctrine of complete preemption applies. Ordinary preemption is a defense and does not support Article III subject matter jurisdiction (usually under 28 U.S.C. § 1331), a prerequisite for removal. *See Merrell Dow Pharmaceuticals v. Thompson*, 478 U.S. 804 (1986). In contrast, complete preemption is "really a jurisdictional rather than a preemption doctrine, [as it] confers exclusive federal jurisdiction in certain instances where Congress intended the scope of a federal law to be so broad as to entirely replace any state-law claim." *Marin General Hosp. v. Modesto & Empire Traction Co.*, 581 F.3d 941, 945 (9th Cir. 2009) (quoting *Franciscan Skemp Healthcare, Inc. v. Cent. States Joint Bd. Health & Welfare Trust Fund*, 538 F.3d 594, 596 (7th Cir. 2008) (internal quotations omitted). Relatively few statutes completely preempt.

[1] The PREP Act is the Public Readiness and Emergency Preparedness Act, Pub. L. No. 109-148, div. C, § 2, 119 Stat. 2818 (Dec. 30, 2005), codified at 42 U.S.C. §§ 247d-6d, 247d-6e. It has been amended through the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013, Pub. L. No. 113–5, title IV, § 402(g)(2), (3), 127 Stat. 196 (Mar. 13, 2013) and further amended by § 6005 of the Families First Coronavirus Response Act, Pub. L. No. 116-127, 134 Stat. 177 (March 18, 2020) and § 3103 of the Coronavirus Aid Relief, and Economic Security Act, Pub. L. No. 116-136, 134 Stat. 281 (March 27, 2020).

A. The PREP Act is a "Complete Preemption" Statute

The Supreme Court first articulated the doctrine of complete preemption as a basis for federal question removal jurisdiction under 28 U.S.C. § 1441(a) in *Avco Corp. v. Aero Lodge No. 735, Intern. Ass'n of Machinists and Aerospace Workers*, 390 U.S. 557, 559 (1968) (holding that the Labor Management Relations Act, 1947 completely preempted state court jurisdiction). Thereafter, the doctrine was extended to the Employee Retirement Income Security Act of 1974 in 1987, the National Bank Act in 2003, and the Air Transportation Safety and System Stability Act in 2005. *See Metropolitan Life Insurance Co. v. Taylor*, 481 U.S. 58 (1987) (ERISA completely preempts state law); *Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004) (the same); *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 7–11 (2003) (National Bank Act completely preeempts); *In re WTC Disaster Site*, 414 F.3d 352, 375 (2d Cir. 2005) (Air Transportation Safety and System Stability Act completely preempted state claims and ousted state courts of jurisdiction by creating an exclusive federal cause of action). The *sine qua non* of a statute that completely preempts is that it establishes either a federal cause of action, administrative or judicial, as the only viable claim or vests exclusive jurisdiction in a federal court. The PREP Act does both.

Once complete preemption attaches, the district court is usually obligated to dismiss the case as pleaded, either because no federal cause of action is alleged or the exclusive initial venue is a federal administrative agency.

All that is well and good, but it does not address the issue that appears to have perplexed district courts, namely when is the PREP Act triggered. District courts appear to have labored hard attempting to ordain whether the non-use of a covered countermeasure triggers the PREP Act and its complete preemption regime. At one extreme, plaintiff may have pleaded that the facility failed *in toto* to provide any of its staff or patients with any PPE, a covered countermeasure if NIOSH approved or FDA cleared or waived. Other plaintiffs allege that the quantity of PPE was inadequate, that staff were not timely provided PPE or that staff were not adequately trained to use PPE. The latter three complaints reflect many of the complaints that we have reviewed.

The PREP Act's immunity provision, which triggers exclusive federal jurisdiction, states as follows:

> Subject to the other provisions of this section, a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure if a declaration under subsection (b) has been issued with respect to such countermeasure.

Public Health Service Act § 319F-3(a)(1), 42 U.S.C. § 247d-6d(a)(1) (emphasis supplied).

