DEPARTMENT OF HEALTH AND HUMAN SERVICES Office of the Secretary

Assistant Secretary for Health
Office of Public Health and Science
Washington D.C. 20201

MAR 2 7 2006

Arthur Bracey, M.D.
Chair, Advisory Committee on Blood Safety and Availability
1101 Wootton Parkway, Suite 250
Rockville, MD 20852

Dear Dr. Bracey:

I want to thank you for your willingness to serve as Chairman of the Advisory Committee on Blood Safety and Availability.

I realize the Committee has been extremely concerned with the availability of the immune globulin, intravenous (IGIV). Within the Department we have taken several steps to promote availability and reduce the risk of compromised health care to bona fide patients. First, through discussions with each of the IGIV manufacturers, we have determined that their release of IGIV has not declined and that government is not delaying lot release of products through regulatory processes. In response, the manufacturers increased available inventory for three consecutive months (August, September, and October); this pushed the available inventory into the "green" zone as measured by the Plasma Protein Therapeutic Association. In addition, the manufacturers created emergency inventories and toll-free numbers so that physicians can talk directly with the manufacturers' medical directors for emergent needs.

The issue of the Centers for Medicare and Medicaid Services (CMS) reimbursement of IGIV in the current marketplace is complex. The Medicare payment for IGIV administered in physicians' office is determined by averaging the IGIV manufacturers' quarterly sales prices submitted to CMS. The payment limit for IGIV is 106 percent of the average sales price (ASP), as mandated by Congress. CMS recalculates the ASP quarterly based on the most recent sales pricing data from the manufacturers. Beginning in 2006, reimbursement for IGIV in hospital outpatient departments is based on 106 percent of ASP. The payment for IGIV is in addition to the payment to physician offices or hospital outpatient departments for administration of IGIV.

Based on the Committee's recommendation for immediate steps to address reimbursement for IGIV and our ongoing work with patient groups, manufacturers, and other stakeholders, we continue to be concerned about reports of providers experiencing difficulties in obtaining adequately priced IGIV product on a consistent basis to meet their patients' needs.

For 2006, CMS established a temporary add-on payment for physicians and hospital outpatient departments that administer IGIV to Medicare beneficiaries. Due to factors such as increasing IGIV demand and manufacturers placing many IGIV formulations on "allocation," physician and hospital staff expend extra resources to locate and obtain appropriate IGIV products and to schedule patient infusions. As a result, CMS established an add-on payment for 2006 to reflect these extra expenses, including the additional pre-administration-related services required to locate and acquire an adequate product and to prepare for an infusion of IGIV.

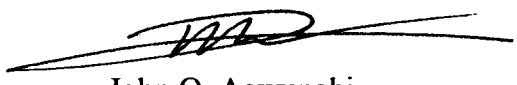
Some stakeholders have indicated to us that the infusion of IGIV in physician offices is more complex and resource intensive, particularly during the actual infusion, than many other types of infusions currently reported using the same drug administration Common Procedural Terminology (CPT) codes established by the American Medical Association's CPT Editorial Panel. We have encouraged these stakeholders to discuss their concerns with the CPT Editorial Panel to assess whether alternative coding or additional CPT guidance would be appropriate.

The Department and its Agencies are working with the IGIV patient community, product manufacturers, distributors, physicians, and hospitals to develop a common understanding of the evolving IGIV marketplace, to assure continued collection of accurate ASP data, and to focus attention on the evidenced-based medical necessity of the utilization of IGIV. The Department's Office of the Inspector General is examining these issues as well. Please assure the Committee that we are monitoring the status of the IGIV supply and the factors that influence its availability, as well as reviewing options within the Department's authority to alleviate the availability of IGIV and access to care. If I need additional specific recommendations on this issue or similar issues, I will bring the topic and appropriate questions back to the Committee.

The Committee's recommendations for a coordinated strategic plan to ensure blood safety and availability are excellent and support the Secretary's 500-day plan for the Department. We will consider this recommendation as we move forward in shaping the strategic plan for the future.

Thank you again for your dedication to the Department and I look forward to your leadership of the committee.

Sincerely yours,



John O. Agwunobi
Assistant Secretary for Health