Supporting Statement – Part A

SimpleReport Mobile Application

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." A CLIA-certified laboratory or testing site must also report all COVID-19 test results to their respective state, local, tribal, or territorial health department. CMS-certified long-term care facilities must also report SARS-CoV-2 point-of-care antigen test data and other on-site COVID-19 laboratory testing data.

SimpleReport is a free web-based application that provides an easy way to manage the testing workflow, to record results for rapid point of care COVID tests, to report the results to the appropriate public health department on behalf of the testing site, and to comply with existing requirements.

The data collected through this app is crucial for public health departments to take action during the current health crisis. Currently, many point of care tests are reported on paper, on fax, or are not reported at all. Admiral Giroir, who leads the Diagnostics and Testing task force, estimates that only 10% of point of care tests are being reported today. Paper and fax test results create a large burden for health departments to digitize the data and much of it is incomplete or has typos.

Many community mitigations are based on laboratory positivity rate in the community. If the percentage increases, schools and restaurants may close and hospitals may cancel elective surgeries. The negative results are critical to ensuring an accurate positivity rate and the current hypothesis is that many of these negative results from point of care tests are not being reported. Millions of point of care tests are being sent to the states for distribution and soon the point of care tests will outnumber the traditional PCR tests.

SimpleReport will help public health departments get faster, better data and help them:

- Do contact tracing and case investigation faster with positive cases
- Identify outbreaks in the community faster
- Calculate percent positivity for testing continuously

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.

This data is being collected in order to record and data about point of care test results for the facility doing the testing and report the data to public health departments on behalf of the testing facility.

SimpleReport will allow the user after the administration of a test to load in patient data, data about the facility, data about the testing device. The user can then use the application as a part of their testing workflow to manage their work. At present, SimpleReport is being implemented and has the following capabilities:

1. Test Queue
    - Add a person/people to the queue
    - Complete 'time of test questions' (do you have symptoms, when was your last test, are you pregnant). These are Ask at Order Entry questions in the HL7 specification as designated in the HHS reporting requirements.
    - If there are multiple options at the facility, select device type and swab type
    - Enter the result for the test
    - Submit the result

2. Manage People
    - Add new profile of a person
    - Upload bulk CSV of people (possibly future version)
    - Edit profiles of people
    - Look at person's profile
        - Current data about that person
        - Test and symptom history for a person

3 Results
    a. View results of tests performed for this organization

4 Settings

a. Update settings for the facility
    i. Name
    ii. CLIA Number
    iii. Ordering provider name, phone, address, NPI
b. Add testing devices (BD Veritor, Quidel Sofia, Abbott IDNow, Abbott BinaxNow card)
c. Set default device

Future versions may include a range of capabilities based upon feedback and user testing. These may include, among others: the ability to collect additional data for people who test positive, describing the swab type and default, setting of timers, appointments and testing schedule management. Future versions may have greater capability to sort, filter and search test results, filters based on role, and downloadable CSVs of results. Future versions may also be able to capture more information about facilities, including contact information, whether there are multiple ordering providers, viewing multiple facilities within an organization, and roles for users within an organization. Finally, the application may ultimately include patient access to edit, enter, and view information.

Outside of the capabilities and future capabilities of the application, the fields currently collected for each POC test administered include:

- Patient Name
- Lookup ID (The ID an organization uses for its own purposes, e.g., MRN, employee ID, student ID)
- Role (resident, staff, visitor, student)
- Date of Birth
- Phone
- Email
- Address
- Race
- Ethnicity
- Sex
- Resident in congregate care setting (y/n)
- Employed in Healthcare (y/n)
- Result date
- Result (Positive/Negative/Inconclusive

Future versions may include additional identifiers as necessary or legally required by the states.

2. Information Users

Information submitted to the application will be send to the appropriate State, Local, Territorial, or Tribal Public Health Department. The Health Department, as appropriate, may share the anonymized data with CDC for public health purposes. Public Health Departments will receive the data through a secure connection using either HL7 ELR (electronic lab reporting) or a CSV document. The public health department will using the data for public health activities, such as surveillance, case investigation, and contact tracing. It is used to alert them to outbreaks and to include with other test results for calculating their jurisdiction's percent positivity rate.

3. Use of Information Technology

The application is a web application only and is a responsive website.

The facility doing the testing and creating the data will own this data. The federal government is providing this tool as a service to the testing facilities but does not get use of the data. The federal government can only use the data for operational purposes (e.g. debugging, performance evaluations, monitoring of systems) and to facilitate reporting the data to the state or local public health department. The data is the testing facilities data, and a copy is sent to the state and local public health department so that they have their own copy.

Data will be stored for 10 years. If needed, the users could be directed to download the csv file of their data for record keeping purposes if the data needed to be archived or purged prior to 10 years. Data will be encrypted over the wire and at rest. Administrator users at each organization will have a verified identity before being allowed to add other users and before being able to submit results to the state and public health. Okta will use 2factor auth for user accounts.

