The attached file is being sent to assisted living facilities from the Virginia Department of Social Services Email Distribution Service.

Please do not reply to this email.

NOTE: Please disregard the previous email. The correct memo has been attached.

SCROLL DOWN TO VIEW ATTACHMENT

COMMONWEALTH of VIRGINIA

DEPARTMENT OF SOCIAL SERVICES

DATE: **March 16, 2022**

TO: **Assisted Living Facilities**

FROM: **Tara Ragland, Director, Division of Licensing Programs**

RE: **Virginia COVID-19 LTC Task Force - March Newsletter/Testing Reminders**

Attached you will find the Virginia Long-Term Care Task Force March Newsletter as well as reminders about required COVID-19 reporting for LTCFs. Testing information for ALFs can be found on page 2. Please review this information and ensure you are reporting the results of any COVID-19 testing taking place in your facility.

As a reminder, current and updated information regarding COVID-19 can be found on the Virginia Long-Term Care Task Force website. You can also find previous Virginia Long-Term Care Task Force Newsletters on the website.

The Virginia Department of Social Services Division of Licensing Programs would like to express our gratitude for your ongoing commitment and dedication to some of the Commonwealth's most vulnerable individuals.

Reminder: Long-term Care Facility COVID-19 Test Results Reporting Requirements

This document will be updated as federal and state requirements change.

Nursing Homes

Reporting requirements
- According to Virginia [Regulations for Disease Reporting and Control](#) 12 VAC 5-90-80, nursing homes are required to submit individual point-of-care (POC) SARS-CoV-2 testing data, including antigen testing data, to VDH.
- On January 8, 2021, the U.S. Department of Health and Human Services (DHHS) updated their [Reporting Guidance](#) for the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Additionally, on January 8th, CMS released a [memo](#) with this update. [CMS testing requirements](#) were updated September 10, 2021.
  - You are required to obtain a [CLIA certificate](#) if you are conducting diagnostic tests for COVID-19. If you are conducting COVID-19 testing, you are required to report both the positive and negative results of COVID-19 diagnostic and screening tests. This includes data for all diagnostic and screening testing completed, which includes molecular, antigen, and antibody testing for each individual tested. **Individual POC test results (positive and negative) must be reported daily, within 24 hours of test completion**. Failure to report may result in enforcement action.
  - **Facilities that perform POC testing are required to report results for all POC testing that is performed within the facility (residents, staff, visitors).** If the National Healthcare Safety Network (NHSN) is the method by which POC test results are reported, then POC test results for visitors must be reported to NHSN.
  - Language in the document was modified to state that the NHSN POC Test Reporting tool is the preferred (but not required) method for CMS-certified LTCFs (i.e., nursing homes) to submit COVID-19 POC test results to state health departments and HHS.

How to report
- CMS-certified skilled nursing homes may report the POC test results to either the [VDH portal](#) or to NHSN. **Facilities only need to report to one system**, as results from NHSN are reported to appropriate state and local health departments using standard electronic laboratory messages.
  - If facilities choose to report to NHSN, they must first upgrade their SAMS access to Level 3. **Facilities should report individual POC test results (positive and negative) within 24 hours regardless of the system that is utilized.**
  - Information on reporting to NHSN, including [POC Testing Reporting Tool FAQs](#), can be found on the NHSN LTCF [website](#). CDC training slides are located [here](#).
    - Batch reporting is possible in NHSN via upload of a CSV (Excel) file.
  - Nursing homes are encouraged to have, at minimum, two individuals with access to NHSN at all times so that the facility maintains access to report into NHSN if a staff member leaves their position.

Penalties for failing to report
- VDH is reiterating that nursing homes that choose NHSN as their method of reporting, are required to report individual POC test results, not **just** summary data. Failing to report the required data may result in citations and civil monetary penalties for CMS-certified skilled nursing facilities.
- If a facility holds a CLIA certificate and performs COVID-19 testing, they are held accountable to all reporting requirements, including the CLIA requirement for reporting.

Note: Nursing homes that have not been reporting individual POC test results into NHSN or the VDH Portal should report their retrospective data.

