

Frequently Asked Questions: Implementation of TN Together

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PRESCRIPTION LIMITS

1. When do the dose and duration limits of TN Together apply?

Most provisions of <u>Public Chapter 1039</u> go into effect on July 1, 2018, but there is a six-month grace period for dispensers to submit ICD-10 codes to the Controlled Substance Monitoring Database (CSMD) if they have not updated the dispensing software system to enable submission of ICD-10 codes. This grace period lasts until January 1, 2019. Dispensers are expected to use updated software for submission of ICD-10 codes once software updates are complete. Software systems used by dispensers include all software required to partial fill a controlled substance prescription during the normal course of business.

2. Why is it important to limit the duration of the initial opioid therapy?

A growing body of medical evidence supports the idea that the duration of the initial episode of treatment with opioids is a (and perhaps *the*) major risk factor for ongoing use, subsequent misuse, and abuse of opioids.

For additional information, please refer to the following publications:

- "Characteristics of Initial Prescription Episodes and Likelihood of Long-Term Opioid Use," CDC
 2017
- "New Persistent Opioid Use After Minor and Major Surgical Procedures in US Adults," JAMA 2017
- <u>"Effect of Opioid vs Nonopioid Medications on Pain-Related Function in Patients With Chronic Back Pain or Hip or Knee Osteoarthritis Pain," JAMA 2018</u>
- <u>"Postsurgical prescriptions for opioid naive patients and association with overdose and misuse:</u> retrospective cohort study," *BMJ* 2018

3. What are the requirements for prescribing a three-day supply of opioids?

As with prior to the passage of <u>Public Chapter 1039</u>, a healthcare practitioner can treat a patient with a three-day supply of an opioid at a total dosage of 180 morphine milligram equivalent (MME) total dosage without any new requirements. As with before the new law, a healthcare practitioner still must complete a history and physical as well as diagnosis and treatment plan before prescribing for three days.

4. If a patient received a three-day supply of opioid pain medicine and now needs a new prescription, how should a healthcare practitioner proceed?

After completion of a three-day prescription, a patient must be reevaluated before receiving additional controlled substances. If the patient has ongoing pain of the same etiology, then the prescriber should consider the medically appropriate options for longer duration treatment of pain, which may include additional opioid medication which conform to the requirements of Public Chapter 1039. If the patient has an adverse reaction to an opioid, the practitioner may treat the patient with a different opioid within a 10-day period if:

- 1. The healthcare practitioner is employed by the same practice that initially treated the patient with the opioid that caused the adverse reaction;
- The healthcare practitioner personally evaluates the patient, assesses the adverse reaction, and determines a different course of treatment is more medically appropriate;
- 3. The healthcare practitioner confirms with the dispenser that the remainder of the initial prescription has been cancelled by the dispenser;
- 4. The healthcare practitioner counsels the patient to appropriately destroy any remaining opioids that were previously dispensed to the patient; and
- 5. The treatment of the patient conforms to the requirements of Public Chapter 1039.
- 5. If a five-day prescription is written, can all five days be dispensed at once? Yes.
- 6. Why are partial fill prescriptions required for 10-day, 20-day, and 30-day prescriptions? The most common way that people who are not currently taking opioid medications gain access to opioids is through diversion taking the extra opioids friends and family have received from healthcare. It is well documented that most patients do not use all of the opioid pain medications they are prescribed after surgery, and this is a major source of medications which are subsequently diverted to other people. By breaking the dispensing up into two parts, the goal is to reduce the amount of leftover medications. Partial fill prescriptions allow patients to take control and, if needed, receive the full duration of the prescription without going back to the prescriber.

USE OF ICD-10 CODE AND EXEMPTIONS

7. What is an "exempt" patient, and why are these patients exempt?

Patients that are considered exempt are those with established medical conditions listed in the law. For these patients, the primary disease must be documented in the patient's chart. The prescription must include the word "exempt" with the relevant ICD-10 code. The exempted categories are as follows:

- (1) Patients who are undergoing active or palliative cancer treatment or who are receiving hospice care;
- (2) Patients with a diagnosis of sickle cell disease;
- (3) Administration of opioids directly to a patient during the patient's treatment at any facility licensed under title 68, chapter 11, or hospital licensed under title 33, chapter 2, part 4. For example, such facilities include: hospitals, recuperation centers, nursing homes, homes for the aged, residential HIV supportive living facilities, assisted-care living facilities, home care

organizations, residential hospices, ambulatory surgical treatment centers, and adult care homes.

- (4) Prescriptions issued by healthcare practitioners who are:
 - (A) Pain management specialists, as that term is defined in §63-1-301, or who are collaborating with a pain management specialist in accordance with §63-1-306(a)(3); provided, that the patient receiving the prescription is personally assessed by the pain management specialist, or by the advanced practice registered nurse or physician assistant collaborating with the pain management specialist; or
 - (B) Treating patients in an outpatient setting of a hospital exempt under §63-1-302(2) that holds itself out to the public as a pain management clinic.
- (5) The treatment of patients who have been treated with an opioid daily for ninety (90) days or more during the three hundred sixty-five (365) days prior to April 15, 2018, or those who are subsequently treated for ninety (90) days or more under one (1) of the exceptions listed in subdivision (d)(4) or this subsection (e);
- (6) The direct administration of, or dispensing of, methadone for the treatment of an opioid use disorder to a patient who is receiving treatment from a healthcare practitioner practicing under 21 U.S.C. §823(g)(1);
- (7) The treatment of a patient for opioid use disorder with products that are approved by the U.S. food and drug administration for opioid use disorder by a healthcare practitioner under 21 U.S.C. §823(g)(2);
- (8) The treatment of a patient with a product that is an opioid antagonist and does not contain an opioid agonist; or
- (9) The treatment of a patient who has suffered a severe burn or major physical trauma, as those terms are defined by the controlled substance database committee by rule and adopted by the licensing boards created pursuant to title 63, and sound medical judgment would determine the risk of adverse effects from the pain exceeds the risk of the development of a substance use disorder or overdose event.

