UTAH DEPARTMENT OF HEALTH

Questions and Answers Regarding Centers for Medicare and Medicaid Services (CMS) Interim Final Rule, CMS-3401-IFC

(Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency Related to Long-Term Care Facility Testing Requirements and Revised COVID19 Focused Survey Tool)

1) **Which facilities are covered?**
   The rule says "long-term care facilities," but the sanctions are for facilities receiving CMS payments. So, the rule impacts licensed nursing and skilled nursing facilities.

2) **What types of tests qualify for compliance with this regulation?**
   Either PCR or antigen tests can be used to comply with this regulation. Antibody tests do not meet the requirements under this regulation.

3) **Which facility staff are required to be tested?**
   Facility staff required to be tested include employees, consultants, contractors, volunteers, and caregivers who provide care and services to residents on behalf of the facility. This includes contracted healthcare workers employed by outside agencies, such as home health and hospice providers, delivering services in your facility. It also includes students in the facility's nurse aide training programs or from affiliated academic institutions. Enforcement of the rule is at the facility level. It is, therefore, the facility's responsibility to ensure all testing requirements are met for facility staff regardless of employer.

4) **What are public health's responsibilities in assisting facilities with implementation?**
   The responsibility to implement the rule rests with each facility's administration using point-of-care (POC) testing machines and test kits and funds from the Skilled Nursing Facility Infection Control Relief Fund provided by the federal government. The Department of Health and Human Services plans to distribute another $2 billion to nursing homes later this fall based on certain performance indicators that will be shared in the future. If these resources are inadequate to meet the testing requirements, the rule instructs facilities to contact state and local health departments to assist with testing shortages, obtaining testing supplies, etc.

5) **Will public health continue supporting the response to outbreaks in long-term care facilities?**
   Public health has been supporting outbreak responses in long-term care facilities throughout the pandemic with access to infection preventionists, mobile testing resources, and crisis response teams. This support will continue as it has previously, including the availability of needed testing to support such a response. In some instances, targeted testing will be

recommended by the state's outbreak response team. Under these circumstances, it will the facility's responsibility to complete any additional testing needed to comply with the CMS rule to perform facility-wide testing of residents and staff when any new case arises in a facility.

6) Who should be tested and how often?

The rule requires prioritized testing in the following sequence: 1) symptomatic individuals (staff or residents) termed "diagnostic testing," 2) outbreaks (staff and residents), and 3) routine testing of all staff in facilities not currently experiencing a COVID-19 event termed "screening testing." The frequency of routine screening testing of staff is based on the county's positivity rate as determined by CMS and is available here.

Facilities should monitor the positivity rate for their county every other week and, for routine screening testing, adjust frequency of staff testing accordingly. If the county positivity rate decreases to a lower activity level, 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. If a county positivity rate increases to a higher level of activity, the facility should immediately adjust to that testing frequency.

7) Who needs to be re-tested when using POC antigen tests?

The POC antigen tests were validated for use in diagnostic not screening testing. The FDA has stated that "off-label" use of POC antigen testing is allowed for screening testing as directed by the rule. However, early use of POC antigen testing for screening testing by facilities in Utah has demonstrated concerns for false positive results. At this time, all facilities using POC antigen testing for screening of asymptomatic staff should be prepared to conduct confirmatory testing of any positive test results using a PCR test from a CLIA-certified laboratory with an emergency use authorization (EUA) from the FDA to perform PCR testing for SARS-CoV-2. Such testing should occur as soon as possible--ideally, specimen collection for the PCR confirmatory test should be done the same day as the POC test. While awaiting the results of confirmatory testing, any staff member with a positive result from POC antigen testing should be sent home and asked to quarantine until the results of confirmatory PCR testing are available. All positive results on POC antigen testing should be reported to the Utah Department of Health to initiate an investigation by contacting HAI@utah.gov. Asymptomatic staff testing negative on routine screening do not need to be re-tested using PCR.

Asymptomatic residents and patients should not be tested using the POC antigen test. Should you be requested to perform screening testing of residents (e.g., prior to undergoing surgery or receiving ambulatory care services), PCR testing from a CLIA-certified laboratory with an EUA from the FDA to perform PCR testing for SARS-CoV-2 is recommended.

For symptomatic staff or residents, POC antigen testing is a reliable method of rapidly detecting SARS-CoV-2. All symptomatic individuals need a confirmatory PCR with the POC antigen test whether positive or negative POC results return. For any positive POC antigen test in staff or residents with symptoms, initiate Transmission-based Precautions immediately, obtain a confirmatory PCR test from a CLIA-certified laboratory with an EUA from the FDA to perform

PCR testing for SARS-CoV-2 as soon as possible (within the same day), and initiate an outbreak investigation by contacting HAI@utah.gov. If patients or staff have symptoms of COVID-19 or have had a high-risk exposure to COVID-19 and test negative on POC care antigen testing, then they should be re-tested using a PCR test.

