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April 15, 2021

To whom it may concern:

On behalf of the American Society for Clinical Pathology (ASCP), I am writing to provide our support for AABB's proposed "Biologically Derived Product" data element for the United States Core Data for Interoperability (USCDI).

As a 501(c)(3) nonprofit medical specialty society, ASCP is dedicated to improving quality outcomes for patients. Accordingly, we believe that AABB's proposed data element will help enhance the nation's understanding of blood availability and utilization, advance hemovigilance capabilities and improve healthy outcomes. The proposal should also help improve our nation's ability to determine whether the current inventory of blood components is sufficient to meet patient need and to monitor safety and effectiveness.

ASCP strongly supports the proposed data element (see below) and urges its adoption.

ASCP appreciates the opportunity to comment on this proposed rule. If we can be of any assistance, please contact me at (202) 735-2285 or Matthew.Schulze@ASCP.org.

Sincerely,

Matthew Schulze
Director, Center for Public Policy
American Society for Clinical Pathology

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AABB Comments: Support for "Biologically Derived Product" Data Element for the USCDI

AABB is an international, not-for-profit association representing institutions and individuals involved in transfusion medicine and cellular therapies. The association is committed to "improving lives by making transfusion medicine and biotherapies safe, available and effective worldwide." AABB works toward this vision by developing and delivering standards, accreditation, and educational programs that focus on optimizing patient and donor care and safety. AABB individual membership

includes physicians, nurses, scientists, researchers, administrators, medical technologists, and other health care providers.

AABB supports the addition of a Biologically Derived Product data element to the United States Core Data for Interoperability (USCDI) and believes that using the ISBT-128 standard will enhance the nation's understanding of blood availability and utilization, advance hemovigilance capabilities and improve health outcomes.

A Biologically Derived Product data element would enable providers to uniformly capture the utilization of individual blood components as well as adverse events for hemovigilance. As noted in the FDA's use case description, the absence of interoperability in this area was particularly problematic during the rollout of COVID-19 convalescent plasma (CCP) and limited the ability of regulators and researchers to perform safety and effectiveness surveillance. The data could be used to assess whether the current supply of specific blood components is adequate to satisfy patient needs and to monitor safety and effectiveness.

Additionally, a Biologically Derived Product data element has the potential to inform policies and guide clinical practices early in the course of treatment (e.g., capturing blood group genotyping in chronically transfused patients or patients initiating novel monoclonal therapies known to cause complication in transfusion workups). It would also serve as a tool to help identify non-infectious complications, such as transfusion-associated circulatory overload (TACO), the transfusion-related acute lung injury (TRALI), and transfusion of an incompatible unit of blood. Importantly, interoperability in this area would facilitate the ability of providers to have access to a patient's transfusion history, regardless of where a previous transfusion occurred. This can help prevent incompatible transfusions, support red blood cell antigen matching, and ultimately improve health outcomes for chronically transfused individuals, such as patients with sickle cell disease.

AABB believes that adding a Biologically Derived Product data element to the USCDI is key to strengthening the nation's blood system, advancing patient safety, and improving health outcomes.