

## **Supporting Statement – Part A**

### CLIA Collection of Information Requirements Related to SARS-CoV-2 Test Results Reporting (CMS-10757)

#### **A. Background**

On March 13, 2020, the President declared a national emergency in response to the public health emergency (PHE) caused by the SARS-CoV-2 virus, otherwise known as COVID-19. The CARES Act was published in response to the PHE that requires “every laboratory that performs or analyzes a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 shall report the results from each such test.” The September 2, 2020 interim final rule with comment (CMS-3401-IFC) requires laboratories to report SARS-CoV-2 test results in a manner and frequency specified by the Secretary. Consistent with the CARES Act laboratory reporting requirements, CMS made modifications to the CLIA regulations to meet the SARS-CoV-2 test result reporting provisions related to the Secretary’s Public Health Emergency declaration with respect to COVID-19.

In order to be in compliance with the new CLIA mandatory SARS-CoV-2 test results reporting requirements, laboratories will need to develop a mechanism to track, collect, and report test results as well as update policies and procedures. In addition, Accreditation Organizations (AOs) and Exempt States (ESs) will need to update laboratory standards to reflect the reporting requirements and update policies and procedures related to reporting laboratories that do not report test results as required.

The CDC has an information collection request (OMB Control Number 0920-1299) in order to collect laboratory data related to the COVID-19 Pandemic Response. The CMS package (ICR) is for laboratory implementation and CMS monitoring of compliance with the CMS-3401-IFC CLIA-certified laboratory reporting requirements.

#### **B. Justification**

##### 1. Need and Legal Basis

The information required is necessary to determine a laboratory’s compliance with the CLIA SARS-CoV-2 test reporting requirements at 42 CFR §§493.41, 493.555(c) and 493.1100(a).

Legislative authority for these requirements and the supporting regulations is found in Section 353 of the Public Health Service Act. This information collection reflects a series of records required to be maintained by laboratories participating in the CLIA program and are based upon the publication of an interim final rule with comment (CMS-3401-IFC) on September 2,

2020.

## 2. Information Users

The information collected by the Centers for Medicare and Medicaid Services (CMS) or its designee, such as a CMS agent or CMS approved laboratory accreditation organization, when conducting inspections will be used to determine a laboratory's compliance with the CLIA SARS-CoV-2 test result reporting requirements. During an on-site survey, the Condition-level laboratory requirement at 42 CFR §§493.41 and 493.1100(a) are assessed for compliance. The information is used by CMS in determining appropriate Civil Money Penalties (CMPs) when laboratories fail to report as required.

The regulatory amendments at §§ 493.41 and 493.1100(a) require all CLIA-certified laboratories, including those holding a CoW and PPM, to report SARS-CoV-2 test results to the Secretary for the duration of the PHE for COVID-19, and, that failure to do so will result in a condition level violation of the CLIA regulations. If a laboratory does not report required SARS-CoV-2 test results, CMS will impose a CMP as required under §§ 493.1804 and 493.1834. Such CMPs will be \$1,000 for the first day of noncompliance with the new reporting requirements, and \$500 for each subsequent day the laboratory fails to report SARS-CoV-2 test results.

The Exempt States (ESs) are generally approved by CMS to operate their own oversight programs so we would expect that the ESs would report those laboratories that fail to report SARS-CoV-2 test results as required to CMS. In this case, the ES would impose the CMPs based on their updated CMS-approved standards. We would expect ESs to have an equivalent CMP imposition structure to CMS. Please see CMS-3401-IFC for detail related to imposition of CMPs.

## 3. Use of Information Technology

This regulation does not prescribe how the facility should prepare or maintain necessary records. Facilities are free to take advantage of any technological advances that they find appropriate for their needs.

## 4. Duplication of Efforts

These requirements do not duplicate any current information collection. They contain the information necessary to ascertain compliance with requirements established in the CLIA regulations.

## 5. Small Businesses

These requirements impact small businesses that are operating as laboratories regulated under CLIA. However, the general nature of the requirements allows flexibility for facilities to meet the requirements in a way consistent with their existing operations.

6. Less Frequent Collection

The laboratory must maintain these records on an ongoing basis in order to maintain their CLIA certification and approval to participate in the Medicare or Medicaid programs. If the information related to 42 CFR 493.555(c) is not collected, we are unable to monitor continued comparability of licensure or accreditation standards to those of CLIA. This information is necessary to fulfill the regulatory provisions to approve organizations and State licensure programs and monitor the performance of laboratory accreditation/State licensure programs.

7. Special Circumstances

There are no special circumstances associated with this collection.

8. Federal Register/Outside Consultation

CMS-3401-IFC was published on September 2, 2020 (85 FR 54820). CMS-3401-IFC is currently in the 60-day comment period.

