



EXPRESS SCRIPTS®

July 16, 2013

The Honorable Morgan Griffith
U.S. House of Representatives
Washington, DC 20515

Dear Congressman Griffith:

Express Scripts would like to thank you for your hard work in drafting the Compounding Clarity Act of 2013. Express Scripts is the nation's largest pharmacy benefit manager (PBM). We administer the prescription drug benefits on behalf our clients – employers, health plans, unions and government health programs — for approximately 100 million Americans. Headquartered in St. Louis, we provide integrated pharmacy benefit management services including specialty pharmacy and patient-care services.

Through our specialty pharmacies, Express Scripts does engage in a traditional pharmacy compounding. For example, we compound sterile saline cassettes for Remodulin® for patients with a certain form of pulmonary arterial hypertension (PAH). Patients on this therapy—generally the most progressively ill patients with PAH—are required to have a continuous course of therapy for the remainder of their lives. Going without therapy for even a few hours is fatal. In order for these patients to process the drug, Remodulin® needs to be diluted with a small amount of salt water via these saline cassettes. This product is not commercially available from any manufacturer—nor is it likely to be given the extremely small patient population. Essentially what Express Scripts does is purchase commercially available sterile saline and subdivide it into approximately 150 cassettes. Every batch is sent out to an independent lab for testing per United States Pharmacopeia (USP) 797 standards for potency, purity, and sterility. All shipments are quarantined until we receive the results. When they come back they have a “beyond use” date and are tracked exactly back to the original saline product by lot number and put on the patient prescription all before being shipped out the door via the mail. We obviously know how many PAH patients we have and roughly how many saline cassettes they will need. We do this sort of “anticipatory compounding” for quality control reasons and as a patient benefit to keep them on continuous therapy. This allows us to ship 14-30 cassettes (depending on the patient's therapy) with a month's supply of drug. And, the patient doesn't run the risk (which could be fatal) of being out of cassettes or having to obtain them every week.

We believe your bill, as currently drafted, elevates the practice of pharmacy compounding by applying the USP 797 standard to all sterile compounding while preserving the traditional role pharmacies have had in providing these preparations for critical patient populations. It also properly recognizes the distinction between pharmacy compounding and drug manufacturing.

We have concerns with S. 959 as passed by the U.S. Senate Committee on Health, Education, Labor and Pensions (HELP). While well meaning, this legislation would subject the sort of

compounding that Express Scripts' engages in to current good manufacturing practices (cGMP) because we do anticipatorily compound (albeit for a known patient population) and we deliver our preparations as prescribed to patients through the mail. We have assessed that it would be extraordinarily difficult, if not impossible, to convert our compounding pharmacy into a manufacturing facility for these small groups of patients (e.g. in this case, approximately 35 nationwide.) It actually would make more sense for the patients to self-compound their saline cartridges—a result we believe would not be in the patients' best interest.

As drafted, the Compounding Clarity Act of 2013 would strike the right balance between preserving traditional pharmacy compounding, while improving compounding standards and increasing coordination between the various state boards of pharmacies and the U.S. Food and Drug Administration. We thank you for your efforts and look forward to working with you on its passage.

Sincerely,

Mary Rosado
Vice President
Express Scripts