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American Red Cross

October 23, 2020

The Honorable Alex M. Azar
Secretary
U.S. Department of Health and Human Services
200 Independence Ave, S.W.
Washington, DC 20201

Ms. Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Dear Secretary Azar and Administrator Verma:

AABB, America's Blood Centers and the American Red Cross, which collectively represent the nation's blood collection establishments, transfusion services, and transfusion medicine professionals, are submitting these comments on the interim final rule with comment period, CMS3401-IFC: *Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments of 1988 (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency*.

We are collectively concerned about CMS' interpretation that the reporting requirements apply to blood centers' antibody testing on donations from healthy individuals during the manufacture of convalescent plasma because:

1. The test reporting requirements in the Coronavirus Aid, Relief, and Economic Security (CARES) Act, HHS' June 4th guidance, and the interim final rule apply only to tests to detect the SARS-CoV-2 virus or diagnose a possible case of COVID-19 and therefore do not apply to antibody testing performed by blood centers;
2. CMS' interim final rule, if applied to blood center antibody testing, has the potential to negatively impact the availability of the blood supply during the COVID-19 pandemic; and
3. The requirements in the interim final rule will be unduly burdensome for blood centers without increasing donor or patient safety.

We urge the Department of Health and Human Services (HHS) to clarify that its June 4th guidance on laboratory data reporting for COVID-19 testing was not intended to apply to antibody testing

performed by blood centers.[1] Similarly, we request that CMS specify that the interim final rule does not apply to antibody testing performed by blood centers.

1. **Since the testing performed by blood centers is intended to detect the antibodies in healthy donors who meet all donation criteria and is not "intended to detect SARS-CoV-2 or diagnose a possible case of COVID-19," the reporting requirements in the CARES Act and HHS' guidance do not apply to these tests. Thus, CMS' interim final rule should not apply to antibody testing performed by blood centers.**

The CARES Act requires "[e]very laboratory that performs or analyzes a test that is intended to detect SARS–CoV–2 or to diagnose a possible case of COVID–19…" to report results. HHS reiterated the statutory language in its June 4th guidance implementing the reporting requirements, and CMS' interim final rule adopts this standard as well. As detailed below, antibody tests that blood centers perform on donations from healthy individuals are not "intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19" and therefore should not be subject to CMS' interim final rule.

Since the beginning of the COVID-19 pandemic, the nation's blood centers have been working tirelessly to manufacture and distribute COVID-19 convalescent plasma (CCP), which contains the antibodies used to treat patients with COVID-19. In order to supply current patient needs and build a stockpile of CCP for future needs, blood centers are actively screening the donor population for antibodies to COVID-19. This screening, and the identification of COVID-19 antibody positive plasma, is a critical first step in manufacturing CCP.

Importantly, antibody testing of healthy blood donors does ***not*** detect the SARS-CoV-2 virus or diagnose a possible case of COVID-19. Instead, it identifies healthy donors who have been exposed to the virus in the past, developed antibodies to fight the infection, and are not infected at the time of donation. Individuals who previously had COVID-19 are not permitted to donate CCP unless they are healthy on the day of donation *and* 14 days have passed since their symptoms have completely resolved or, if they were asymptomatic, 14 days after the date of the positive diagnostic test. Likewise, CCP donors are eligible to donate other blood products for transfusion regardless of COVID-19 antibody test results, and plasma with COVID-19 antibodies may be labeled as CCP. COVID-19 antibody positive donors may then be recruited for additional donations of CCP as long as there is detectable antibody in the plasma. Thus, antibody testing performed by blood centers falls outside the scope of the reporting requirements included in the CARES Act and HHS guidance, and therefore should not be subject to CMS' interim final rule.

2. **CMS' interim final rule, if applied to blood center antibody testing, has the potential to negatively impact the availability of the blood supply during the COVID-19 pandemic.**

We are extremely concerned that CMS' interim final rule will have a chilling effect on blood centers' abilities to recruit blood donors as well as CCP donors. The blood supply in the United States is already critically low and the majority of the country's blood centers are reporting

[1] HHS Announces New Laboratory Data Reporting Guidance for COVID-19 Testing, *available at* https://www.hhs.gov/about/news/2020/06/04/hhs-announces-new-laboratory-data-reporting-guidance-for-covid-19-testing.html (last visited October 19, 2020).

significant declines in their blood collections. The interim final rule has the potential to exacerbate these challenges and threaten the stability of the blood supply.

