California Department of Public Health
Center for Health Care Quality
AFC Skilled Nursing Facilities Infection Prevention Call
September 29 & 30, 2021

Recordings, notes and slides for the Wednesday Webinars and Thursday calls can be accessed at the Health Services Advisory Group (HSAG) registration website:
https://www.hsag.com/en/covid-19/long-term-care-facilities/cdph-ip-webinars-past/

CDPH Weekly Call-in Information:
Tuesday 8:00am All Facilities Calls: 844.721.7239; Access code: 7993227
Wednesday 3:00pm SNF Infection Prevention Webinars: Register at: https://www.hsag.com/cdph-ip-webinars
Thursday 12:00pm SNF Infection Prevention Calls: 877.226.8163; Access code: 513711

The Wednesday Webinar presentation covered:

- CDPH Updates
- Testing Task Force Updates
- Immunization Branch Update
- Monoclonal Antibody Update
- National Healthcare Safety Network (NHSN) Vaccine Reporting Updates
- Healthcare-associated Infections (HAI) Updates
- Q&A

Important Links to State and Federal Guidance	
Important Links and FAQs to State Guidance	https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Guidance.aspx
September 9, 2021 CMS Press Release to expand vaccination requirements.	https://www.cms.gov/newsroom/press-releases/biden-harris-administration-expand-vaccination-requirements-health-care-settings
August 18, 2021 CMS Press Release: Regarding Requiring Staff Vaccinations within Nursing Homes	https://www.cms.gov/newsroom/press-releases/biden-harris-administration-takes-additional-action-protect-americas-nursing-home-residents-covid-19
August 5, 2021 State Public Health Officer Order: Health Care Worker Vaccine Requirement Q&A	https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx
August 5, 2021 State Public Health Officer Order: Requirements for Visitors in Acute Health Care and Long-Term Care Settings	https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Order-of-the-State-Public-Health-Officer-Requirements-for-Visitors-in-Acute-Health-Care-and-Long-Term-Care-Settings-FAQ.aspx
July 26, 2021 State Public Health Officer Order: Health Care Worker Protections in High-Risk Settings Q&A	https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/Unvaccinated-Workers-in-High-Risk-Settings-State-Public-Health-Order-FAQ.aspx
CDPH AFL 21-28: Testing, Vaccination Verification and PPE for HCP at SNFs	https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-21-28.aspx
CDPH AFL 20-22.9: Guidance for Limiting the Transmission of COVID-19 in SNFs	https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-22.aspx
CDPH AFL 20-53.5: Mitigation Plan Recommendations for Testing	https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-53.aspx
CDPH AFL 21-08.4: Guidance on Quarantine for HCP Exposed to COVID-19	https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-21-08.aspx
CDPH AFL 21-34: COVID-19 Vaccine Requirement for HCP	https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-21-34.aspx

CDC: Interim Infection Prevention and Control Recommendations to Prevent SARS-CoV-2 Spread in Nursing Homes	https://www.cdc.gov/coronavirus/2019-ncov/hcp/long-term-care.html
CMS QSO-20-38-NH: Revision to Long-Term Care (LTC) Facility Testing Requirements	https://www.cms.gov/files/document/qso-20-38-nh-revised.pdf
CDPH AFL 21-37: (NEW): BYD Field Action Notification	https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-21-37.aspx

Updated Guidance on September 30, 2021 Vaccination Deadline

The information shared regarding the September 30, 2021 vaccination deadline in the last two weeks reflected preliminary approaches under consideration by CDPH, not official guidance. At this time, CDPH is not issuing any additional guidance for implementing the requirements of the August 5, 2021 State Public Health Officer Order. Temporary exceptions to address staffing shortages will not be issued at this time, therefore we are not including those in these notes.
https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/COVID-19/FAQ-Health-Care-Worker-Vaccine-Requirement.aspx

