COVID-19 CORONAVIRUS

Coding Updates

UPDATED 4/23/20

UPDATED INFO

See yellow highlights for updated content from previous published version.

Laboratory Waiver Update

Background

New laboratory waivers released on March 30, 2020 introduce additional flexibilities and further expansion of previous waivers. These waivers are **retroactive back to March 1, 2020**.

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A summary of these provisions can be found at: https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf

Additional links related to Coronavirus waivers and flexibilities can be found at: https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers

Clinical Laboratory Improvement Act (CLIA) Guidance

Health plans are directed to pay providers of laboratory services the full negotiated rate or, if the provider and plan do not have a contract in place, they must reimburse the provider the cash price for the service. Each provider of such laboratory services will be required to post a cash price for COVID-19 testing on a public website and failure to comply could result in civil monetary penalties.[1]

CMS is allowing laboratories within a hospital/University Hospital Campus to hold a single certificate for the laboratory sites within the same physical location or street address to expand testing capacity in these shared locations. CMS has clarified that alternate specimen collection devices and media may be used to collect and transport COVID-19 samples.

CMS guidelines state that a CLIA program is unable to approve section 1135 waiver requests with respect to waivers of CLIA program requirements. The section 1135 waiver authority is only applicable to specified programs (or penalties) authorized by the Social Security Act (SSA). The CLIA program does not fall into this category of programs. CMS does not have the authority to grant waivers or exceptions that are not established in statute or regulation. However, "CMS is willing to explore flexibilities, as we have, under our current authorities."[2]

- ✓ CMS will allow laboratories to utilize temporary testing sites for remote review and reporting of laboratory data/slides/images if specific criteria are met. See QSOG memo at: https://www.cms.gov/medicareprovider-enrollment-and-certificationsurveycertificationgeninfopolicy-and-memos-states-and/clinical-laboratory-improvement-amendments-clia-laboratory-guidance-during-covid-19-public-health.
- ✓ If the laboratory is performing proficiency testing (PT) and providing patient results, PT is still required and must be performed, as required by the CLIA regulations. Details for actions required if PT activities are suspended may be found at: https://www.cms.gov/files/document/clia-laboratory-covid-19-emergency-frequently-asked-questions.pdf.
- ✓ To perform COVID-19 testing labs must be a CLIA-certified laboratory that meets applicable regulatory requirements. To apply for a CLIA certificate, submit the application form (CMS-116, CLIA Application Form) to the state (SA Contacts) where the laboratory is located.
- ✓ Almost all current Emergency Use Authorization (EUA)-authorized tests for COVID-19 are FDA-authorized for use by laboratories that meet the CLIA requirements for either moderate or high complexity testing. Therefore, testing personnel must meet the appropriate moderate or high complexity CLIA testing personnel qualification requirements depending on which EUA authorized tests are being used by the laboratory
- ✓ If the facility has the appropriate CLIA certificates and follows applicable CLIA regulations, state regulations and guidelines, the laboratory may perform testing in the parking lot or any other designated overflow location in its facility.
- ✓ Laboratories with questions related to biosafety levels should consult CDC biosafety guidance found at: https://www.cdc.gov/coronavirus/2019-nCoV/lab/lab-biosafety-guidelines.html. The Lab may also email the CDC at DLSinquires@cdc.gov.

CMS COVID-19 Specimen Collection

To identify and reimburse specimen collection for COVID-19 testing, CMS established two HCPCS codes, effective with line item date of service on or after March 1, 2020. The following codes were initially billable only by freestanding clinical diagnostic laboratories. However as nThrive heard on the April 21 "Office Hours" call with CMS, and supported by the I/OCE updated for April, the specimen collection codes for COVID-19 testing (G2023 and G2024) were assigned SI "N", and are now reportable on the UB-04 under OPPS. While the status indicator represents items and services packaged into APC payment for other services under OPPS, it does provide an opportunity to capture the costs involved. In addition, other non-Medicare payers may reimburse the hospital.[3]

- ✓ **G2023** – *Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source*
- ✓ **G2024** – *Specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), from an individual in a skilled nursing facility or by a laboratory on behalf of a home health agency, any specimen source*

Medicare will pay when laboratories can send trained technicians to a beneficiary's home, including a nursing home, to collect a sample for COVID-19 diagnostic testing.