Assisted Living Facilities and other LTCFs conducting POC testing

Reporting requirements
- On January 8, 2021, the U.S. Department of Health and Human Services (DHHS) updated their Reporting Guidance for the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). Additionally, on January 8th, CMS released a memo with this update.
  - You are required to obtain a CLIA certificate if you are conducting diagnostic tests for COVID-19. If you are conducting COVID-19 diagnostic testing, you are required to report both the positive and negative results of COVID-19 diagnostic and screening tests. This includes data for all diagnostic and screening testing completed, which includes molecular, antigen, and antibody testing for each individual tested. **Individual POC test results (positive and negative) must be reported daily, within 24 hours of test completion**. Failure to report may result in enforcement action.
  - **Facilities that perform POC testing are required to report results for all POC testing that is performed within the facility (residents, staff, visitors).**

How to report
- Assisted living facilities (ALFs) and other LTCFs should report POC test results to the VDH Portal.
- Note ALFs can voluntarily report into NHSN; they would need to gain access via CDC (see instructions above).
- Facilities with both nursing home and assisted living components can either:
  - Report data for nursing home component to NHSN and ALF component to VDH POC portal OR
  - Facility can work with CDC to set-up ALF as a facility in NHSN; facility can then report both nursing home and ALF data into NHSN (likely under different facility numbers)

Penalties for failing to report
- If a facility holds a CLIA certificate and performs COVID-19 testing, they would be held accountable to all reporting requirements, including the CLIA requirement for reporting.

VDH VIRGINIA DEPARTMENT OF HEALTH

March 2022

Long-Term Care Facility Task Force Monthly Updates

In this Newsletter:

Long Term Care Facility Task Force Updates

- o [Data Update](#)
- o [Vaccine Update](#)
- o [Infection Control Update](#)
- o [Testing Check-In](#)
- o [Therapeutics Update](#)

Data Update

- There were 32 LTCF COVID-19 outbreaks reported in the past 30 days (as of 03/14). The number of reported nursing home resident and staff cases have been on the rise since the beginning of the year 2022, however there is a decrease in the number of cases reported in the past couple weeks
- Please refer to slides 5 through 13 of the LCTF Task Force slide deck for specific data on LCTF COVID-19 outbreaks

Vaccine Update

- The Centers for Disease Control and Prevention (CDC) endorsed the Advisory Committee on Immunization Practices' (ACIP) recommendation for use of Moderna's vaccine for people ages 18 years and older; this follows FDA's approval
- The Moderna COVID-19 vaccine, which will be marketed under the brand name 'Spikevax,' will continue to be available under Emergency Use Authorization (EUA) for:
  - o Individuals 18 years of age and older for the administration of a 2 dose primary series,
  - o a third primary dose in immunocompromised individuals, and
  - o as a single booster dose

- - Spikevax has the same formulation as the EUA Moderna COVID-19 vaccine and can be used interchangeably with the EUA Moderna COVID-19 vaccine
- Visit the CDC website on [Moderna COVID-19 Vaccine Overview and Safety](#).
- FDA has updated factsheets for [healthcare providers](#) and [recipients and caregivers](#).
- COVID-19 vaccine terminology update:
  - Additional primary dose:
    - For patients with immunocompromising conditions:
      - Eligible for an additional dose 28 days after primary series of two mRNA (3 total doses)
      - OR those who received Johnson & Johnson's Janssen, are eligible for an mRNA additional dose after 28 days (2 doses total)
  - Booster:
    - For patients with immunocompromising conditions:
      - Eligible for a booster dose 3 months after completion of primary series of 3 mRNA (4 doses total)
      - OR those who received J&J + one mRNA for primary series, are eligible for a booster dose after 2 months (3 doses total)
    - For general population (without immunocompromising condition)
      - Eligible for a booster dose 5 months after completion of primary series of 2 mRNA (3 doses total)
      - OR those who received J&J, are eligible for a booster dose after 2 months (2 doses total)
  - Up-to-date versus fully vaccinated:
    - Up-to-date – a person has received all recommended COVID-19 vaccines, including any additional or booster doses, when eligible
    - Fully vaccinated – a person has received their primary series of COVID-19 vaccines

COVID-19 vaccine dosing schedule changes and clarifications:
  - For people who are moderately or severely immunocompromised:
    - Who have completed a primary series of an mRNA vaccine (Pfizer-BioNTech or Moderna) are recommended to receive an mRNA booster dose 3 months (instead of 5 months) after the last primary dose
      - A clarification of a current recommendation to confirm that those who have completed their primary series of 3 mRNA doses should receive an mRNA vaccine booster dose for a total of **4** doses
    - Who have received a single J&J's Janssen vaccine should receive one additional dose of an mRNA COVID-19 vaccine and one booster dose (preferably mRNA) for a total of **3** vaccine doses
  - For those who previously received passive COVID-19 antibody products:
    - A simplification of existing guidance in that they do not need to wait for any period prior to COVID-19 vaccination.
- View the updated [Interim Clinical Care Considerations for COVID-19 Vaccination](#)
- Pfizer-BioNTech COVID-19 Vaccine for Children 6 months through 4 years of Age Postponed
  - Pfizer-BioNTech new data have recently emerged regarding its COVID-19 vaccine in children 6 months through 4 years of age
  - Based on the FDA's preliminary assessment, and to allow more time to evaluate additional data, additional information regarding the ongoing evaluation of a third dose will be considered as part of the agency's decision-making for potential authorization

o FDA has postponed the Vaccines and Related Biological Products Advisory Committee meeting originally scheduled for Feb. 15 to a later date

