

October 26, 2015

CDR Krista Pedley
Director, Office of Pharmacy Affairs
Health Resources and Services Administration
5600 Fishers Lane
Mail Stop: 08W05A
Rockville, MD 20857

Emergent BioSolutions
920 Cassatt Road, Suite 100
Berwyn, PA 19312 USA

t 484 318 8840
f 484 318 8841
www.emergentbiosolutions.com

Submitted via regulations.gov

Re: RIN 0906-AB08 - 340B Drug Pricing Program Proposed Omnibus Guidance

Dear Commander Pedley:

Emergent BioSolutions is pleased to support the work of the Hemophilia Alliance in ensuring that people with hemophilia have access to health care specialists, services, and treatments they need to lead active and productive lives. We are committed to ensuring that patients obtain the most appropriate treatment based on their individual healthcare needs, including access to Hemophilia Treatment Centers (HTCs) and the full range of FDA approved clotting factors, including factor supplied by pharmacy programs administered by HTCs as part of the 340B drug discount program.

Emergent BioSolutions support the Alliance's work toward creating an environment where people with hemophilia can tailor the care they receive to meet their individual needs by having access to providers of their choice, affordable medicines and services, health plans that include HTCs in their networks, and a wide range of products included in health plan formularies.

With respect to the recent Health and Human Resources and Services Administration (HRSA) omnibus guidance on the 340B Drug Pricing Program, we support the Alliance's positions that:

- Eligibility should explicitly include sub-recipients of Federal grants, which constitute the majority of HTCs that participate in the 340B program, and that the guidance clearly state that sub-recipients are responsible for program registration, operation, and compliance
- Patient eligibility criterion should be changed to more clearly accommodate the typical HTC network operating structure. Specifically,
 - Criterion 1 should be clarified to add clinical services and expand the stated site of care to include outreach locations covered under the grant, sub-grant, or project of the registered, covered entity
 - Criterion 2 should include health care providers who perform their services under an agreement with the 340B entity as a covered entity-provider relationship
 - Criterion 6 should be edited to remove reference to "auditable health care records" or explicitly describe what the term means, and it should not exclude prescriptions resulting from elements of care coordinated by the HTC but provided by a collaborating physician who is not employed by the covered entity
- The guidance should apply Government Auditing Standards in HRSA's audits of covered entities

Emergent continues to believe that HTCs are indispensable contributors to hemophilia care and also bring significant value to the larger U.S. health care system. As more and more innovative products

are created to treat this serious disorder and the health care delivery system continues to evolve, HTCs and the Alliance will become increasingly important in helping to shape policies that will improve hemophilia care.

Sincerely,



Michael Adelman
Vice President, Commercial Operations
BioSciences Division