Q-1: If an HCP got their second vaccine dose on September 30th, can they work on October 1st, or do they need to wait until two weeks have passed from the second dose to be fully vaccinated?
A: Since the HCP received their second dose on September 30th, they are compliant with the SPHO order, and do not have to wait until they meet the criteria of fully vaccinated to work. They can continue working but must be tested twice a week and wear appropriate source control (N95 preferred, but not required) until they meet criteria for being fully vaccinated. Consider a lower-risk assignment (e.g., not working with unvaccinated or severely immunocompromised residents who are less likely to have a robust immune response to vaccination) until the criteria for being fully vaccinated is met (but this is not a requirement).

Q-2: Regarding the SPHO order, if staff gets the first shot of the series before September 30, 2021 but have not received the second dose yet, do they need to be removed from the schedule? Or can they have a temporary medical exemption and continue to work with twice weekly testing until fully vaccinated?
A: A staff member who does not have an exemption on file and did not complete the second dose of the two-dose regimen by September 30, 2021 is not compliant with the SPHO order, and therefore is not able to work until they receive the second dose of the two-dose regimen.

Q-3: Has the HCP vaccine deadline been extended to November 30, 2021 for SNF'S? The new Health Care Order "California Extends Worker Vaccine Requirement to Protect Vulnerable Californians from COVID-19" issued on September 28, 2021 is confusing (https://www.cdph.ca.gov/Programs/OPA/Pages/NR21-289.aspx).
A: No, the vaccine deadline for nursing homes has NOT been extended. The deadline is still September 30, 2021. The health order issued on September 28, 2021 is for different settings, including adult and senior care facilities, certain persons who provide In-Home Supportive Services (IHSS), certified home care aides, and Waiver Personal Care Services (WPCS) providers, hospice workers who provide services in the home or a licensed facility, and all employees, as well as service provider workers, who provide services through the state's regional centers that serve individuals with developmental and intellectual disabilities.

Q-4: For new staff hires after September 30, 2021, do they need to prove their vaccination, or can we accept exemptions, both medical and/or religious?
A: New hires will need to meet the criteria of the State Public Health Officer Order and be fully

vaccinated before beginning to work. Medical and religious exemptions will still be accepted after September 30, 2021 for new hires.

Q-5: Will there be a new AFL distributed to clarify the staffing alternatives following the September 30, 2021 vaccine deadline?
A: No, there will not be an additional AFL being distributed. The August 5, 2021 State Public health Officer Order stands as written. In order for health care workers to continue working, they must be vaccinated by September 30, 2021, unless they have an approved exemption.

Q-6: Do we need to schedule our unvaccinated workers with medical or religious exemptions to lower risk assignments?
A: If possible, it would be a best practice to consider a lower-risk assignment (e.g., not working with unvaccinated or severely immunocompromised residents who are less likely to have a robust immune response to vaccination), but this is not a requirement.

Vaccination Questions & Answers

Q-7: What do we do if the resident does not have proof of their vaccination status? Do we need to consider them unvaccinated?
A: We recommend that residents try to obtain their vaccination status by completing the California Digital COVID-19 Vaccine Record at https://myvaccinerecord.cdph.ca.gov/. Nursing homes can also validate vaccine status for residents by utilizing the California Immunization Registry (CAIR2). CAIR2 is a secure, confidential, statewide computerized immunization information system for California residents. SNFs are encouraged to register with CAIR2 to record vaccine doses administered and get access to immunization records (such as flu, COVID-19, pneumococcal vaccine). Visit the immunization registry website to request an account with the registry that serves your county.