Infection Control Update

- CDC COVID-19 infection prevention and control guidance, including guidance specific to nursing homes was recently updated
    - o An overview of the recommendations can be found on slides 15-22 of the LTC Task Force slide deck
    - o The VDH Healthcare-Associated Infections & Antimicrobial Resistance team presented highlights of these recommendations on a webinar on February 23. Slides and a recording of the webinar are available on the VDH HAI/AR Education & Training website.
- VDH recently updated the following materials on the COVID-19 LTC Task Force site
    - o COVID-19 Guidance for Nursing Homes (2/16/2022)
    - o COVID Outbreak Response Method in LTCFs (2/15/2022)
    - o Personal Protective Equipment and Cohorting in LTCFs (2/15/2022)
    - o Tips for Safely Visiting a Loved One in a Nursing Home (1/7/2022)
    - o Recommendations for Hospitalized Patients Being Discharged to a LTCF (2/9/2022)
- Frequently asked questions about COVID are now located on the following sites; each is searchable and has a section specific to long-term care
    - o Main FAQs
    - o Vaccination FAQs

Testing Check-In

- VDH supplemental Point-of-Care COVID-19 AntigenTest Resource Program ended as of 2/18/2022
- VDH continues to encourage facilities to develop and prepare a sustainable plan for future testing needs by finding a vendor to purchase tests or contract with to perform tests on the facility's behalf. Connect toTest is a helpful resource to identify the appropriate test for facilities, as well as buying options
- HHS is consistently shipping over 50,000 **BinaxNOW Ag POC tests** per week to LTCFs in Virginia. Questions regarding this distribution may be directed to hhsbinax@hhs.gov
- HHS is distributing 5 million **Celltrion DiaTrust™ COVID-19 Ag Rapid Tests** to over 15,000 CMS-certified skilled nursing facilities. This is a **one-time distribution**. The Celltrion tests require nasopharyngeal specimen collection and thus may differ from tests previously used at these facilities. Each skilled nursing facility will receive approximately **four tests per resident**. Test kits began shipping on February 7, 2022. Virginia facilities will receive a projected allocation of 99,700 tests over the coming weeks**.** Test distribution will be coordinated by Cardinal Health and their contractors, and deliveries will arrive by truck. Facilities will be notified of their shipment by the distributor stating the anticipated week of delivery. **Any questions regarding this distribution should be directed to the ESD TF State Engagement mailbox: eocevent588@cdc.gov**
- The recent FDA-issued safety communication regarding Celltrion DiaTrust COVID-19 Ag Rapid Tests applies to tests with green and white packaging. VDH has been assured that the U.S. Government has **not** received any of these unauthorized kits, therefore it should not affect HHS-allocated tests received by SNFs. Please see the attachment
- Please share reminders about SARS-COV-2 point of care (POC) test results reporting requirements with LTCFs

Therapeutics Update

- COVID Therapeutics Webinar will transition to every other week
    - Next webinar: March 23, 2022 12:00pm-1:00pm
- On alternate weeks there will be an Office Hours session
    - Next Office Hours: March 16, 2022 12:00pm-1:00pm
- FDA News Release - FDA granted Emergency Use Authorization (EUA) for new monoclonal antibody (mAb) Bebtelovimab
    - Shown in lab testing that it has activity against: Omicron variant, including the BA.2 subvariant
    - Indication: treatment of mild-moderate disease in adults and pediatrics (≥12 years, ≥40 kg), with positive COVID-19 test result, AND at high risk for severe disease progression (hospitalization or death)
    - For use when alternative treatment options approved or authorized by FDA are not accessible or clinically appropriate
- Unavailable mAbs:
    - FDA revised EUAs for bamlanivimab and etesevimab (bam/ete) and REGEN-COV
        - Limits use to only patients who are likely to have been infected with or exposed to a susceptible variant (unlikely against Omicron)
        - Per HHS, do not discard current supplies of bam/ete and/or REGEN-COV
        - May retain activity against future circulating SARS-CoV-2 variants, other than Omicron
        - Alternative therapies remain: EVUSHELD, Sotrovimab, Bebtelovimab

    Resources:
    - How to access therapeutics
        1. Enroll as a Therapeutics Provider
        2. Submit orders through VaxMax
        3. Fulfill reporting requirements
    - Additional Resources:
        - VDH COVID-19 Therapeutics Website
        - COVID-19 Treatment Locator Tool

Have any important updates or information for the Virginia Department of Health's Long-Term Care Task Force? Email to Maya Nilkant (maya.nilkant@vdh.virginia.gov)