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Texas Health and Human Services Commission
Attn: Stacey Johnston
Policy Analyst
Medicaid/Children's Health Insurance Program
P.O. Box 85200
Austin, TX 78708

Comments on the Proposed Rule Regarding Specialty Drugs

Dear Ms. Johnston and Members of the Commission:

The Biotechnology Industry Organization (BIO) is the largest international trade association representing the biotechnology industry. Our organization, based in Washington, D.C., represents more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and 31 other nations. BIO members are involved in the research and development of healthcare, agricultural, industrial, and environmental biotechnology products. On behalf BIO, please accept the following comments on the proposed rule concerning specialty drugs relating to Texas Administrative Code Title 1, Part 15, Chapter 354, Subchapter F, Division 3, § 345,1853.

Biotechnology products are unique, unlike traditional small molecule drugs, which are synthesized chemically to produce a desired mechanism of action, biotechnology harnesses cellular and biomolecular processes to develop therapies that combat many debilitating and rare diseases. Currently, there are more than 250 biotechnology health care therapies and vaccines that are widely available to patients. Many of these impact previously untreatable diseases, and many require some sort of special handling, administration, or follow-up to ensure the most effective patient care can be extracted from a given therapy. Because of this uniqueness, several biotechnology products could likely be classified by the Commission as "specialty drugs" as outlined in the proposed rule.

As the Commission continues its efforts to define this unique class of products, BIO believes it is crucial to keep in mind the importance of biotechnology therapies in treating rare and intractable diseases and we urge the Commission to ensure that any final rule protects patients' access to these products. We understand the desire to try and better manage the distribution chain for some specialized biopharmaceutical products; however, we also recognize that by calling attention to a class of products, or in some way separately classifying them, there could be efforts to subvert the stated intent of the classification by using it as a means to control short-term costs or limit access for other utilization purposes. We believe than any actions in this manner will do more harm than good. By ignoring the long-term health gains afforded patients from the effective use of biotechnology products in favor of short-term priorities, everyone loses. Patients could be limited in their access to needed therapies, which could result in unnecessary hospitalizations or disease progressions. All of this costs more in the long-run. Accordingly, we strongly urge the Commission to

address access concerns in any further rulemaking to ensure that all patients in Texas have robust access to a range of biotech therapies regardless of their insurance provider.

Additionally, we ask that the Commission take into account the increased costs often-times associated with appropriate use of biotech therapies. Unlike more traditional prescription drugs, which can generally be dispensed by a pharmacy directly to a patient, most biologics are infused or otherwise administered in a physician's office or other specialized setting. There are administrative and other costs associated with this process that we hope are accounted for in the Commission's deliberations and ultimately in the managed care and specialty pharmacy contracts that result from this process. Failing to account for these particularities in the biologics space not only hinders access to care but also hinders the drive to innovate.

In sum, BIO urges the Commission to make every effort possible to ensure Texas Medicaid recipients have unburdened access to the range of biotechnology therapies on par with the privately insured population.

Thank you for your consideration of our comments. I am available at any point to discuss these concerns further. Please do not hesitate to contact me.

Sincerely,

John A. Murphy, III
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