- **CAIR2:** Serves 49 California counties https://cairweb.org/enroll-now/
- **San Diego Regional Immunization Registry (SDIR):** http://www.sdiz.org/cair-sdir/enrollment.html
- **Healthy Futures:** Serves the San Joaquin Region, including Alpine, Amador, Calaveras, Mariposa, Merced, San Joaquin, Stanislaus, and Tuolumne counties http://www.myhealthyfutures.org/

Q-8: Do staff and residents need to receive the same booster as the first two doses they received? Some of us had Pfizer and some Moderna. Does the type of booster shot matter?
A: At this time, booster dose recommendations only apply to those who received the Pfizer vaccine as their primary series. More data on the effectiveness and safety of booster shots in people in the recommended age groups who received the Moderna or J&J/Janssen vaccine are expected in the coming weeks.

Q-9: Is it possible to get the FDA approved Comirnaty vaccine?
A: Yes, the vaccine now branded "Comirnaty" is the vaccine that we commonly call the "Pfizer Vaccine". It is the same mRNA Pfizer vaccine that many of us have already received. Please visit https://www.fda.gov/vaccines-blood-biologics/qa-comirnaty-covid-19-vaccine-mrna for more information.

Q-10: When should SNFs start booster shots?
A: The FDA and CDC have both endorsed "booster" vaccines for people who have received the Pfizer vaccine at least 6 months ago, are 65+, 18+ with underlying medical conditions, 18+ working in high risk settings, and 18+ who live in high risk settings. People meeting these criteria may receive their booster. More details here: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/booster-shot.html.

Q-11: Should a person who received one Moderna shot and one Pfizer shot receive a Booster?
A: No, since they did not receive the Pfizer as their primary series. We expect to hear more from FDA and CDC in coming weeks on mixed vaccine series.

Q-12: If our facility wants to administer boosters to residents/staff (like flu vaccine), do nurses have to undergo special training to administer the COVID vaccine?
A: CDC website has a module for "COVID-19 Vaccination Training" https://www.cdc.gov/vaccines/covid-19/training-education/index.html. CDPH also has a vaccination training: https://www.cdph.ca.gov/Programs/CID/DCDC/Pages/Immunization/COVID-19VaccineTraining.aspx. Vaccinators who do not plan on enrolling in the program to potentially receive vaccine doses and will only administer vaccine should review the technical training for new vaccinators.

Q-13: We have been getting calls from dialysis centers stating they administered the booster doses to our residents before the 6 months from their last vaccine to our residents. What do we have to do on our end if they aren't following the CDC guidance?
A: Please reach out to your local health department for assistance to the dialysis centers with education and outreach on booster dose recommendations. Some dialysis patients may have other medical conditions that are immunocompromising conditions for which the additional vaccine dose is recommended >=28 days after primary series.

Q-14: How much are the Pfizer vaccines immunity waning? What are the % after being vaccinated for 6+ months?
A: Please see this CDC info for details: www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-9-23/03-COVID-Oliver.pdf.

Q-15: Can you comment on FDA EUA on August 12 that allows an additional dose of Moderna in immunocompromised people. Are we able to follow this?
A: Yes, for immunocompromised individuals who received Moderna primary series, an additional dose of Moderna is recommended for these immunocompromised individuals.

NHSN Questions & Answers

Q-16: Is the annual NHSN survey still required?
A: From what we've heard, it is not required. However, we suggest you complete it to avoid any potential issues in the NHSN application.

Q-17: I emailed NHSN regarding Level 3 access using HSAG's instructions on 9/17, however, I haven't received an email from NHSN. What should I do?
A: Based on experience, it may take up to a week for NHSN to respond. Please contact Rose Chen from HSAG at rchen@hsag.com with your information for additional assistance.

Q-18: When we respond to the NHSN weekly report, do we answer the "qualified for booster" question with the immunocompromised # or the all over 65 and/or lives in SNF, etc. #
A: Refer to https://www.cdc.gov/vaccines/covid-19/clinical-considerations/covid-19-vaccines-us.html.