The 15-day Federal Register notice published on November 4, 2020 (85 FR 70167).

9. Payments/Gifts to Respondents

There is no payment or gift to respondents. A laboratory must have a current CLIA certificate and in good standing to receive Medicare reimbursement.

10. Confidentiality

We make no pledges of confidentiality.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimates (Hours & Wages)

We estimate that approximately 30 percent (n (number) =77,024) of the total CLIA-certified laboratories could potentially be performing SARS-CoV-2 testing<sup>1</sup>.

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1 Includes Certificate of Waiver (CoW), Certificate of Provider-Performed Microscopy (PPM), Certificate of Compliance (CoC) and Certificate of Accreditation (CoA). Based on the [CLIA webpage](#) the total number of laboratories as of March 2020 are as follows: CoW, n=193,474; PPM n=30,120; CoC n=17,432; CoA n=15,721; total =256,747.

Please see Tables 1 through 3 for a summary of the narrative information related to burden hours and cost.

Table 1 includes the burden hours and cost as published in CMS-3401-IFC related to the Collection of Information Section of the IFC. The burden hours and cost reflect the high estimate based on a one-time, per day, or ongoing estimate.

#### Laboratory Costs to Develop a Mechanism to Track SARS-CoV-2 Test Results

Each of laboratory would incur a one-time cost for the time needed to develop a mechanism to track and collect SARS-CoV-2 test results to be in compliance with this new requirement. We estimate it would take each laboratory 5 to 7 hours to develop such a mechanism. The burden hours range from 385,120 to 539,168 (77,024 laboratories x (5 or 7 hours)). A management level employee (11-9111) would perform this task at an hourly wage of \$55.37 per hour as published by the Bureau of Labor Statistics (BLS) in 2019).<sup>2</sup> The wage rate would be doubled to \$110.74 to include overhead and fringe benefits. In addition, a database administrator/architect (15-1245) would be needed to perform this task at an hourly wage of \$46.21 per hour as published by the BLS in 2019.<sup>3</sup> The wage rate would be doubled to \$92.42 to include overhead and fringe benefits. The total hourly wage would be \$203.16 (\$110.74+ \$92.42). The total cost would range from \$78,240,979 to \$109,537,371(385,120 to 539,168 x \$203.16).

#### Laboratory Costs to Collect SARS-CoV-2 Test Results for Reporting

We estimate that a low volume laboratory may report out 20 test results in a 24-hour period and a high throughput laboratory may report out 500 test results during the same period. We estimate it would take each laboratory approximately 0.5 hours for low volume laboratories and approximately 3 hours per day for a high throughput laboratory to collect this information to be in compliance with this new requirement. The burden hours range from 38,512 to 231,072 (77,024 laboratories x 0.5 or 3 hours). A clinical laboratory technician would perform this task at an hourly wage of \$26.34 per hour as published by the BLS in 2019<sup>4</sup> . The wage rate would be doubled to \$52.68 to include overhead and fringe benefits. The total cost would range from \$2,028,812 to \$12,172,873 (38,512 to 231,072 x \$52.68) *per day* to collect the required information. Collection of test results would be an ongoing burden for each laboratory performing this type of testing. For purposes of the annual cost, we estimated 200 days/year for testing/reporting (365 days/year-104 weekend days-10 federal holidays-approximately 50 days to account for laboratories who do not test 7 days/week.). This would result in a total annual estimated cost of \$405,762,400 to \$2,434,574,600.

#### Laboratory Costs to Report SARS-CoV-2 Test Results

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<sup>2</sup> [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm). (11-9111)

<sup>3</sup> [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm). (15-1245)

<sup>4</sup> [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm). (29-2010)

We estimate it would take each laboratory approximately 0.5 hours for low volume laboratories and approximately 3 hours for a high throughput laboratory to report this information to be in compliance with this new requirement. The burden hours range from 38,512 to 231,072 (77,024 laboratories x 0.5 or 3 hours). A healthcare support worker (31-9099) would perform this task at an hourly wage of \$19.24 per hour as published by the BLS in 2019.<sup>5</sup> The wage rate would be doubled to \$38.48 to include overhead and fringe benefits. The total cost would range from \$1,481,942 to \$8,891,651 (38,512 to 231,072 x \$38.48) *per day* to collect the required information. Reporting of test results would be an ongoing burden for each laboratory performing this type of testing. For purposes of the annual cost, we estimated 200 days/year for testing/reporting (365 days/year-104 weekend days-10 federal holidays-approximately 50 days to account for laboratories who do not test 7 days/week.). This would result in a total annual estimated cost of \$296,388,400 to \$1,778,330,200.