Staff and residents who have recovered from COVID-19 and are asymptomatic should not be retested for COVID-19 within three (3) months after the date of symptom onset or the first positive test, whichever comes first.

8) **How many facilities have received POC testing machines and can these be used for fulfilling the rule's requirements?**

The goal is to distribute Quidel and Becton-Dickinson POC antigen testing machines to all nursing and skilled nursing facilities soon, but the time frame is unknown. Currently, 32 facilities have received Quidel POC antigen testing machines. Facilities are categorized into five groupings based on their estimated testing needs: 1) Small facilities – 150 tests, 1 instrument; 2) Small-medium facilities – 240-250 tests, 1 instrument; 3) Medium facilities – 325-330 tests, 1 instrument; 4) Large facilities – 600 tests, 1 instrument; and 5) Major outlier facilities – 900+ tests, 2 instruments.

CMS expects facilities to use these machines to conduct the required testing. Specific waivers for off-label use for testing of asymptomatic persons have been authorized by the Food and Drug Administration (FDA) for facilities that have a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver. Facilities conducting POC tests under a CLIA Certificate of Waiver are subject to regulations that require laboratories to report data for all individual tests completed regardless of results.

Until facilities receive their POC testing machines, they should document their efforts in trying to meet the CMS screening requirements using other testing resources. This documentation should be provided to CMS inspectors and should avoid sanctions for non-performance.

9) **Where do I find documentation of the waivers for the off-label use of the antigen testing machines?**

The FDA stated this "off label" use is acceptable in their FAQ found here. (See Q9 under General FAQs, updated September 2, 2020).

10) **How do I get a CLIA Certificate of Waiver?**

The waiver can be obtained by following instructions found here.

11) **Is there training available for using the machines?**

The Utah Department of Health (UDOH) has issued instructions for use of the Quidel Sofia-2 machine and will develop and issue similar instructions for use of the Becton-Dickinson Veritor machine when these become available. The instructions provided with the machines focus on individual, low volume testing. However, instructions for how to conduct batch processing of a

large number of tests have not been provided; UDOH will work with laboratory experts to find or develop these instructions for facilities.

Click here to find information regarding the Sofia-2 POC antigen test where you can access training, kit reordering instructions, technical support, and FAQs.

Click here for training and information long-term care providers need to get started with the BD Veritor. Providers must log into the BD website to access training resources. If you need to establish an account, please complete the registration form by clicking on "Register yourself!"

12) Where can we order POC test kits?

Follow the instructions provided from the manufacturer included with the POC testing machine or online with the resources listed above for ordering more testing supplies.

13) What if we cannot order more test kits for the POC testing machines once the supplies provided run out?

Facilities receiving the Quidel Sofia-2 machines received an initial supply of 150-900+ test kits depending on facility supply. Once these supplies are depleted, the facility is expected to order and pay for additional test kits. These test kits may be in short supply and not immediately available. Facilities should document their efforts in reordering test kits and provide this documentation to CMS or UDOH inspectors if they cannot obtain test kits in a timely manner.

14) Can facilities schedule routine screening testing of staff with the UDOH?

The Utah Public Health Laboratory (UPHL) currently has a daily capacity of about 1,500 PCR tests per day. This testing capacity needs to be reserved for response to COVID-19 events and outbreaks in long-term care facilities and other high priority issues. Screening testing is considered lower priority and can only be performed with UDOH assistance if higher priority testing is not needed. It is unlikely that UDOH will be able to process requests for screening testing to meet the requirements for a 48-hour turn-around time specified in the CMS rule. To demonstrate a facility's efforts to obtain quick turnaround test results, the facility should continue to make these requests as a part of their outreach to health departments as specified in the CMS rule if other testing options are not available. Click here to make a request for screening testing. Retain documentation of all requests for future reference.

15) What does the CMS rule mean by a 48-hour turn-around time?

The intent of the CMS rule is quick turnaround testing and it is the reason for widespread distribution of POC testing machines that can be used onsite. When onsite testing is not possible, facilities are expected to seek contracts with CLIA-approved laboratories that can fulfill a quick turnaround time for testing. Generally, laboratories define their turnaround time as the time a sample is received to the time a result is available. Testing options that include out-of-state shipping add additional delays and may not meet the quick turnaround time intended by CMS even if the laboratory claims a 48-hour turnaround time. When a facility cannot meet the testing requirements of the CMS rule due to limited access or inability of laboratories to process

tests within 48 hours, the facility should retain documentation of these efforts to obtain these quick turnaround test results with laboratories.

16) **Where are facilities supposed to send the routine test results to?**
In Utah, COVID-19 negative **and** positive test results are required to be reported within 24 hours. As facilities begin using POC antigen test machines, they should contact edx@utah.gov for specific guidance on how test results should be reported. Click here for more information. In addition, there is a CMS and CDC requirement that all nursing facilities should sign up for reporting COVID-19 cases into the National Healthcare Safety Network (NHSN). If a facility has not yet started reporting to NHSN, contact the UDOH Healthcare-Associated Infections (HAI) team at HAI@utah.gov for assistance.

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