

**§482.13(e)(1)(i)(B) [A restraint is - ] A drug or medication when it is used as a restriction to manage the patient's behavior or restrict the patient's freedom of movement and is not a standard treatment or dosage for the patient's condition.**

### **Interpretive Guidelines §482.13(e)(1)(i)(B)**

Drugs or medications that are used as part of a patient's standard medical or psychiatric treatment, and are administered within the standard dosage for the patient's condition, would not be subject to the requirements of standard (e). These regulations are not intended to interfere with the clinical treatment of patients who are suffering from serious mental illness and who need therapeutic doses of medication to improve their level of functioning so that they can more actively participate in their treatment. Similarly, these regulations are not intended to interfere with appropriate doses of sleeping medication prescribed for patients with insomnia, anti-anxiety medication prescribed to calm a patient who is anxious, or analgesics prescribed for pain management. The regulatory language is intended to provide flexibility and recognize the variations in patient conditions.

Whether or not an order for a drug or medication is PRN (Latin abbreviation for pro re nata - as needed; as circumstances require) or a standing-order does not determine whether or not the use of that drug or medication is considered a restraint. The use of PRN or standing-order drugs or medications is only prohibited if the drug or medication meets the definition of a drug or medication used as a restraint.

Criteria used to determine whether the use of a drug or medication, or combination of drugs or medications is a standard treatment or dosage for the patient's condition includes all of the following:

- The drug or medication is used within the pharmaceutical parameters approved by the Food and Drug Administration (FDA) and the manufacturer for the indications that it is manufactured and labeled to address, including listed dosage parameters;
- The use of the drug or medication follows national practice standards established or recognized by the medical community, or professional medical associations or organizations; and,
- The use of the drug or medication to treat a specific patient's clinical condition is based on that patient's symptoms, overall clinical situation, and on the physician's or other licensed independent practitioner's (LIP) knowledge of that patient's expected and actual response to the medication.

Another component of "standard treatment or dosage" for a drug or medication is the expectation that the standard use of a drug or medication to treat the patient's condition enables the patient to more effectively or appropriately function in the world around them than would be possible without the use of the drug or medication. If the overall effect of a

drug or medication, or combination of drugs or medications, is to reduce the patient's ability to effectively or appropriately interact with the world around the patient, then the drug or medication is **not** being used as a standard treatment or dosage for the patient's condition.

As with any use of restraint or seclusion, staff must conduct a comprehensive patient assessment to determine the need for other types of interventions before using a drug or medication as a restraint. For example, a patient may be agitated due to pain, an adverse reaction to an existing drug or medication, or other unmet care need or concern.

There are situations where the use of a drug or medication is clearly outside the standard for a patient or a situation, or a medication is not medically necessary but is used for patient discipline or staff convenience (neither of which is permitted by the regulation).

- **EXAMPLE 1:** A patient has Sundowner's Syndrome, a syndrome in which a patient's dementia becomes more apparent at the end of the day rather than at the beginning of the day. The patient may become agitated, angry, or anxious at sundown. This may lead to wandering, pacing the floors, or other nervous behaviors. The staff finds the patient's behavior bothersome, and asks the physician to order a high dose of a sedative to "knock out" the patient and keep him in bed. The patient has no medical symptoms or condition that indicates the need for a sedative. In this case, for this patient, the sedative is being used inappropriately as a restraint for staff convenience. Such use is not permitted by the regulation.

A drug or medication that is not being used as a standard treatment for the patient's medical or psychiatric condition, and that results in restricting the patient's freedom of movement would be a drug used as a restraint.

In addition, the regulation does not permit a drug or medication to be used to restrain the patient for staff convenience, to coerce or discipline the patient, or as a method of retaliation. While drugs or medications can be a beneficial part of a carefully constructed, individualized treatment plan for the patient, drug and medication use should be based on the assessed needs of the individual patient, and the effects of drugs and medications on the patient should be carefully monitored.

- **EXAMPLE 2:** A patient is in a detoxification program. The patient becomes violent and aggressive. Staff administers a PRN medication ordered by the patient's physician or other LIP to address these types of outbursts. The use of the medication enables the patient to better interact with others or function more effectively. In this case, the medication used for this patient is not considered a "drug used as a restraint." The availability of a PRN medication to manage outbursts of specific behaviors, such as aggressive, violent behavior is standard for this patient's medical condition (i.e., drug or alcohol withdrawal). Therefore, this patient's medication does not meet the definition of "drug used as a restraint" since it is a standard treatment or dosage for the patient's medical or psychiatric condition. The use of this medication for this patient is not affected by standard (e).

If a drug or medication is used as a standard treatment (as previously defined) to address the assessed symptoms and needs of a patient with a particular medical or psychiatric condition, its use is **not** subject to the requirements of this regulation. However, the patient would still need to receive assessments, monitoring, interventions, and care that are appropriate for that patient's needs.

The regulation supports existing State laws that provide more vigorous promotion of the patient's choice and rights. Therefore, when a State's law prohibits the administration of drugs against the wishes of the patient without a court order, the State law applies.

- Determine whether the hospital's policies and procedures employ a definition or description of what constitutes the use of drugs or medications as a restraint that is consistent with the regulation.
- Interview hospital staff to determine whether they can identify when the use of a drug or medication is considered a chemical restraint.