

Concerns:

- **Small Numbers of Doses and Custody/Handling Requirements:** Many facilities are experiencing difficulty in accessing the small quantities of vaccine that they need. To obtain vaccine on-site, they generally must have 10 residents or staff ready to be vaccinated, but they may have only 2 or 3 consenting recipients at any one time. LTC pharmacies and other vaccine providers are unwilling to open a vial for less than the required number of doses. Many believe that they are not permitted to open a vial and transport pre-filled syringes to different facilities for small numbers of doses (we believe this is permitted). Further, LTC pharmacies and vaccine providers have been instructed that they must maintain custody of the vaccine at all times, but they do not have the staff to send to facilities to oversee or administer just a few doses of vaccine. Thus, facilities must wait until they have a critical mass of staff and residents who have consented to vaccination before they can schedule a vaccine clinic.
- **Limits on Supply:** We are hearing that the suspension of the Janssen vaccine has created a supply shortage in some areas. LTC pharmacies are cancelling previously scheduled vaccine clinics because they were relying on the Janssen vaccine for first doses.

Response: The Janssen vaccine can be used as of April 24.

- **Second Doses:** When residents are admitted having received the first dose of a 2-dose vaccine, it is difficult for nursing homes and ACFs to find that second dose of the proper product, particularly when only one or two people need it.

Response: The Department will continue to work with individual providers to eliminate barriers to vaccine access and administration. NHs should also be mindful that, if it has made diligent efforts to administer the vaccine within the required 14-day period but is unable to, the facility should maintain evidence that they have at a minimum offered the vaccine within 14 days and have made diligent attempts to vaccinate residents within the 14-day period; for example, the NH should be prepared to offer proof of outreach to its hospital or pharmacy partners requesting the specific vaccine dose needed and the date needed (within 14 days of hire, admission, or readmission), and their response.

Questions Raised by Both Nursing Homes and ACFs:

- **Timing:** Is the ACF/NH required to ensure that the resident or staff member is able to *receive* the vaccine within 7 (ACF) or 14 days (NH) of admission or hiring, or is the facility required to ensure that the opportunity is offered or an appointment scheduled within the required time frame?

Response: The regulations require that the actual vaccine be administered within 7 days for ACFs and 14 days for NHs – not merely an appointment for vaccination. More specifically:

- **FOR NHs:** In accordance with 66-4.2 Requirements for Nursing Homes, within 14 days of staff being hired or residents being admitted, every nursing home is required to offer all consenting, unvaccinated existing personnel and residents an opportunity to receive the first or any required next dose of the COVID-19 vaccine. The intent of this regulation is to get residents vaccinated, which means having the shot administered within 14 days. However, as indicated above, NHs that have made diligent efforts to administer the vaccine within the required 14-day period but are unable to, should maintain evidence that they have at a minimum offered the vaccine within 14 days and have made diligent attempts to vaccinate residents within the 14-day period; for example, the NH should be prepared to offer proof of outreach to its hospital or pharmacy partners requesting the vaccine doses needed and the date needed, and their response.

- **FOR ACFs:** Adult Care facilities are required within 7 days of hire, admission or readmission to make diligent efforts to arrange for all consenting, unvaccinated existing personnel and residents to register for a vaccine appointment within 7 days. As we have stated for the last several months, residents and personnel should be prioritized. Therefore, ACFs should make diligent efforts to secure an actual vaccination appointment for personnel and residents within 7 days of hire, admission, or readmission; in the event that is not possible and an appointment must be scheduled beyond the 7 days, the facility should document that; documentation may include, for example, a print-out of available appointment dates at time of scheduling.
- If a new resident or staff member has received a first dose prior to his/her admission or hiring and is not due for the second dose until day 15 or later after admission or hire, we assume that the facility is not required to provide a second dose prematurely to comply with the 7-day or 14-day timeline. If this is not correct, please let us know.

Response: Correct, as with any medication or vaccination, the individual who received the first dose, must follow the instructions provided at that time of the first shot irrespective of the emergency regulations. However, a facility must document the date the personnel or resident is required to get any necessary second dose, which will assist with DOH monitoring should this date fall outside of the 14-day window.

- **Declinations:** Does staff declination have to be obtained after the effective date of the new regulation or would a prior declination satisfy the requirement?

