

## UPDATED INFO

See yellow highlights for updated content from previous published version.

## Laboratory Data Reporting

### Background

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.<sup>1</sup>

The bulletin referred 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.<sup>2</sup> 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](mailto: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](mailto:NHSN@CDC.gov) and place COVID-19 Module in the subject line.

A subsequent bulletin released on June 4, 2020 by the U.S. Department of Health and Human Services (HHS) announced new guidance, outlined below, that specifies what additional data must be reported to HHS by laboratories along with Coronavirus Disease 2019 (COVID-19) test results. The guidance standardizes reporting to ensure that public health officials have access to comprehensive and nearly real-time data to inform decision making in their response to COVID-19.<sup>3</sup>

On June 9, 2020, nThrive submitted a question to CMS as well, asking during the Office Hour provider call on that date if the new guidance replaces the previous guidance. The CMS representatives on the call believed that it did but were unable to provide a definitive answer. The response received from CMS was also inconclusive. However, a new supplemental document associated with an Interim Final Rule (IFR) released on August 25, 2020 advises not using the NHSN any longer. More information is available at: <https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf>. The directives in the June 4 bulletin applies to all laboratories – including laboratories, testing locations operating as temporary overflow or remote locations for a laboratory, and other facilities or locations performing testing at point of care or with at-home specimen collection related to SARS-CoV-21 – shall report data for all testing completed, for each individual tested, within 24 hours of results being known or determined, on a daily basis to the appropriate state or local public health department, based on the individual’s residence.

Providers that are only collecting and submitting specimens to a lab should be aware that the CLIA regulations provide that “facilities only collecting or preparing specimens (or both) or only serving as a mailing service and not performing testing are not considered laboratories.” However, facilities collecting specimens may be directed by testing laboratories to provide the information required to be reported by the laboratories. In these instances, a mechanism to capture the necessary data still needs to be in place.

Laboratories can begin reporting the data immediately, however all labs must be compliant by August 1, 2020.

The following data elements must be collected and reported for SARS-CoV-2 laboratory tests:

- ✓ Test ordered – use harmonized LOINC codes provided by CDC
- ✓ Device Identifier
- ✓ Test result – use appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC
- ✓ Test result date (date format)
- ✓ Accession #/Specimen ID
- ✓ Patient age
- ✓ Patient race
- ✓ Patient ethnicity
- ✓ Patient sex
- ✓ Patient residence zip code
- ✓ Patient residence county
- ✓ Ordering provider name and NPI (as applicable)
- ✓ Ordering provider zip
- ✓ Performing facility name and/or CLIA number, if known
- ✓ Performing facility zip code
- ✓ Specimen Source - use appropriate LOINC, SNOMED-CT, or SPM4 codes, or equivalently detailed alternative codes
- ✓ Date test ordered (date format)
- ✓ Date specimen collected (date format)

The following additional demographic data elements should also be collected and reported to state or local public health departments, but these data will not be collected by CDC or the Secretary's designee.

- ✓ Patient name (last name, first name, middle initial)
- ✓ Patient street address
- ✓ Patient phone number with area code
- ✓ Patient date of birth
- ✓ Ordering provider address
- ✓ Ordering provider phone number

In addition to these data elements that are to be reported, the following data fields are specific to SARS-CoV-2 and considered “ask on order entry” (AOE) questions for traditional electronic health records or laboratory information management systems. These elements should be collected and be conformant with the HL7 Version 2.5.1 Lab Order Interface Implementation Guide and associated standards, and comprehensive of the above data fields.

- ✓ First test (Y/N/U)
- ✓ Employed in healthcare? Y/N/U
- ✓ Symptomatic as defined by CDC? Y/N/U; if yes, then Date of Symptom Onset mm/dd/yy
- ✓ Hospitalized? Y/N/U
- ✓ ICU? Y/N/U
- ✓ Resident in a congregate care setting (including nursing homes, residential care for people with intellectual and developmental disabilities, psychiatric treatment facilities, group homes, board and care homes, homeless shelters, foster care or other setting): (Y/N/U)
- ✓ Pregnant? Y/N/U

Laboratory data serves not only as important information to support decision making related to the public health emergency, but also as a critical piece to better understanding the performance of tests in real-world conditions, the effectiveness of clinical interventions, and patient outcomes and interventions. Better understanding the characteristics and performance of tests can help ensure that healthcare providers are equipped with the maximum information necessary to make clinical decisions, develop recommendations, and provide the most appropriate care for their patients.

To ensure that data can be captured in the electronic health record (EHR), HHS also recommends, **but does not require**, that the transmission of laboratory results back to the ordering provider (whenever possible) include the following information.