#### Laboratory Costs to Update Policies and Procedures

We expect that the approximately 77,024 laboratories performing SARS-CoV-2 testing would incur costs for the time needed to review the revised reporting regulations and update their policies and procedures to be in compliance. We estimate the total one-time burden per laboratory to review and update affected policies and procedures is 5 hours. The burden hours are 385,120 (77,024 laboratories x 5 hours). A management level employee would perform this task at an hourly wage of \$55.37 per hour as published by the BLS in 2019<sup>6</sup>. The wage rate would be \$110.74 to include overhead and fringe benefits. The total estimated cost would be \$42,648,189 (385,120 hours x \$110.74).

#### Accreditation Organization (AO) and Exempt State (ES) Costs to Update Standards for Reporting SARS-CoV-2 Test Results

We assume a one-time cost of 25 to 30 hours to identify the applicable legal obligations and to develop the updated standards needed to reflect the new requirements for SARS-CoV-2 testing. The burden hours range from 225 to 270 (9 AO/ESs x 25 or 30 hours). A management level employee (11-9111) would perform this task at an hourly wage of \$55.37 per hour as published by the BLS in 2019<sup>7</sup>. The wage rate would be doubled to \$110.74 to include overhead and fringe benefits. The total cost would range from would range from \$24,917 to \$29,900 (225 to 270 hours x \$110.74).

#### Accreditation Organization (AO) and Exempt State (ES) Costs to Update Policies and Procedures Related to Reporting Laboratories Performing SARS-CoV-2 Testing that Do Not Report Results as Required

We assume a one-time cost of 10 to 15 hours to develop the policy and procedures needed to

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<sup>5</sup> [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm). (31-9099)

<sup>6</sup> [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm). (11-9111)

<sup>7</sup> [https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm). (11-9111)

reflect the new requirements for reporting of SARS-CoV-2 test results. The burden hours range from 90 to 135 (9 AO/ESs x 10 or 15 hours). A management level employee (11-9111) would perform this task at an hourly wage of \$55.37 per hour as published by the BLS in 2019. The wage rate would be doubled to \$110.74 to include overhead and fringe benefits. The total cost would range from \$9,967 to \$14,950 (90 to 135 hours x \$110.74). In addition, the AOs and ESs would be required to report to CMS every 10 days those laboratories that have not reported test results as required. The annual total number of times each AO and ES is required to report to CMS is 36.5. We assume a weekly cost of 2 to 4 hours to identify the laboratories and submit the information to CMS. The total burden hours range from 18 to 36 (9 AO/ESs x 2 or 4 hours). A computer network support specialist (15-1231) would perform this task at an hourly wage of \$33.10 per hour as published by the BLS in 2019<sup>8</sup>. The wage rate would be doubled to \$66.20 to include overhead and fringe benefits. The total cost would range from would range from \$1,192 to \$2,383 (18 to 36 hours x \$66.20) per 10 days for an annual total of \$43,508 to \$86,980 (\$1,192 to \$2,383 x 36.5).

**Table 1. Total Burden and Associated Costs for the Provisions included in this IFC**

<b>Information Collection Requests</b>	<b>Burden Hours Increase/Decrease (+/-)</b>	<b>Cost (+/-)</b>
A. Laboratory Costs to Develop Mechanism to Track Results ( <i>one time cost</i> )	+539,168	+109,537,371
B. Laboratory Costs to Collect Results for Reporting ( <i>per day cost*</i> )	+231,072	+12,172,873
C. Laboratory Costs to Report Results ( <i>per day cost*</i> )	+231,072	+8,891,651
D. Laboratory Costs to Update Policies/Procedures ( <i>one time cost</i> )	+385,120	+42,648,189
E. AO/ES Costs to Update Standards ( <i>one time cost</i> )	+270	+29,900
F. (a) AO/ES Costs to Update Policies/Procedures ( <i>one time cost</i> )	+135	+15,971
F. (b) AO/ES Costs to Report Laboratories to CMS for not Reporting Results ( <i>every 10 days</i> )	+36	+86,980
<b>TOTAL</b>	<b>+1,386,873</b>	<b>+173,381,824</b>

### 13. Capital Costs

There are no capital costs.

### 14. Cost to Federal Government

Congress intended for the CLIA program to be self -funding, and laboratories are assessed user fees to fund the operation of the program.

<sup>8</sup> [https://www.bls.gov/oes/current/oes\\_nat.htm.\(15-1231\)](https://www.bls.gov/oes/current/oes_nat.htm.(15-1231))

15. Changes to Burden

This is a new information collection.

16. Publication/Tabulation Dates

There are no publication and tabulation dates associated with this collection.

17. Expiration Date

The expiration date will be posted on the CLIA website at <https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA/index>.

18. Certification Statement

There are no exceptions to the certification statement.