For privacy reasons, when donors are healthy, they do not want their detailed identifying and demographic information shared with authorities. If blood centers are unable to give healthy donors assurances that their identifiable information will not be disclosed, some of these individuals will refuse to donate, putting the blood supply in jeopardy.

While blood centers regularly report positive infectious disease results, such as results indicating that a person is HIV-positive, to their local health department in accordance with law, these reports of active infectious diseases are fundamentally different from reporting antibody test results for healthy donors who have previously been exposed to SARS-CoV-2 virus, developed infection fighting antibodies and are fully recovered prior to donation. Unlike a patient with a positive infectious disease test result, the presence of COVID-19 antibodies in a healthy donor demonstrates recovery from COVID-19. Similarly, reporting detailed, donor-identifying data about negative antibody test results serves no public health purpose. Thus, donors' privacy concerns should outweigh the public health benefit of reporting the antibody test results.

In addition, businesses have raised concerns about blood centers being required to report positive and negative COVID-19 antibody testing results that are associated with their companies. Since these businesses host blood drives, these concerns can contribute to an increase in blood drive cancellations, which threatens the availability of the blood supply.

3. **The requirements in the interim final rule will be unduly burdensome for blood centers.**

Reporting voluminous, identifiable data to dozens of health authorities across the country would impose a significant burden on blood centers that are already facing a variety of new challenges due to the pandemic. Many blood centers operate in multiple states, further complicating this piecemeal reporting. State and local health departments differ in their desire and ability to receive extensive data from blood centers and their technical capability to handle the data. In fact, many health departments have already told blood centers they do not want the data or do not have the capacity to use it. Blood centers should not have to submit information that cannot be received or used by state or local health departments.

Blood center antibody testing data are inherently and complexly redundant. For donors who are being qualified for CCP, many of them received diagnostic tests prior to presenting to donate and now are healthy and have recovered. Thus, the diagnostic tests are followed by initial antibody testing at the blood center. The antibody testing is repeated each time the CCP donor returns because it is a requirement of manufacturing. This could lead to redundant reporting - as many as 8 antibody tests from a single donor could be reported throughout the process of donating CCP. As a result, the duplicative data will be confusing, demonstrating substantially higher rates of positivity based on a skewed population of likely donors selected for their expected positive test results.

Additionally, blood centers are not well positioned to report identifiable, detailed data to health departments. When positive results are obtained, some samples must be tested again to confirm the result. Under the Emergency Use Authorization, a titer must also be obtained to qualify the donation as CCP. This testing is performed in-house at the blood center or contracted to an outside testing

facility. While contract laboratories have the results of the antibody testing, they do not have access to the donor demographics required for reporting. This necessitates extra steps to reconcile the information for reporting, requiring a change in the normal flow of information between the outside laboratory and the blood center or requiring the blood center to undertake the reporting on behalf of the lab.

Furthermore, due to the large amount of COVID-19 testing data generated at blood centers daily, electronic file transfers will require significant IT development, customized for the needs of dozens of local health departments. This process will add undue burden and expense to an already over-burdened operation. Early financial loses during the pandemic, coupled with increased workload inherent in the ramp up and collection of CCP, have blood centers already stretched thin. Additional burdens will necessarily impact centers' ability to dedicate staff time and resources to blood and expanding CCP collections.

Many blood centers are already reporting de-identified, summary testing data to many of the states and have received positive feedback on its value to public health activities. This important data will continue to be shared to support states' interest in understanding seroprevalence in their communities.

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Our organizations appreciate the important public health activities being performed in response to the COVID-19 pandemic. While we support the need for data and surveillance, we do not believe that the results of antibody tests performed by blood centers will provide the government or public health officials with meaningful or useful information.

If you have any questions, please contact Leah Stone (301-215-6554, lmstone@aabb.org), Diane Calmus (202-654-2988, dcalmus@americasblood.org) or Scott Webber (404-427-1414, scott.webber@redcross.org).

Sincerely,

Debra BenAvram
Chief Executive Officer
AABB

Kate Fry
Chief Executive Officer
America's Blood Centers

J. Chris Hrouda
President, Biomedical Services
American Red Cross