8. Where should a healthcare practitioner write the ICD-10 code and "exempt" or "medical necessity" on a written controlled substance prescription?

The ICD-10 code, "exempt" and "medical necessity" can be placed in the area available for patient instructions or anywhere on the prescription where the information will be transmitted to the pharmacy as part of the prescription.

9. If the healthcare practitioner is not a pain medicine specialist, can he or she still write "exempt" prescriptions?

Yes.

10. If a patient's primary care doctor is writing a monthly prescription for an opioid, is the patient considered "exempt" or should the prescription be partially filled?

If the patient is exempt from <u>Public Chapter 1039</u>, then the Drug Enforcement Administration (DEA) standard limit of 30-days for a prescription fill applies.

11. If a patient is exempt due to the length of time he or she has been prescribed opioid medications, is the healthcare practitioner required to write "exempt" on the patient's prescriptions?

Yes; the prescriber should also include the ICD-10 code for the primary condition being treated.

12. Do healthcare practitioners have to write "exempt" and the ICD-10 code on the prescription or can the dispenser write "exempt" or the ICD-10 code on the prescription after verifying?

<u>Public Chapter 1039</u> specifies that prescribers will document that the patient is exempt and the appropriate ICD-10 code of the primary diagnosis being treated.

13. Why does a healthcare practitioner need to identify an ICD-10 code for prescriptions lasting 10-days, 20-days for surgical indications, 30-days, or for "exempt" patients?

The primary purpose of putting the ICD-10 code in medical documentation is to ensure good documentation and communication with the dispenser and the CSMD. By including the appropriate ICD-10 code for the condition causing the patient's pain, the dispenser fulfills their obligations under state law and federal regulations and can better assess the prescription and better counsel the patient upon dispensing. Additionally, when prescribing under one of the exemptions or exceptions (i.e., medical necessity or perioperative care), the ICD-10 code efficiently communicates the exemption or exception being used which can obviate the need for unnecessary phone calls with dispensers.

14. How can a healthcare practitioner determine the ICD-10 code for the primary disease causing the pain?

Examples of resources for selecting the proper code include the following:

- https://icd10coded.com/
- http://hipaaspace.com/Medical_Billing/Coding/International_Classification_Of_Diseases/I CD10_Codes_Lookup.aspx
- https://www.findacode.com/search/search.php
- 15. If an electronic health record (EHR) system recently has started allowing electronic prescribing of controlled substances, but there is no clear place for the ICD-10 code,

"exempt" or "medical necessity," where can a healthcare practitioner make these notations?

Any system field which can transmit the information to the dispenser can potentially be used for indicating the ICD-10 code, "exempt" status, or "medical necessity" status.

OTHER QUESTIONS

16. What is meant by "more than minimally invasive surgery?"

Major surgery is more than minimally invasive. Minor surgery is not more than minimally invasive.

17. What is a pain management specialist?

Pain management specialist is defined in T.C.A. § 63-1-301.

18. Has the role of the pharmacist changed? If so, how?

Pharmacists are important members of the medical team who have been responsible for ensuring that dispensed medications are in the patient's best interest (T.C.A. § 53-10-112). Pharmacists have been rejecting prescriptions when they were not, in their best judgement, safe and effective. In that sense, nothing has changed, except the pharmacist has access to the ICD-10 code for the primary condition causing the patient's pain.

19. Do any of the provisions of the new law apply to veterinarians?

Public Chapter 1039 applies to human patients only.

20. How do TennCare's rules and the TN Together legislation differ?

The TN Together legislation governs how practitioners can prescribe opioids in different clinical circumstances, regardless of an individual patient's insurance coverage. TennCare, the state's Medicaid program, has specific rules about what medications will be covered for a TennCare recipient. For full information on TennCare's opioid benefits and restrictions for reimbursement, prior authorization forms for opioid prescription approval, and other frequently asked TennCare questions, please visit https://tenncare.magellanhealth.com/.

21. How does a practitioner counsel a patient on appropriate and effective forms of birth control? Is there a model of informed consent which will document appropriate counseling?

Informed consent 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 medication; 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).

22. If the healthcare practitioner is a pain management specialist, is the nurse practitioner or physician assistant who collaborates with the pain management specialist and who is writing the prescription covered?

Yes, provided that the supervising physician, advanced practice nurse, or physician assistant personally assesses the patient.

23. Is the dispenser responsible for verifying that the prescriber is a licensed pain management specialist?

<u>Public Chapter 1039</u> does not specify the responsibility of the dispenser with regard to verifying the prescriber is a pain management specialist.

24. Is Tramadol considered an opioid and thus a controlled substance under the provisions of the new law?

The U.S. Food and Drug Administration (FDA) and the National Institutes of Health (NIH) classify Tramadol as opioid analgesic used for the therapy of mild-to-moderate pain. It is now considered a controlled substance for purposes of the CSMD.

25. How does a healthcare practitioner calculate the number of morphine milligram equivalents (MME) in a prescription?

The Center for Disease Control and Prevention (CDC) publishes conversion tables for opioids which have become the basis of calculators which are available online or in smartphone apps.

Helpful resources:

- https://www.cdc.gov/drugoverdose/prescribing/app.html
- https://www.cdc.gov/drugoverdose/pdf/calculating total daily dose-a.pdf
- https://tenncare.magellanhealth.com/static/docs/Program_Information/TennCare_MME _Conversion_Chart.pdf