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August 5, 2019

Ms. Seema Verma
Centers for Medicare & Medicaid Services
Department of Health and Human Services,
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS Action Requested to Provide Relief to Hospitals and Patients from the Ongoing National Intravenous Immune Globulin Shortage

Dear Ms. Verma:

The Conference of Boston Teaching Hospitals (COBTH) is a nonprofit trade organization that represents twelve academic medical centers and teaching hospitals in the Greater Boston area. On behalf of our member institutions, we are reaching out to CMS to highlight the impact of the ongoing Intravenous Immune Globulin (IVIG) shortage on our patients and hospitals and to request that CMS take action to provide relief to hospitals and mitigate the impact of the shortage on patient health.

IVIG is an essential drug that millions of patients nationwide rely upon to treat often debilitating and life threatening immunodeficiency and immune dysregulatory conditions. For many patients, IVIG treatment is necessary to prevent infection, serious illness, and other complications that arise among immune-compromised patients.

Due to the critical nature of IVIG treatment for many patients, COBTH member hospitals have had to take significant action to ensure that our patients receive the optimal care possible with a severely restricted supply of the drug. Our member institutions have variously reported:

- Activating their Incident Command system reserved for emergencies and public health crises
- Creating internal task forces and working groups charged with triaging patients and developing criteria to prioritize the allocation of IVIG among patients
- Contacting each manufacturer of IVIG drugs in an effort to replenish a dwindling supply of the drugs and gain certainty on the future production and distribution of IVIG
- Convening with state and city officials to monitor the ongoing shortage and coordinate action to mitigate the impact on our patients

We understand that the causes of this shortage are varied and complex, but we urge CMS to take action to both provide short term relief to hospitals and our patients and to also address the underlying causes of this shortage and put in place a regulatory framework that prevents future

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Brigham and Women's Hospital · Cambridge Health Alliance · Dana-Farber Cancer Institute · Lahey Hospital & Medical Center
Massachusetts Eye and Ear · Massachusetts General Hospital · Steward St. Elizabeth's Medical Center · Tufts Medical Center

shortages and bolsters the ability of providers and the federal government to respond to these crises in the future.

Request for CMS Action on IVIG Shortage & Preventing Future Shortages

In the short term, there are available substitutes for outpatient administered IVIG, including subcutaneous immune globulin and home administration of human immune globulin. However, due to how these services are coded and reimbursed under Medicare, many providers are unable to offer these alternative services to patients. Therefore COBTH, on behalf of our member hospitals, requests that Medicare temporarily expand the list of qualifying ICD-10 codes for home administration of intravenous or subcutaneous immune globulin (IVIG/SCIG) to mirror those codes approved for outpatient administration. This temporary expansion is requested given the severe national shortage of IVIG to provide Medicare recipients with improved access to the limited pool of IVIG and SCIG products available in the marketplace while healthcare buyers remain on allocation from manufacturers.

We also request that CMS undertake regulatory action to ameliorate or prevent future critical drug shortages. COBTH recommends that CMS pursue the following actions to tackle future shortages:

- Develop a list of critical drugs that are lifesaving or are required for responses to emergencies and work with the FDA and manufacturers to create strategic stockpiles of these essential drugs in preparation for emergencies or high demand
- Create a multi-stakeholder advisory panel in conjunction with the FDA, providers, and other industry stakeholders to address the logistics of creating, managing, and storing a strategic stockpile of essential drugs
- Enhance communication between providers, manufacturers, and across the entire drug supply chain; charge the FDA with providing real time information to all stakeholders on developing shortages, their causes, and the duration of shortages
- Increase drug manufacturer transparency and reporting requirements on drug availability to give providers certainty in managing their patient panels' needs during times of shortage
- Prevent inventory hoarding and inequitable distribution of shortage drugs by requiring manufacturers to put these drugs on allocation to ensure equitable distribution
- Streamline regulations to create incentives for manufacturers to produce higher quantities of critical drugs in the long term
- Encourage FDA to consider how reducing the number of unapproved (pre-1938 FD & C) drugs on the market might impact shortages

COBTH hospitals remain committed to providing the best care possible to each of our patients, and drug shortages like the ongoing IVIG shortage threaten this mission. We appreciate the complexity of these shortages and the conditions that lead to them, but in the interest of patients and their providers we urge CMS to take the recommended regulatory actions to both provide short term relief from the current crisis and to lessen/prevent future shortages.

Please feel free to contact COBTH at alebovitz@cobth.org if you have any questions or would like more information. We thank you for your consideration and look forward to working collaboratively to address the ongoing IVIG shortage and prevent future shortage crises.

Sincerely,

A handwritten signature in black ink, appearing to read 'A. Lebovitz', with a long horizontal flourish extending to the right.

Alec Lebovitz
Government & Community Affairs Specialist
Conference of Boston Teaching Hospitals