



Joint Statement on Therapeutic Substitution

Therapeutic Substitution—Switches at the Pharmacy Counter

“Therapeutic substitution” is the requested or required substitution of one drug for a completely different drug when a consumer fills a prescription. Required therapeutic substitution poses serious risks to the health and safety of persons taking mental health medications and interferes with appropriate medication decisions made between a patient and his or her doctor.

Therapeutic substitution occurs when the consumer tries to fill a prescription for a drug that his or her drug plan will only cover after certain requirements are met. The drug plan requires that the pharmacist contact the physician and ask for permission to dispense a different medication than what the physician prescribed. This may occur, for example, when a plan requires a step therapy protocol that demands the consumer have tried other drugs before the prescribed one is dispensed. If the physician refuses to grant permission for a substitution, the prescribed drug may be dispensed, but it may not be paid for.

Therapeutic substitution is not the dispensing of a different brand of the same drug, which pharmacists are permitted to do in many states without checking with the physician. It is, instead, the substitution of an entirely different medication than the one the patient discussed with his or her doctor.

Therapeutic Substitution is not Generic Substitution

Therapeutic substitution is not the same as generic substitution. Generic substitution is when a generic form of a prescribed brand name drug is dispensed by the pharmacy. Although a generic may differ in inactive ingredients and some other aspects, such as rates of release, a generic contains the same active ingredient(s) in the same dosage as the brand name medication. It should be noted that despite the fact that generics are defined as being equivalent to brand drugs, some individuals have different reactions to the generic and brand version of the same drug.

Therapeutic Substitution Requires Dispensing a Completely Different Drug

In contrast, therapeutic substitution means a person is given a different medication in the same broad “therapeutic class,” even though drugs in the same class often work in different ways and have important differences in side effects and effectiveness for individuals. The main therapeutic classes for mental health drugs are:

- Antidepressants
- Antipsychotics
- Anticonvulsants
- Anti-anxiety medications

Each class contains multiple types of medications. For example, there are at least four different types of antidepressants alone and several medications among each type. Among the antipsychotics, there are particularly significant biochemical differences among medications. Choosing the correct mental health medication requires extensive knowledge of both the patient and available medications.

Individual Responses Vary

According to the National Institute of Mental Health, “A medication that works well for one person with schizophrenia often doesn’t work well for another. Genetic variations are thought to

play a key role in this difference in response.” These individual responses to mental health medications, along with differing symptoms and frequent, co-occurring physical health conditions, emphasize the need for carefully considered medication decisions.

Physicians Are in the Best Position to Make Clinical Decisions

Physicians, in partnership with consumers, make medication decisions based on their knowledge of the individual’s illness and treatment history, other medical conditions, drug-to-drug interactions, and drug-disease interactions. Only the physician has sufficient clinical information to make these decisions. Pharmacists and pharmacy plans may have some limited information about a consumer, but they are unlikely to have the all of the information necessary to make an informed decision about switching an individual’s medication.

Inappropriate Drug Switches Can Have Serious Consequences

One study of the Medicare drug benefit followed beneficiaries who were stable on medications but were switched to others by the drug plans providing the prescription benefit. The outcomes were costly and serious: Over one in three individuals had an emergency room visit, and 15 percent were hospitalized. An inappropriately treated psychotic or manic episode can lead to even more tragic results: lasting cognitive damage, homelessness, incarceration, or suicide. Other studies have confirmed this data.

Summary

Substituting one medication in a therapeutic class for another carries substantial risk of serious adverse outcomes and should not be used for medications used to treat mental illness. Instead, policies should provide patient protections that promote appropriate access to medications and acknowledge the necessity of shared patient-physician decisions based on the unique needs of individuals.