

**Testimony in Support of MA S.439 (Finegold) re: Step Therapy in Insurance Plans
Joint Committee on Financial Services
Public Hearing – October 16, 2013**

Chairmen Petruccelli and Costello, and Members of the Committee:

On behalf of the Leukemia & Lymphoma Society and the blood cancer patients we serve throughout the state of Massachusetts, we thank you for the opportunity to comment on Senate Bill 439, which would create guidelines for the use of step therapy in drug formularies.

Step therapy, also known as “fail first,” is a widely-used technique that insurers use to control drug costs. Step therapy requires patients to first try and fail on medications selected by their insurer—based on cost—before a patient is granted coverage for the medication that had been initially prescribed by the patient’s healthcare provider.

In 2010, almost 60% of commercial insurers were utilizing step therapy.ⁱ The practice is applied to drugs used to treat a wide range of diseases and conditions, including cardiovascular disease, cancer, diabetes, HIV/AIDS, mental health, hemophilia and other rare diseases. In fact, I am joined today by local organizations representing patients in many of these communities, along with the Massachusetts Medical Society and other healthcare providers.

When used in tandem with appropriate patient protections, step therapy can indeed function as an effective and safe strategy for controlling healthcare costs. When these protections are in place, the need for effective cost containment is balanced with the recognition that a healthcare professional—rather than an insurer—should ultimately determine what treatment a patient is on and for how long.

Unfortunately, these protections are not in place in much of the country, including Massachusetts. This has led to patient harm due to serious side effects from inadequate medications and to disease progression due to delays in appropriate treatment. Also concerning are the studies showing that a significant number of patients—when faced with a step therapy program—end up receiving no medication at all. According to a recent study, a total of 67% of patients whose specialty drugs were rejected under step therapy did not receive an alternate drug within a 30 day window.ⁱⁱ These situations could result in costly episodes of care that might have been avoided, if not for misuse of the step therapy technique.

For many patients—including those with cancer—every day is a battle. From the moment of diagnosis, patients rightfully want to know that they will have access to the treatment plan determined by their medical team to offer the greatest clinical benefit. Many of them who are forced to abide by step therapy programs will suffer for long periods of time on older, less effective, more toxic forms of treatment. Data from 2012 shows that an increasing percentage of plans are applying step therapy programs specifically to oncology products: 54% of plans, up from only 36% the year before.ⁱⁱⁱ This trend is deeply worrying to the cancer community, given that recent treatment breakthroughs are driven by the principles of “precision medicine”: today, oncologists have access to more diagnostic information than ever before, allowing them to make treatment decisions based on a patient’s specific profile. Fundamentally, an insurer using a step

therapy approach is not taking into account unique patient responses to different forms of treatment. That is because step therapy relies upon information that makes generalizations about large patient populations.

Fortunately, Senator Finegold's bill offers some common-sense, balanced solutions that enable insurers to realize their goals of cost-savings through step therapy while also ensuring that treatment decisions are left to the patient and his/her medical team. The bill does so by providing the prescriber with a process to request an override of the insurer's step therapy protocols, when medically necessary. This override shall be granted only if the provider can demonstrate the presence of certain clinical characteristics enumerated in the bill:

- The patient is currently stabilized on the treatment which is being requested, or
- The preferred treatment required under the step therapy program:
 1. Has been ineffective in the treatment of the patient's condition in the past,
 2. Is expected to be ineffective, or to adversely effect treatment compliance and thereby diminish the efficacy of the treatment,
 3. Will cause or is likely to cause an adverse reaction or other physical harm to the patient, or
 4. Is not approved by the FDA for the condition being treated.

In cases where step therapy is appropriate for use, the bill would also limit the amount of time a patient could be subjected to step therapy so that patients cannot be obligated for an indefinite period of time to risk treatment delays or adverse reactions. That limit would be the earlier of either ten days or the period of time that the healthcare provider deems necessary for determining the clinical effectiveness of the insurer's preferred treatment.

Legislatures around the country are taking steps to address this issue, having recognized the importance of establishing step therapy protocols^{iv}. Fortunately these simple protections do not lead to increases in cost for insurers.

In closing, I urge you to support this legislation so that treatment decisions are driven by clinical considerations and medical expertise, which in the long-run will most effectively promote cost-savings.

With questions, please contact:

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ⁱ Motheral, Brenda. *Journal of Managed Care Pharmacy*. Vol. 17, No. 2. March 2011.

ⁱⁱ Belazi, Dea. *The American Journal of Managed Care*. Vol. 19, Special Issue 4. May/June 2013.

ⁱⁱⁱ Report from Health Strategies Group, published by *Managed Care Oncology* during the 4th quarter of 2012.

^{iv} In 2013 alone, four states passed legislation related to step therapy: CT, LA, NM, and VT.