The organization that creates the data will have access to the data for their own record keeping needs. The organization consents to the federal government reporting the data to the appropriate state and local public health departments for both the testing location and the patient's address. The federal government will only have access to the data to facilitate the reporting to the state and local health departments and to use the information for operational purposes, such as debugging issues and system performance monitoring. The data is exempt from FOIA.

SimpleReport users will be trained on the privacy and security needs of securing PII/PHI. A brief training on this topic will be added to the user onboarding process to have the user acknowledge understanding prior to being able to view or enter patient information. Logins will timeout after 10 minutes of inactivity.

4. Duplication of Efforts

In the future, facilities will also able to submit POC testing data to NHSN. This duplication is intended to provide additional workflow flexibility to respondents in order to meet reporting requirements and reduce burden.

5. Small Businesses

These requirements impact small businesses

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 use of this application is voluntary.

7. Special Circumstances

There are no special circumstances associated with this collection.

8. Federal Register/Outside Consultation

This information collection request was submitted for emergency review and approval in accordance with the implementing regulations of the Paperwork Reduction Act (PRA) at 5 CFR 1320.13(a)(2)(ii).

No emergency Federal Register notice was required and there was no additional outside consultation used in the development of this information collection request. The public will be notified and have the opportunity to review and comment on the information collection request when HHS publishes a regular (non-emergency) notice seeking a standard approval for the ICR within the next 6 months.

9. Payments/Gifts to Respondents

There is no payment or gift to respondents.

10. Confidentiality

We make no pledges of confidentiality.

11. Sensitive Questions

There are no questions of a sensitive nature.

12. Burden Estimates (Hours & Wages)

For this information collection request, we have broken down the burden (time and cost) as follows. There are two main burden categories, that is, the burden associated with the implementation and the ongoing or long term burden associated with the continued use of the application. Within both categories, the burden is broken down into the same three tasks: user training, data entry and reporting, and repeat testing.

With respect to user training, we estimate laboratory staff will require 2-5 minutes to manually enter their information into the system. Similarly, we estimate it will require laboratory staff an additional 1-3 minutes to perform the necessary CSV files uploads, which brings the total burden for the task to approximately 0.16 hours (9.6 minutes). For next category, data entry and reporting, we estimate it will take laboratory staff (both administrative and non-administrative system users) approximately 0.1 hours (6 minutes) to authenticate and submit data. For the last burden category, we again estimate it will require laboratory staff approximately 0.1 hours (6 minutes) per response.

All estimates and related burden calculations are illustrated in the burden tables below moving from left to right.

Time Burden Associated with SimpleReport Use

Task	**Respondent**	**Number of Respondents**	**Average Number of Responses per Respondent**	**Average Burden per Response (hours)**	**Total Burden (hours)**
User Training	Testing Facility Users	10,000	1	0.16	1,600
Inputting Patient Data and Test Result Reporting	Testing Facility Users	10,000	1	0.1	1,000
Repeated Tests on Existing Users	Testing Facility Users	10,000	12	0.1	12,000
Total					14,600

Cost Burden Associated with SimpleReport Use

Respondent	Occupation	Hourly Wage (dollars)**	Total Time Burden (hours)	Total Cost Burden (dollars)
Testing Facility Users	Clinical Laboratory Technologists and Technicians	$51.08	14,600	$745,768

* https://www.bls.gov/oes/current/oes292010.htm

** This value accounts for fringe benefits and overhead costs at a rate of 100% of the median hourly wage. ($25.54 + $25.54)

Time Burden Associated with Long Term Program

Task	Respondent	Number of Respondents	Average Number of Responses per Respondent	Average Burden per Response (hours)	Total Burden (hours)
User Training	Testing Facility Users	250,000	1	0.16	40,000
Inputting Patient Data and Test Result Reporting	Testing Facility Users	250,000	1	0.1	25,000
Repeated Tests on Existing Users	Testing Facility Users	250,000	12	0.1	300,000
Total					365,000

Cost Burden Associated with Long Term Program

Respondent	Occupation*	Hourly Wage (dollars)**	Total Time Burden (hours)	Total Cost Burden (dollars)
Testing Facility Users	Clinical Laboratory Technologists and Technicians	$51.08	365,000	$18,644,200

* https://www.bls.gov/oes/current/oes292010.htm

** This value accounts for fringe benefits and overhead costs at a rate of 100% of the median hourly wage. ($25.54 + $25.54)

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

The Federal costs to build this are estimated as $1 – 2 million through October 2021

15. Changes to Burden

This is a new emergency information collection.

16. Publication/Tabulation Dates

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

17. Expiration Date

Demonstration of the control number and expiration date on the homepage of the application is appropriate.

18. Certification Statement

There are no exceptions to the certification statement.