Testing Questions & Answers

Q-19: Currently, we are rapid antigen testing all 145 of our HPC with a 98.6% staff vaccination rate. Could we use a statistically meaningful sampling in lieu of 100% testing? If so, what would that sample size be?
A: Only unvaccinated HCP with exemptions are required to be tested twice a week, as long as over 70% of staff in the facility are vaccinated. For antigen testing, the testing frequency any less frequently than weekly testing is not anticipated to provide any benefit to prevent an introduction of COVID into the facility. If you're doing screening with antigen testing, we recommend twice weekly or at least once weekly.

Q-20: How often does an unvaccinated per-diem staff member with a medical exemption (only works 1-2x/week) need to be tested? Twice a week or do they only need to produce a negative test result within the last 48 hours before their shift.
A: Testing frequency guidance based on shift frequency can be found in CDPH AFL 20-53.5 (https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-20-53.aspx). For staff that work no more than one shift per week, they need to undergo weekly testing within 48 hours of their shift. If this staff member is sometimes working more than 1 shift per week, then the testing should be done twice weekly.

Q-21: If we have a staff vaccination rate below 70%, do all staff need to be tested twice a week?
A: Yes, all staff need to be tested twice weekly if the staff vaccination rate is below 70%.

Quarantine Questions & Answers

Q-22: Can you verify if the quarantine guidance for fully vaccinated residents has recently changed? Will CDPH adopt CDC guidelines from Sept 10, 2021 of response-driven testing and quarantine based on a tracer and identified exposures rather than the current one of response-drive testing and quarantine of all residents and response-driven testing of all HCWs? If so, is there an AFL that will be published?
A: Currently the CDPH guidance on quarantine has not changed. See CDPH AFL 21-08.4 for current guidance https://www.cdph.ca.gov/Programs/CHCQ/LCP/Pages/AFL-21-08.aspx. CDC has updated their guidance for SNFs and that included a recommendation for facilities to take a contact tracing-based approach to identify close contacts as opposed to the facility wide approach. CDPH is reviewing these recommendations and determining when this contact tracing approach can be considered safe. We anticipate these updates in a forthcoming AFL.

Q-23: If fully vaccinated HCP develops symptoms, no known contact, tested negative with an antigen test, pending PCR result, can they come back to work if the PCR test is negative? Or after symptoms are resolved? Or do they need to complete 14 days of quarantine?
A: With a negative PCR result the individual could come back to work from a COVID standpoint, but there may be other etiologies for their symptoms such as influenza. It would be wise to test for influenza as we are entering flu season.

PPE Questions & Answers

Q-24: What is the N95 expectation for unvaccinated HCP in non-patient care areas?
A: This is addressed in the July 26, 2021 public health order. The July 26th order includes testing and source control requirements for unvaccinated HCP. The language around N95s is that they are "strongly encouraged", which means they are not required. However, facilities must offer N95s to unvaccinated HCPs.

Visitation Questions & Answers

Q-25: What if a visitor does not have proof of vaccination with them, but we have proof that they tested positive for COVID in the last 30 days. Are they allowed to visit the facility without testing?
A: Yes, as long as they are asymptomatic. Individuals who were positive within the prior 90 days and remain asymptomatic do not need to be tested. It's prudent to ensure and maintain a copy of the documentation and ensure the person is asymptomatic.

Other Questions & Answers

Q-26: Our SNFs continue to receive Mitigation Plan inspections, with the most recent survey being done on 9/15. The SOD letter and AspenWeb identify them as such. When will they be retired?
A: A few weeks ago, we mentioned that we acknowledge that former mitigation surveys have been retired as of March 31, 2021. We've reinstated a state focused infection control survey that includes additions from the public health orders. Because it's still focused on infection control mitigation, we are looking at how we are working on mitigation moving forward. These surveys are not intended to occur on a 6–8-week cycle like they were before. The former requirement for facilities to have a stand-alone mitigation plan is not necessary, but the mitigation plan protocols are to be integrated into your longer-term infection control policies and overall emergency preparedness plan.

