AIMED ALLIANCE
Alliance for the Adoption of Innovations in Medicine

December 18, 2018

ADDRESS BLOCK
ADDRESSS
CITY, STATE #####

Re: Nonmedical switching by Ohio health care systems

Dear [Ohio health systems and hospitals]:

We, the undersigned organizations, are writing to express our concern about the growing number of health systems in Ohio adopting policies that require medical practitioners to switch patients from a biologic to a biosimilar. Nonmedical switching not only can have a devastating impact upon patient health, but it also creates a conflict of interest for medical practitioners and could constitute fraud. We urge you to cease this practice immediately and work with physicians to ensure that patients receive the most effective care for their individual needs.

I. Impact to Health

Nonmedical switching describes any policy that forces a stable patient to switch from his or her current medication to a less costly alternative drug that could be less effective and lead to adverse outcomes. In a recent study, 69 percent of stable patients subject to nonmedical switching had adverse and negative reactions as a result of the change. We believe that once a patient achieves stability on a prescribed medication, only the prescribing practitioner in consultation with the patient—not an insurer or health system—should determine when it is appropriate to change the patient's medication. In fact, Ohio law even requires pharmacists to notify a prescribing physician if the pharmacist substitutes a biosimilar that has received an interchangeability designation from the U.S. Food and Drug Administration (FDA), given the potential health complications.[1]

II. Conflict for Doctors

In addition to putting patients at risk, nonmedical switching can also create a conflict of interest for health care practitioners. Physicians take an oath to put patients first and to provide them with the best possible treatment. Yet, as employees of health care systems, they are also influenced by employer directives—including those focused on cost reduction rather than patient care. Nonmedical switching can put these physicians in the impossible position of being forced to choose between violating an employer's orders or a patient's trust.

III. Fraudulent Practice

Nonmedical switching may amount to fraud under certain circumstances, putting health care systems that engage in the practice at significant legal risk. In justifying a switch from a biologic

[1] Ohio Rev. Code § 4729.38.

to a biosimilar, some health care systems' pharmacy and therapeutics committees have determined that the biosimilar is "interchangeable" with the original biologic.

However, interchangeability is a term of art and such status can only be conferred by the FDA. For the FDA to consider a medication interchangeable, it must "produce the same clinical results as the reference product in any given patient." The process of obtaining an interchangeability designation is scientifically rigorous, and thus far, no product has been able to meet that standard. For this reason, Ohio law defines "interchangeability" as a designation that must be determined by the FDA.[2] Therefore, a pharmacy and therapeutics committee that knowingly misrepresents a biosimilar as such could engage in fraud.

IV. Questionable Cost Benefit

Finally, the perceived cost savings associated with nonmedical switching are seriously flawed. Due to its long-term impacts on patient care, nonmedical switching can actually *increase* costs over time. Physicians, pharmacists, and other healthcare administrators have reported that nonmedical switching increases administrative time, increases side effects or new unforeseen effects, and increases downstream costs to plans and providers. In addition, when a stable patient is switched for nonmedical reasons, his or her care is more likely to be interrupted by a second switch. These cost-motivated switches increase patients' health care utilization and disrupt their course of care, and, as a result, increase related health care costs.

Even if a health care system is able to achieve some short-term savings, those savings are rarely passed along to the patient. In some instances, copays can be even higher for the new medication than for the original treatment. For example, based on a federal regulation (*i.e.*, the 340B passthrough rule), the Centers for Medicare and Medicaid Services (CMS) pays health systems more for administering new biosimilars than for biologics (*i.e.*, biosimilars are reimbursed at a rate of the average sales prices (ASP) minus 22.5%, and biosimilars are reimbursed at a rate of ASP plus 6% for the first three years that a biosimilars is on the market). Medicare beneficiaries must then pay 20% of that Medicare-approved rate. Therefore, the health system gets paid more for the biosimilar, but it costs the patient more out of pocket.

V. Conclusion

With health care costs on the rise, we understand the impulse to look for ways to reduce short-term costs—but such efforts should never come at the expense of a patient's health. Nonmedical switching puts health care systems' interests over the interests of doctors and patients. We urge you to put Ohio patients first and stop nonmedical switching in all of your hospitals and clinics.

Sincerely,

Aimed Alliance
Alliance for Patient Access
Association of Women in Rheumatology
Children with Diabetes

[2] Ohio Rev. Code § 3715.01.21.

Coalition of State Rheumatology Organizations
Diabetes Patient Advocacy Coalition
Global Healthy Living Foundation
Lupus and Allied Diseases Association, Inc.
Ohio Gastroenterology Society
Ohio Association of Rheumatology
US Pain Foundation