TOC descriptor
COVID-19 CORONAVIRUS
Coding Updates
UPDATED 6/19/20

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.

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


A key statement in this latest release is that "laboratories need a Clinical Laboratory Improvement Amendments (CLIA) certificate to perform severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) testing. Under CLIA, laboratories are prohibited from testing human specimens for the purpose of diagnosis, prevention, treatment, or health assessment without a valid CLIA certificate. This also applies to facilities not typically considered to be laboratories that are performing SARS-CoV-2 testing."

"Clinical laboratories and facilities such as academic laboratories, research laboratories, pharmacies, physician offices, urgent care clinics, and veterinary laboratories need CLIA certification to perform SARS-CoV-2 testing on human specimens."

"CLIA has four different certificate types, which are Certificate of Waiver, Certificate of Provider-Performed Microscopy, Certificate of Compliance, and Certificate of Accreditation. The required certificate type depends on whether the test was issued an EUA, and if so, the authorized settings included in the Emergency Use Authorization (EUA)."

https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ivd

See yellow highlights for updated content from previous published version.

UPDATED INFO
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


✓ 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/cla-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 initially 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 when the I/OCE updated for April, the specimen collection codes for COVID-19 testing (G2023 and G2024) were assigned SI "N", which is typically reportable on the UB-04 under OPPS.3 These left hospitals asking if they too could now report G2023.

To address this, on April 30, 2020 CMS released new specimen collection guidelines for various testing and/or collection sites, including the hospital as shown below:4

The Interim Final Rule (IFR) published on April 30, 2020 clarified the two G-codes were limited to Independent Clinical Laboratories:

✓ 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.5

Physician practice sites billing on a 1500 claim form that operate as a testing/collection site are instructed to use an E/M level:

- Practitioners can be paid for assessment and specimen collection for COVID-19 testing using the level 1 evaluation and management code CPT code 99211. In light of the public health emergency, Medicare will recognize this code to be billed for all patients, not just established patients. This approach may help physician practices to operate testing sites during the PHE.

Finally, Hospitals have been provided a mechanism to report collection of specimens for COVID-19 testing as well. CMS created the code to be equivalent to the low-level visit reported by the physician practice and as such categorized it with other evaluation and management services. The code includes any assessment provided to determine if testing is appropriate as well as the collection of the specimen.

- Hospital outpatient departments can be paid for symptom assessment and specimen collection for COVID-19 using a new HCPCS code C9803, Hospital outpatient clinic visit specimen collection for severe acute respiratory syndrome coronavirus 2 (sars-cov-2) (coronavirus disease [covid-19]), any specimen source retroactive to March 1, 2020. The service would be paid as conditionally packaged when furnished with another payable service under the OPPS. This approach helps hospitals to operate testing sites during the PHE. Medicare will pay a national rate of roughly $23 for C9803 when it is not billed with a separately payable hospital outpatient service.

Any claims previously submitted on or after May 1, 2020 with specimen collection HCPCS codes G2023 (SPECIMEN COLLECT COVID-19) or G2024 (SPEC COLL SNF/LAB COVID-19) will be returned to the hospital with edit W7062 indicating these codes are not recognized under OPPS and an alternate code may be appropriate. These claims should be resubmitted with code C9803. Reimbursement will be packaged with other services as it is considered conditionally packaged by Medicare.6

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.

On June 4, 2020 the Department of Health and Human Services (HHS) released addition data reporting requirements. Due to the volume of information nThrive has moved all information related to Laboratory Data Reporting to a new coding update located at www.nthrive.com/covid19.

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.
  - If a hospital previous built G2023 in the CDM for COVID-19 specimen collection replace this HCPCS with C9803.
- Report services with appropriate code when specimens are collected at home.
- Educate applicable staff to submit required data through NHSN.

Sources


© 2020 nThrive, Inc. (“nThrive”). All rights reserved.