was posted on the ONC Web site on March 25, 2011 and originally open for public comment through Friday, April 22 at 11:59 p.m. (Eastern). This notice serves to announce that the public comment period for the Plan has been extended through Friday, May 6 at 11:59 p.m. (Eastern).

In order for your comments to be read and considered, you must submit your comment via the Federal Health IT Buzz Blog: http://www.healthit.gov/buzzblog/from-the- onc-desk/hit-strat-plan/.

Dated: April 19, 2011.

Erin Poetter,
Office of Policy and Planning, Office of the National Coordinator for Health Information Technology.

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BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Request for Information (RFI) To Identify and Obtain Relevant Information From Public or Private Entities With an Interest in Biovigilance

AGENCY: Office of the Assistant Secretary for Health, Office of the Secretary, Department of Health and Human Services.

ACTION: Notice.

SUMMARY: This Request for Information (RFI) seeks to identify and obtain relevant information regarding the possible development of a public-private partnership (PPP) designed to facilitate the identification of risks and strategies to assure safety of the U.S. supply of blood and blood components, tissues, cells, and organs. This RFI is intended to inform the Department of Health and Human Services (HHS) regarding stakeholders, mechanisms, and approaches on issues related to developing and managing a PPP and scope of PPP activities. Replies are invited from (1) public or private entities with an interest in biovigilance, and (2) entities with experience and capabilities managing public-private partnerships (PPPs) in the biological sciences and public health domains. This RFI is for information and planning purposes only and is not a solicitation for applications or an obligation on the part of the U.S. Government to provide support for any ideas identified in response to it. Please note that the U.S. Government will not pay for the preparation of any information submitted or for its use of that information.

DATES: All responses must be received no later than 4 p.m. EDT on June 9, 2011 at the address listed below.

ADDRESSES: All responses should be e-mailed to Biovigilance@hhs.gov (attention Dr. Jerry Holmberg). Please limit responses to 10 pages. Include in the subject line, the following information:

• Name of the institution or site.
• Respondent, title, and full contact information.

FOR FURTHER INFORMATION CONTACT: Dr. Jerry Holmberg, Senior Advisor for Blood Safety, Office of the Assistant Secretary for Health, Office of the Secretary, U.S. Department of Health and Human Services, 1101 Wootton Parkway, Tower Building, Suite 250, Rockville, MD 20852.

SUPPLEMENTARY INFORMATION: In 2009, the Advisory Committee on Blood Safety and Availability (ACBSA) within the Department of Health and Human Services (HHS), Office of the Assistant Secretary of Health, reviewed and discussed a report on the current state of biovigilance. In that report (“Biovigilance: Efforts to Bridge a Critical Gap in Patient Safety and Donor Health” http://www.hhs.gov/ash/bloodsafety/biovigilance/index.html), biovigilance was defined as “a comprehensive and integrated national patient safety program to collect, analyze, and report on the outcomes of collection and transfusion and/or transplantation of blood components and derivatives, tissues, cells, and organs. This definition does not include vaccines, allergic products, and most recombinant human proteins.” Safety surveillance for plasma derivatives, while a logical part of biovigilance, already falls under FDA mandated drug adverse event reporting and is not addressed in the current HHS initiative. Among the recommendations in that report was for HHS to develop an HHS action plan to support a national biovigilance program, integration of systems within government and private sectors, and steps to enhance mechanisms for surveillance.

HHS is continuing its efforts to develop an action plan to support a national biovigilance program for blood and blood components, tissues, cells, and organs. As part of these efforts, HHS is exploring the feasibility of a PPP. HHS believes that a PPP potentially could serve as an appropriate mechanism for achieving the broad goals and mission of biovigilance. A PPP might provide the American public with a mechanism for leveraging and maximizing resources, for collaborating on research and problem solving, for creating new opportunities, and for advancing the Department’s public health mission as it relates to challenges associated with disease prevention (including emerging infectious diseases or EIDs), adverse events, and process improvements.

Biovigilance is an area of growing importance, with a potential role in any of the following areas:

• Identifying strategies for protecting recipients and living donor health;