

Informed Consent Information

Public Chapter 1039 requires obtaining informed consent from the patient prior to prescribing opioids in certain scenarios. The following language is part of [PC1039](#):

“Informed Consent” means consent voluntarily given in writing by the patient or the patient’s legal representative after sufficient explanation and disclosure by the healthcare practitioner of the subject matter involved to enable the person whose consent is sought to make a knowing and willful decision. This explanation and disclosure by the healthcare practitioner to the patient or the patient’s legal representative before consent may be obtained must include, at a minimum:

(i) Adequate information to allow the patient or the patient's legal representative to understand:

(a) The risks, effects, and characteristics of opioids, including the risks of physical dependency and addiction, misuse, and diversion;

(b) What to expect when taking an opioid and how opioids should be used; and

(c) Reasonable alternatives to opioids for treating or managing the patient's condition or symptoms and the benefits and risks of the alternative treatments;

(ii) A reasonable opportunity for questions by the patient or patient's legal representative;

(iii) Discussion and consideration by the patient or the patient's legal representative and the healthcare practitioner of whether the patient should take an opioid medicine; and

(iv) If the patient is a woman of childbearing age and ability, information regarding neonatal abstinence syndrome and specific information regarding how to access contraceptive services in the community. For purposes of this section, childbearing age is between the ages of fifteen (15) and forty-four (44).

Disclaimer: The Tennessee Department of Health does not endorse one particular form or set of language for an appropriate informed consent form. The following language may be used as the building blocks for prescribers to assist them in creating an appropriate informed consent form for their office and the demographic which they treat. This language is being provided for informational purposes only and is not a substitute for legal advice. It is recommended that prescribers consult their own legal counsel before using or relying on this information which is provided as an example.

Example Elements for Informed Consent

___ I understand that when I take opioids, I may experience reactions or side effects that could be dangerous. These side effects include sleepiness, constipation, nausea, itching, allergic reactions, problems with thinking clearly, slowing of my reactions, or slowing of my breathing so much that it can lead to death.

___ I understand that when I take opioids, it may not be safe for me to drive a car, work machines, or take care of other people. If I feel tired, confused or unable to function with this medication, I should not do things that would put me or other people at risk.

___ I understand that usually there are other options to opioids to treat moderate to moderately severe pain, including therapy that does not involve medication. I understand that there are times when these other options may provide more pain relief with less risk. I have talked about the other options with my provider.

___ I understand that using opioids to treat moderate to moderately severe pain comes with possible benefits and risks. When used correctly, opioids may help reduce pain, improve function, and improve quality of life. However, use can also lead to tolerance and dependence, which means the body needs higher and higher amounts to get the same relief and the body craves the medicine and does not feel normal without it. Taking opioids can lead to opioid use disorder which can happen when a person chooses actions they know to be harmful in order to meet the craving for opioid medicine. Using opioids requires both the provider and the patient to work together responsibly to ensure the most benefit, shortest exposure, fewest side effects, and avoid developing substance use disorder.

___ I understand that opioids work to dull pain. They do not fix the actual injury and can lead to further harm due to decreasing pain, which is part of the body's response to injury. Opioids may help prevent acute pain from becoming long-lasting pain, but on the negative side, they often have side effects and may lead to long term use of opioids and development of a life-threatening opioid use disorder.

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___ I understand that I should not expect all pain, anxiety, or stress to go away with the use of opioids.

___ I understand that I may have side effects from opioids, including but not limited to sleepiness, constipation, nausea, unexplained happiness, forgetfulness, itching, dry mouth, sweating, or difficulty urinating. Also, some people will develop an increased sensitivity to pain while taking opioids.

___ I understand that if I become dependent on opioids, when I stop taking them, I may experience stomach pain, nausea, vomiting, diarrhea, sweating, body aches, muscle cramps, anxiety, and difficulty sleeping.

___ I understand that anyone can develop an addiction to opioids, but people who have had poor mental health or problems with drugs or alcohol in the past are at higher risk. I understand it is my responsibility to tell my provider if I or anyone in my family has had any of these problems.

___ I understand that I must safely store and legally get rid of opioids left over after I am better. I understand that medications should always be stored in a safe place and out of the reach of children and other family members. To safely get rid of unused medication, I can take it to any police station, to some pharmacies, and other sites. A list of sites known to be available is at <https://www.tn.gov/health/health-program-areas/pdo/pdo/resources/r/community.html>.

For women who are between 15 and 44 years old and are able to have children,

___ I understand that I should take care to not become pregnant while taking opioids. Nearly half of all pregnancies are not planned. If I do not want or plan to become pregnant, I will work with my provider to find the best contraceptive or birth control method for me.

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It is my responsibility to tell my provider immediately if I think I am pregnant or if I am thinking about getting pregnant.

___ I understand the risk to a developing baby if exposed to opioids during pregnancy includes low birth weight, the baby's dependency on opioids, and long withdrawal after birth (neonatal abstinence syndrome). I understand that a baby's exposure to opioids during pregnancy can cause the baby pain, suffering, and a longer time in the hospital. Access to birth control options, including a long acting reversible contraceptive, is available in many places, including most OB/GYN and primary care offices, and at Health Departments in every county.

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