The PREP Act goes on to provide that its immunity

> applies to any claim for loss that has a causal relationship with the administration to or use by an individual of a covered countermeasure, including a causal

> relationship with the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, or use of such countermeasure.

Id. at § 319F-3(a)(2)(B), 42 U.S.C. § 247d-6d(a)(2)(B) (emphasis supplied).

Some district courts have interpreted the scope of the immunity in subparagraph (B) as requiring "use." Under this view, if a covered countermeasure were not used, then there is no PREP Act immunity. According to one court, "[t]here is simply no room to read [the PREP Act] as equally applicable to the non-administration or non-use of a covered countermeasure." *Lutz v. Big Blue Healthcare, Inc*., ___F. Supp. 3d ___, 2020 WL 4815100, at *8 (D. Kan. 2020) (emphasis in original) (granted remand motion).

However, this "black and white" view clashes with the plain language of the PREP Act, which extends immunity to anything "relating to" the administration of a covered countermeasure. For example, consider a situation where there is only one dose of a COVID–19 vaccine,[2] and a person in a vulnerable population and a person in a less vulnerable population both request it from a healthcare professional. In that situation, the healthcare professional administers the one dose to the person who is more vulnerable to COVID–19. In that circumstance, the failure to administer the COVID–19 vaccine to the person in a less-vulnerable population "relat[es] to . . . the administration to" the person in a vulnerable population. The person in the vulnerable population was able to receive the vaccine only because it was not administered to the person in the less-vulnerable population. Prioritization or purposeful allocation of a Covered Countermeasure, particularly if done in accordance with a public health authority's directive, can fall within the PREP Act and this Declaration's liability protections. There can potentially be other situations where a conscious decision not to use a covered countermeasure could relate to the administration of the countermeasure. In contrast, the failure to purchase any PPE, if not the outcome of some form of decision-making process may not be sufficient to trigger the PREP Act.

Where a facility has been allocated a scarce therapeutic purchased by the federal government and that facility fails to administer that therapeutic to an individual who meets the requirements of the FDA's authorization, approval, or license, and whose physician prescribes that therapeutic, then the facility's refusal to administer that therapeutic could still trigger the PREP Act assuming the non-use of the therapeutic was the result of conscious decision-making. However, the facility may still be liable under the PREP Act, if the plaintiff alleges that the decision to deny him or her the therapeutic was wanton and willful and resulted in death or serious injury. *See* 42 U.S.C. § 247d-6d(d)-(e). Such a case would be transferred to the District Court for the District of Columbia for resolution by a three-judge panel. The facility may also be subject to a federal enforcement action.

[2] For simplicity, this example assumes a patient only requires one dose of the vaccine.

The language of the PREP Act itself supports a distinction between allocation which results in non-use by some individuals, on the one hand, and nonfeasance, on the other hand, that also results in non-use.

Included within the set of "covered persons," *i.e.*, those entitled to immunity, are "program planners." 42 U.S.C. § 247d-6d(i)(2)(B)(iii). A "program planner" is

> a State or local government, including an Indian tribe, a person employed by the State or local government, or other person who supervised or administered a program with respect to the administration, dispensing, distribution, provision, or use of a security countermeasure or a qualified pandemic or epidemic product, including a person who has established requirements, provided policy guidance, or supplied technical or scientific advice or assistance or provides a facility to administer or use a covered countermeasure in accordance with a declaration under subsection (b).

Id. at § 247d-6d(i)(6).