- ✓ Medicare will pay a collection fee and the travel cost.
- ✓ The nominal specimen collection fee for COVID-19 testing for homebound and non-hospital inpatients generally is $23.46 and for individuals in a SNF or whose samples are collected by a laboratory on behalf of an HHA is $25.46.

If a patient is already receiving Medicare home health services, the home health nurse, during an otherwise covered visit, could obtain the sample to send to the laboratory for COVID-19 diagnostic testing.

If a visiting nurse has an otherwise covered RHC or FQHC visit, they can obtain a sample to send to the laboratory for COVID-19 diagnostic testing.

- ✓ Any RHC/FQHC visiting nurse service solely to obtain a nasal or throat culture would not be considered a nursing service because it would not require the skills of a nurse to obtain the culture as the specimen could be obtained by an appropriately-trained medical assistant or laboratory technician.[4]

Data Collection

In a bulletin released on Sunday, March 29th CMS indicated the White House Coronavirus Task Force is already collecting data from public health labs and private laboratory companies but does not have data from hospital labs that conduct laboratory testing in their hospital. According to CMS this hospital data is needed at the federal level to support the Federal Emergency Management Agency (FEMA) and CDC in their efforts to support states and localities in addressing and responding to the virus.

CMS further indicated that Academic, University and Hospital "in-house" labs are performing thousands of COVID-19 tests each day, but unlike private laboratories, the full results are not shared with government agencies working to track and analyze the virus.[5]

The bulletin refers to a letter sent by Vice President Pence to hospital Administrators with a request for data from these "in-house" labs along with instruction for reporting the data to HHS each day and to the CDC's NHSN.[6] A spreadsheet template was attached to the letter to facilitate the data collection.

- ✓ Hospitals that submit all their COVID-19 testing to a private lab on the list below will not need to submit results data.
  - Arup Laboratories
  - Mayo Clinic Laboratories
  - Quest Diagnostics
  - LabCorp
  - BioReference Laboratories
- ✓ Hospitals where testing is done through a Lab not on this list should send the completed spreadsheet, due every day at 5pm ET via email to fema-hhs-covid-diagnostics-tf@fema.dhs.gov.
- ✓ All hospitals should be submitting data daily through the National Healthcare Safety Network (NHSN) Covid-19 Patient Impact and Hospital Capacity Module which has been made available as of March 27, 2020.
  - Although most hospitals already submit data to NHSN on healthcare associated infections for purposes of CMS reporting the data that is now being requested is to monitor the spread of severe COVID-19 illness and death as well as the impact to hospitals.
  - Current users of NHSN received an email from the CDC with instructions on how to report to this new module.
  - For questions on this module email NHSN@CDC.gov and place COVID-19 Module in the subject line.

Guidance

- ✓ Review guidelines prior to implementing in-house COVID-19 testing.
- ✓ Add specimen collection codes/charges to the chargemaster (CDM) and implement charge capture strategies.
- ✓ Utilize all alternative options to collect specimens at home when possible.
- ✓ Based on where COVID-19 testing is being performed determine if the hospital needs to engage in data submission activities.
- ✓ Educate applicable staff to submit required data through NHSN.

Sources

1. https://www.aha.org/special-bulletin/2020-03-26-senate-passes-coronavirus-aid-relief-and-economic-security-cares-act
2. https://www.cms.gov/files/document/clia-laboratory-covid-19-emergency-frequently-asked-questions.pdf
3. April 2020 Integrated Outpatient Code Editor (I/OCE) Specifications Version 21.1, R10053CCP, MLN Matters MM11580 Revised.
4. https://www.cms.gov/files/document/covid-rural-health-clinics.pdf
5. CMS Bulletin, Special Edition, March 29, 2020.
6. https://www.cms.gov/files/document/32920-hospital-letter-vice-president-pence.pdf ■