

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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July 20, 2020

To: All Nursing Home Administrators

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Availability for Skilled Nursing Facilities to Perform COVID Laboratory Testing

In an effort to address the COVID-19 pandemic that is unfortunately having an adverse effect on residents and staff in skilled nursing facilities, the Federal Government, through CMS is moving forward with securing and distributing COVID testing instruments and supplies for skilled nursing facilities to test residents and staff. To be able to take advantage of this testing capability, your facility is required to have a Federal CLIA certificate and a State of Nevada laboratory license. If your facility does not have an active CLIA certificate or an active State of Nevada laboratory license, you will need to do the following:

- 1. You will need to go to our on-line application website at: https://nvdpbh.aithent.com/login.aspx
- 2. On the left-hand side under "NEW APPLICANTS APPLY HERE", you will choose the fifth line down that says, "TO APPLY FOR A NEW MEDICAL LABORATORY LICENSE OR CHANGE OF OWNERSHIP-CLICK HERE".
- 3. You will need to complete all of the required fields, upload a driver's license or passport picture of the person that has been identified as the Laboratory Director, upload a completed CMS 116 form (5 pages), upload a completed Ownership and Disclosure form (2 pages) and pay the \$500 application fee.
- 4. The submitted application will be reviewed and the information will be put into the Federal database to generate a CLIA certificate for your facility. You will receive a bill from CLIA for \$180 for the CLIA certificate. This must be paid before an inspector will perform an inspection of your laboratory.
- 5. Once the application has been reviewed for completion and the information has been entered into the database, the application will be forwarded on to a surveyor. The surveyor will contact your facility to schedule an inspection of your laboratory.
- 6. Once the inspection has taken place, if there are no deficiencies found, the surveyor will complete the paperwork and submit the application for approval. If there are deficiencies found during the inspection, the deficiencies will need to be corrected and a Plan of Correction (POC) will need to be submitted.
- 7. When the application is submitted for approval, the surveyor paperwork will be reviewed and approved.
- 8. When the application has been approved, the laboratory may begin performing laboratory testing. No patient laboratory testing may be performed on anyone until the State of Nevada inspection has been performed and application approved.

If the facility has an active CLIA certificate but does not have a State of Nevada laboratory license, the facility is required to apply for a State laboratory license as outlined above, but on the CMS 116 form, the facility would indicate their current active CLIA certificate number. If the facility has a State of Nevada lab license, but the

State laboratory license has expired, then the facility must follow the steps outlined above and login to "REACTIVATE" the laboratory license.

If the facility has an active State of Nevada laboratory license and an active CLIA certificate, you will need to add a COVID-19 test to the test menu of the facility. The facility would need to login to the website using their login name and password. Once you are into your laboratory's site, you will want to do an "AMENDMENT" to your laboratory license which will be for a "TEST ADDITION" for COVID-19. Once the application has been completed and a \$300 fee has been paid, the application will be reviewed, and a surveyor will contact the facility for an inspection.

To expedite the effort in having the facilities to be able to begin COVID-19 testing, we recommend the following:

- 1. If the facility does not have a CLIA certificate or State of Nevada lab license, then the facility will need to submit the applications (State License & CLIA) before CMS will allow the facility to request an instrument and disposables. Once you obtain your CLIA certificate or if your facility already has a CLIA certificate and state laboratory license, contact the vendor that will be supplying the instrument and disposables to perform the CLIA Waived COVID-19 testing at your facility. During the time that the facility is waiting for the instrument and the disposables to arrive, the State can be processing the Amendment-Test Addition or new State of New lab license, as applicable, and forward it on to a surveyor.
- 2. A surveyor will contact the laboratory and send them information to prepare for the inspection.
- 3. When the instrument and disposables arrive, the facility will use the checklist supplied by the surveyor to prepare for the inspection.
- 4. A surveyor will schedule an inspection and if there are no deficiencies, the surveyor will complete the packet and submit it for approval.
- 5. Once the application is approved, the facility may begin patient/resident/personnel testing.

It is also of importance to report all COVID-19 test results to the State of Nevada. This information needs to be provided daily, so the State has current information available to make important decisions for the safety of the residents of Nevada as well as its visitors. Please contact the Division of Public and Behavioral Health's Office of Public Health Investigations and Epidemiology by email at DPBHHAI@health.nv.gov to set up your facility so that it can meet Nevada's reporting requirements.

CMS has two vendors/-manufacturers for the COVID-19 testing instruments and disposables as follows:

BD Veritor: https://www.fda.gov/media/139755/download Quidel: https://www.fda.gov/media/137885/download

Additional information regarding the specifics of this program can be found at the following website link:

 $\frac{https://www.hhs.gov/about/news/2020/07/14/trump-administration-announces-initiative-more-faster-covid-19-testing-nursing-homes.html}{}$

If you have any questions regarding this process, please contact me at 775-430-0034 or at email bwaples@health.nv.gov