A program planner is someone who is involved in providing or allocating covered countermeasures. Program planning inherently involves the allocation of resources and when those resources are scarce, some individuals are going to be denied access to them. Therefore, decision-making that leads to the non-use of covered countermeasures by certain individuals is the grist of program planning, and is expressly covered by PREP Act

There are going to be circumstances where plaintiff pleads that defendant's culpability is the result of its failure to make any decisions whatsoever, thereby abandoning its duty to act as a program planner or other covered person. Although this is a small hole through which to wiggle to avoid complete preemption, we are confident, were it not for two legal constraints, that it would grow as plaintiffs become more adept at fashioning their pleadings. However, "complete preemption . . . functions as an exception to the well-pleaded complaint rule." *Giles v. NYLCare Health Plans, Inc.*, 172 F.3d 332, 336 (5th Cir. 1999). Thus, federal courts are free to entertain discovery to ascertain, for jurisdictional purposes, the facts underlying the complaint. *See United Surgical Assistants, LLC v. Aetna Life Ins. Co.*, 2014 WL 4059889, at *1 (M.D. Fla. Aug. 14, 2014) (allowing jurisdictional discovery on whether plaintiff's claim was completely preempted by ERISA).

B. Fourth Amendment to the Secretary's Declaration Supports the *Grable* Doctrine

In addition to complete preemption as the basis for article III jurisdiction and removal, the Court recognized a separate doctrine in *Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg.*, 545 U.S. 308 (2005). Under *Grable*, even in the absence of a claim arising under federal law, "a federal court ought to be able to hear claims recognized under state law that nonetheless turn on substantial questions of federal law, and thus justify resort to the experience, solicitude, and hope of uniformity that a federal forum offers on federal issues." *Grable & Sons Metal Products, Inc. v. Darue Engineering & Mfg.*, 545 U.S. 308, 312 (2005) (emphasis supplied). Thus, a substantial federal question is implicated, for example, where "the

interpretation of a federal statute [ ] actually is in dispute in the litigation and is so important that it sensibly belongs in federal court." 545 U.S. at 315. Here, ordaining the metes and bounds of PREP Act protection in the context of a national health emergency necessarily means that the case belongs in federal court. The Secretary, in his Fourth Amendment to his PREP Declaration, similarly concluded, when he stated that

> [t]here are substantial federal legal and policy issues, and substantial federal legal and policy interests within the meaning of *Grable & Sons Metal Products, Inc. v. Darue Eng'g. & Mf'g.*, 545 U.S. 308 (2005), in having a unified, whole-of-nation response to the COVID–19 pandemic among federal, state, local, and private-sector entities.

85 Fed. Reg. at 79,197 (col. c).

See also 42 U.S.C. § 247d-6d(b)(7) ("No court of the United States, or of any State, shall have subject matter jurisdiction to review, whether by mandamus or otherwise, any action by the Secretary under this subsection."). As such, the secretarial determination provides the underlying basis for invoking the *Grable* doctrine with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or the use by an individual of a covered countermeasure. Once invoked, the court retains the case to decide whether the immunity and preemption provisions apply; if they do not apply, then the court would try the case as it would a diversity case. If the court finds, though, that the PREP Act applies, it would dismiss the case or if death or serious physical injury proximately caused by willful misconduct is alleged, transfer it to the District Court for the District of Columbia. *See* 42 U.S.C. § 247d-6d(d)-(e).

II. Limitations

This Advisory Opinion may be supplemented or modified. It is intended to minimize the need for individual advisory opinions. This Advisory Opinion sets forth the current views of the Office of the General Counsel.[3] It is not a final agency action or a final order. It does not have the force or effect of law.

Robert P. Charrow

Robert P. Charrow
General Counsel
January 8, 2021

[3] *See Air Brake Sys., Inc. v. Mineta*, 357 F.3d 632, 647–48 (6th Cir. 2004) (holding that the Chief Counsel of the National Highway Traffic Safety Administration had delegated authority to issue advisory opinions to regulated entities in fulfillment of a congressional directive to promote regulatory compliance); 5 U.S.C. § 301 ("The head of an executive department . . . may prescribe regulations for the government of his department, the conduct of its employees, [and] the distribution and performance of its business[.]"); *Statement of Organization, Functions, and Delegations of Authority*, 85 Fed. Reg. 54,581, 54,583 (Sept. 2, 2020).