Q-27: Where can the PowerPoint slides from the Wednesday webinars be found?
A: Access recordings, notes, and slides at: https://www.hsag.com/en/covid-19/long-term-care-facilities/cdph-ip-webinars-past/

Anti-SARS-COV-2 Monoclonal Antibody Notes

Anti-SARS-COV-2 Monoclonal antibodies are directed against the spike protein of SARS-COV2 and are designed to block the virus' attachment and entry into human cells. Early intervention with anti-SARS-CoV-2 monoclonal antibody treatment reduces the risk of severe illness and hospitalization in high-risk patients with mild to moderate COVID-19. Additionally, monoclonal antibody treatment can be used to decrease the chances of developing COVID-19 after an infectious exposure (as a post-exposure prophylaxis) in at-risk individuals.

The currently available anti-SARS-CoV-2 monoclonal antibodies that have received Emergency Use Authorization (EUA) from the Food and Drug Administration (FDA) include:

- Casirivimab plus imdevimab (administered together as REGEN-COV), given subcutaneously or intravenously
- Bamlanivimab plus etesevimab (administered together, monotherapy with bamlanivimab alone is not authorized for use), given intravenously
- Sotrovimab, given intravenously

All three products cover current variants circulating in California.

Product	Indications	Coverage of Variants Circulating in California	Administration	Acquiring Product
Casirivimab/Imdevimab (REGEN-COV)	• Treatment of mild to moderate outpatients at risk of disease progression • Post-exposure prophylaxis in high-risk individuals	**Yes**	Intravenous; subcutaneous	Federal government allocation of products to states based on previous week indicators; state-coordinated distribution system to facilities through local MHOACs
Bamlanivimab/ Etesevimab	• Treatment of mild to moderate outpatients at risk of disease progression • Post-exposure prophylaxis in high-risk individuals	**Yes**	Intravenous	Federal government allocation of products to states based on previous week indicators; state-coordinated distribution system to facilities through local MHOACs
Sotrovimab	• Treatment of mild to moderate outpatients at risk of disease progression	**Yes**	Intravenous	Facilities may order directly from AmerisourceBergen; although announced on 9/29/2021 that federal government will be purchasing

Who is a candidate for anti-SARS-CoV-2 monoclonal antibody treatment?
The EUAs for anti-SARS-CoV-2 monoclonal antibodies are for the treatment of mild to moderate COVID-19 in adults and pediatric patients (12 years of age and older weighing at least 40 kg) with positive results of direct SARS-CoV-2 viral testing, and who are at high risk for progressing to severe COVID-19 and/or hospitalization.

Timing: The treatment should be administered as soon as possible after positive results of direct SARS-CoV2 viral testing AND within 10 days of symptom onset. The California Department of Public Health (CDPH) recommends initiating treatment as soon as the positive results have been obtained, as early treatment is expected to have the most benefit.

High-risk criteria: include older age, being overweight/obese, pregnancy, chronic kidney disease, diabetes, immunosuppression, cardiovascular disease or hypertension, chronic lung diseases, sickle cell disease, neurodevelopmental disorders, having a medical-related technological dependence, or other medical conditions or factors (for example, race or ethnicity) that may also place individual patients at high risk for progression to severe COVID-19.

Post-exposure prophylaxis: Casirivimab plus imdevimab (REGEN-COV) and bamlanivimab plus etesevimab are authorized for use as a post-exposure prophylaxis for COVID-19 in adult and pediatric individuals (12 years of age and older weighing at least 40 kg) who are at high risk for progression to severe COVID-19.

Post-exposure prophylaxis can be considered in individuals who are not fully vaccinated or individuals who are not expected to mount an adequate immune response to SARS-CoV-2 vaccination (for example, individuals with immunocompromising conditions including those taking immunosuppressive medications).