Response: Since the effective date of the regulations was April 15, 2021, declinations should be obtained on or after that date. All healthcare providers, as a best practice, should routinely assess resident and staff eligibility for and willingness to receive the COVID-19 vaccine.

- **Contract Staff:** Please define "contract staff" as used in the Vaccine Emergency Regulation. For example, would this apply to direct care contract staff only, to medical staff that round at the facility, to contractors that provide onsite services only intermittently (e.g., printer maintenance, flooring installation, HVAC maintenance)?

Response: Nursing homes and adult care facilities are responsible for ensuring that new or existing personnel, including resident-facing personnel working under a contract with the facility (which may be a contract between an employment agency or the individual provider), who are consenting and willing to be vaccinated are offered an opportunity to be vaccinated within the prescribed timeframe. For example, the term "contract staff" would apply to Medicaid staff making rounds, but not to intermittent maintenance staff who do not interact with residents.

- **Eligibility:** Some people are medically-ineligible for the vaccine. Should this be recorded differently than a general declination?

Response: Providers should not be offering any medically-ineligible individual a COVID-19 vaccination. Although a declination form would therefore not be necessary, the facility should document in the resident's or personnel's record the clinical reason for not offering the COVID-19 vaccine.

Questions Raised by Nursing Homes:

- **Complying with 14-Day Timeframes With Few New Admissions or Hires:** It is unlikely that a LTC pharmacy or other vaccine provider will be able to come to facilities within 14 days of each new admission or hire. Instead, LTC pharmacies prefer to schedule vaccine clinics at periodic intervals when a sufficient number of staff and residents are available for vaccination.
 - o If facilities are required to ensure that every resident and staff member *receives* the vaccine within 14 days of admission or hire, how should facilities ensure access within the timeframes for individual new hires and admissions?

Response: As noted above, NHs are required to ensure consenting, eligible, unvaccinated personnel and residents receive the vaccine within 14 days. Providers can utilize all tools/resources available to them in order to meet this requirement. In addition, the objective is to remove any and all barriers to accessing COVID-19 vaccinations

- o Will the Regional Hubs provide nursing homes individual doses of vaccines in pre-filled syringes, if the nursing home does not have enough residents or staff to complete an entire vial?

Response: Questions regarding processes used by regional hospital Hubs, should be directed to those specific clinical partners.

- **On-Site v. Off-Site: Must** a nursing home provide the opportunity to be vaccinated on-site, or may this opportunity be provided in community locations? Some facilities have already entered into arrangements with community vaccine providers and hospitals to schedule appointments for staff.

Response: The intent of the regulation is to provide an opportunity to all consenting and eligible individuals to access COVID-19 vaccinations as expeditiously as possible and remove any and all barriers to accessing COVID-19 vaccinations. Providers can utilize all tools/resources available to them in order to meet the regulatory requirements. Therefore, for NHs, facilities are required to ensure consenting, eligible, and unvaccinated personnel and residents receive the vaccine within 14 days. This should be on-site vaccination for both residents and personnel, to the maximum extent possible. However, a NH may offer residents and personnel opportunities to receive vaccine from an off-site location, including but not limited to a LHD, State-operated mass vaccination site, FEMA-administered vaccination sites, local pharmacies, or any other provider; however, such off-site vaccination appointments may only be arranged by the NH if the facility has made diligent efforts to offer on-site vaccinations to within 14 days of hire, but the NH is unable to do so and such off-site vaccination appointments can be offered more expeditiously than an on-site vaccination appointment, or if personnel indicate that they prefer to be vaccinated in the community, in which case the facility must document that reasoning in their personnel file. As mentioned above, the facility should maintain all documentation to evidence its diligent efforts to first offer on-site vaccinations and, for personnel, provide written evidence that an off-site vaccination would be more expeditious than an on-site vaccination or is preferred by personnel.

- **Pediatric Residents:** We assume that pediatric residents under age 16 need not be offered the opportunity to **receive** a vaccine. The nursing home section of the regulations is written to apply to all unvaccinated, consenting residents regardless of eligibility. Please confirm that our assumption is correct.

Response: Correct. Only those individuals in the appropriate priority and age cohorts should be offered the opportunity to receive vaccine if clinically and medically

appropriate. The facility should, however, document in the resident's medical record the reason for not offering the COVID-19 vaccine (i.e., age).