- ✓ Test result – use appropriate LOINC and SNOMED codes, as defined by the Laboratory In Vitro Diagnostics (LIVD) Test Code Mapping for SARS-CoV-2 Tests provided by CDC
- ✓ Test result date (date format)
- ✓ Unique patient identifier
- ✓ Test ordered – use appropriate LOINC codes
- ✓ Device identifier
- ✓ Accession #/Specimen ID

To ensure that patients receive timely and critical information regarding their own health condition and status, HHS also recommends, **but does not require**, the transmission of laboratory results be sent directly to the patient (or parent/guardian), either by mail (in writing), email (electronically), and/or via a patient portal or secure standard-based application programming interface (electronically), using commonly available standards such as FHIR (for instance, the Argonaut Data Query Implementation Guide).

When possible, all information should be collected using health information technology certified to the ONC 2015 Edition certification criteria, and all information should be structured in accordance with the U.S. Core Data for Interoperability (USCDI) when available or when possible. All data transmission should occur electronically using Health Level 7 (HL7) electronic laboratory reporting (ELR) implementation guides when possible, but a predefined flat file format may also be acceptable. In addition, clinical/point of care testing facilities using electronic health records (EHRs) are encouraged to use electronic case reporting (eCR) standards to report laboratory testing data, at the receiver's discretion, provided the above data elements and timeliness requirements can be met.

To receive these data in the most efficient and effective manner, the Secretary of the HHS is requiring that all data be reported through existing public health data reporting methods, described below. As a guiding principle, data should be sent to state or local public health departments using existing reporting channels (in accordance with state law or policies) to ensure rapid initiation of case investigations by those departments, concurrent to laboratory results being shared with an ordering provider, or patient as applicable.

The required data elements related to Laboratory Data Reporting to HHS may be reported through the following avenues.

- ✓ Submission of laboratory testing data directly to state or local public health departments, as required by state and/or local law or policy. These entities will then submit deidentified data to the CDC daily, using either Health Level 7 (HL7) messaging or the CDC-provided CSV format.
- ✓ Submission of laboratory testing data to state and local public health departments through a centralized platform (such as the Association of Public Health Laboratories' AIMS platform) where such data will then be routed to the appropriate state and local authorities and routed to CDC after removal of elements to achieve de-identification according to applicable rules and regulations.

- ✓ Submission of laboratory testing data through a state or regional Health Information Exchange (HIE) to the appropriate state or local public health department and to the CDC as directed by the state.

Additional details and resources regarding data submission technologies, Laboratory LIS and privacy standards may be found in the bulletin as referenced.

A FAQ regarding the laboratory data reporting is also available at: <https://www.hhs.gov/sites/default/files/laboratory-data-reporting-for-covid-19-testing-faqs.pdf>.

Hospitals were to comply with data reporting requirements by August 1, 2020. Subsequently a new Interim Final Rule was released on August 25, 2020 addressing penalties for failure to submit the required data:

"Should a hospital or CAH fail to consistently report test results throughout the duration of the PHE for COVID-19, it will be non-compliant with the hospital and the CAH CoPs set forth at §§ 482.42(e) and 485.640(d), respectively, and subject to termination as defined at 42 CFR 489.53(a)(3). We have taken a position on the importance of COVID-19 test results reporting in other provider areas, including use of CMPs for nursing homes that fail to report, and find it prudent to enact penalties for hospitals and CAHs that similarly fail to report COVID-19 test results. CMS currently lacks the statutory authority to impose CMPs against hospitals and CAHs; however, intermediate penalties such as CMPs have been an extremely useful tool in the enforcement of reporting requirements for nursing homes, helping to achieve 98 percent compliance. Therefore, we will continue to utilize all enforcement and payment authorities available to incentivize and promote compliance with all health and safety requirements, as allowed by statute and regulation."<sup>4</sup>

The IFR details the sanctions (including exclusion from the Medicare and Medicaid program) as well as monetary penalties for failure to submit all required laboratory testing information for SARS-CoV-2.

A supplemental document was also made available with the IFR that further details requirements for data reporting. This includes a table outlining the daily details required. Providers may view this document at: <https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf>.

## Guidance

- ✓ Ensure methods to collect all necessary data elements from locations collecting and/or submitting specimens to the hospital (including tests that are subsequently transferred to a reference laboratory).
- ✓ Review and confirm timely data submission processes are in place.
- ✓ Ensure adherence to all applicable guidelines.
- ✓ Incorporate necessary information into the electronic health record (EHR).
- ✓ Ensure results and other necessary information are conveyed to the ordering physician and the patient.
- ✓ Ensure a copy of test results is placed in the medical record. (See **Inpatient Hospital Care Update** on the [nThrive COVID-19 portal](#).)
- ✓ Implement order entry requirements as directed.



## Sources

1. CMS Bulletin, Special Edition, March 29, 2020.
2. <https://www.cms.gov/files/document/32920-hospital-letter-vice-president-pence.pdf>
3. <https://www.hhs.gov/about/news/2020/06/04/hhs-announces-new-laboratory-data-reporting-guidance-for-covid-19-testing.html>
4. <https://www.cms.gov/files/document/covid-ifc-3-8-25-20.pdf> ■