Post-exposure prophylaxis can be given to these individuals if:

1. They have been exposed to an individual infected with SARS-CoV-2 consistent with the Centers for Disease Control and Prevention (CDC) close contact criteria (less than 6 feet away from infected person for a cumulative total of 15 minutes or more over a 24-hour period); OR
2. They are at high risk of exposure to an individual infected with SARS-CoV-2 because of occurrence of SARS-CoV-2 infection in other individuals in the same institutional setting.

For individuals who have recurrent exposures for a month or more, anti-SARS-CoV-2 monoclonal antibodies can be subsequently dosed every 4 weeks for the duration of the ongoing exposure.

Activity Against Variants

Anti-SARS-COV-2 Monoclonal Antibody Therapy and Variants

Casirivimab/imdevimab [REGEN COV], bamlanivimab/etesevimab, and sotrovimab have activity against the variants currently circulating in California, including Delta. We have heard on multiple occasions that providers incorrectly believe that bamlanivimab/etesevimab is not active against the Delta variant. And we have seen allocations of bamlanivimab/etesevimab turned down because of this erroneous belief. We wanted to remind everyone that bamlanivimab/etesevimab is currently effective against the predominant Delta variants; and providers should use this therapy at this time. Given the scarce nature of anti-SARS-COV-2 monoclonal products, refusing allocation of bamlanivimab/etesevimab may result in shortages in jurisdictions.

We should note that bamlanivimab/etesevimab does have decreased effectiveness against the AY.1 and AY.2 Delta sublineages, however, at this time, these sublineages make up <1% of circulating variants in the US. At this time, Bamlanivimab/etesevimab is authorized for use by the FDA in all states, including California. This authorization for use will continue unless there is a resistant variant that has a prevalence of over 5%.

Distribution

Both Casirivimab/imdevimab or bamlanivimab/etesevimab are available free of charge to facilities. Given high demand and limited supply, the U.S. Department of Health and Human Services (HHS) transitioned distribution of these products to a state/territory-coordinated distribution system. This means that facilities cannot directly order casirivimab plus imdevimab or bamlanivimab plus etesevimab. At this time, there is no timeline for when direct ordering will be available.

Weekly distribution amounts of casirivimab plus imdevimab (REGEN-COV) and bamlanivimab plus etesevimab for each state/territory will be determined by HHS based on weekly reports of new COVID-19 cases and hospitalizations in addition to data on inventories and use submitted to the federal government.

CDPH will allocate product to local jurisdictions. Once the number of doses has been allocated, each jurisdiction's Medical and Health Operational Area Coordinator (MHOAC) will assist in determining which facilities within the jurisdiction receive product.

Previously, sotrovimab was available for purchase. We have learned on 9/29/2021 that sotrovimab is also going to be purchased by the federal government; so, we expect that HHS will soon start allocating Sotrovimab through the same system.

Reporting of Utilization of Anti-SARS-COV-2 Monoclonal Antibodies

Finally, a note on reporting use of these products. HHS monitors utilization of casirivimab/imdevimab (REGEN-COV) and bamlanivimab/etesevimab in California and, in the future, may use these calculations to determine allocation of these products to the state.
Because of this, accurate reports of utilization are an important step in ensuring an appropriate supply to the state.

Facilities using these products must make sure to report utilization, this can be done via several mechanisms depending on the facility type:

- Hospitals and hospital pharmacies are required to report via HHS Protect.
- Skilled nursing facilities can report via the National Healthcare Safety Network (NHSN)
- Non-hospital facilities such as urgent care clinics, dialysis clinics, and pharmacies must report utilization through the HHS TeleTracking COVID-19 Portal.

Full reporting details as well as a link providing detailed instructions on how to access each of these reporting tools can be found in the meeting notes.
(https://www.phe.gov/emergency/events/COVID19/investigation-MCM/Pages/COVID19-therapeutics-teletracking.aspx)

Please encourage facilities in your jurisdiction to report usage of these products. Failure to report may result in a decrease in the allocation of product to California from HHS.