



Policy Position Paper

Therapeutic Substitution

Issue

Therapeutic Substitution and Therapeutic Interchange have become common practices and can produce negative results in some patients. Therapeutic Substitution not only undermines the physician-patient relationship, but may also harm a patient's health by ignoring critical differences between medications. These policies allow insurance to substitute their medical judgment without consulting the treating medical professional. Likewise, Therapeutic Interchange is a result of two influences: cost containment of medication costs and the rapid expansion of drugs within the same therapeutic class.

Type of Medications	Description of drugs
Therapeutic Interchange	Dispensing <i>chemically different drugs</i> that are considered by insurance providers, not the treating physician, to be therapeutically equivalent
Therapeutic Substitution	Dispensing a drug that is <i>chemically dissimilar</i> but which insurance providers identify as producing a similar outcome and which have similar toxicity profiles. This change could cause adverse reactions, increased toxicity, and adverse drug interactions

Legislative Overview

Currently, there is no federal legislation addressing therapeutic substitution, or interchange. The advancement of legislation on these subjects has been limited to state-level initiatives with six states passing laws to limit this practice. In many states, legislation has been limited in scope, creating restrictions on the substitution of drugs for specific conditions such as epilepsy, but failing to address underlying policy issues.

Example: Nebraska

In Nebraska, State Senator Abbie Cornett introduced the *Patient and Provider Prescription Act* (LB1088) in 2010. The Act would require health plan sponsors and pharmacy benefits managers (PBMs) to send notifications of request for medication changes to patients and their physicians or other prescribing health professionals whenever the insurer or PBM recommends changing a patient's medication to a different therapeutic agent. The legislation requires the notification to also include the following key provisions.

1. Acknowledges that medication changes will not be allowed without the authorization of the original prescribing health care professional.
2. Clearly identifies the originally prescribed medication and the medication to which the patient would be changed.
3. Requires disclosure of financial incentives that may be provided or offered to the prescribing health care

- professional by the health plan sponsor or the PBM.
4. Mandates disclosure of financial incentives the health plan sponsor or PBM may receive to encourage a drug substitution.
 5. An explanation of any cost-sharing changes for which the patient would be responsible should the medication substitution take place.
 6. States the patient has the right to discuss the propose medication change before it occurs.

The Act reaffirms the importance of an active dialogue between patients and physicians about prescription drug benefits and risks.

Alliance Policy

The Alliance is in strong opposition to all state and federal legislation that impedes the ability of health care providers to determine which drugs to prescribe for the treatment of patients, i.e. the act of dispensing a therapeutic alternative without prior authorization of the prescriber.

Further, the Alliance advocates physicians providing this quality care in the most efficient way possible. Physicians know the best treatments for their patients due to knowledge of a patient's medical history and current health status. And, physicians are uniquely qualified to help patients make informed decisions about prescription drug costs, quality, and health benefits. Current IVIG regulations require patients to receive authorization from their insurance provider at least every three months in order to receive treatment. This adds an unnecessary burden to both the patient and physician.

The Alliance is also opposed to switching specialty infusible therapies such as biologics, plasma-derived therapies and their recombinants, interferon, etc., without prior notification to both the patient and treating physician. This practice can result in severe negative reactions during an infusion. Additionally, this practice only serves to undermine the physician-patient relationship, and harms a patients' health by ignoring important differences between medicines, reducing outcomes and adherence to treatment.