



Guidance on Collaborative Drug Therapy Agreements

**Washington State Pharmacy
Quality Assurance Commission**

The Washington State Pharmacy Quality Assurance Commission is providing this guidance document in order to assist practitioners and facilities in determining regulatory requirements applying to collaborative drug therapy agreements.

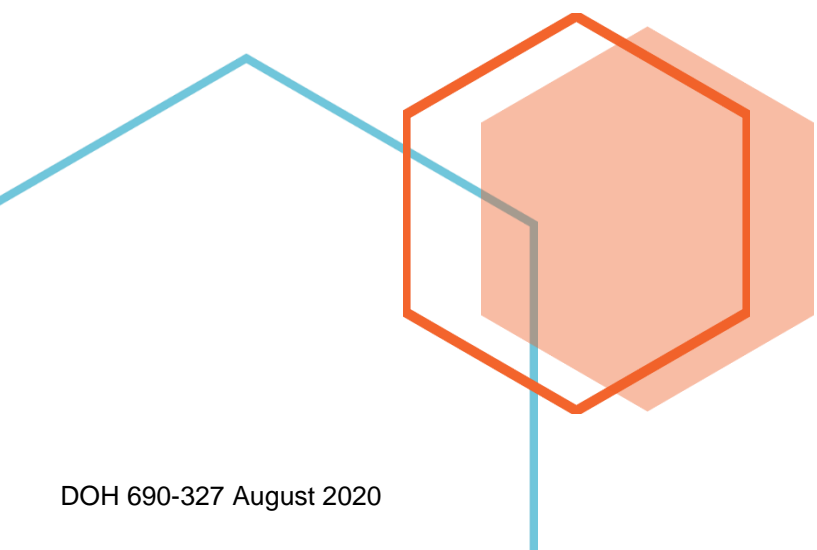




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Introduction

Established in 1891, the Washington State Pharmacy Quality Assurance Commission (Commission) regulates the practice of pharmacy in Washington State.¹ Through its regulation of the practice of pharmacy, the Commission protects and promotes public health and safety.²

Over the past year, the Commission has received a number of inquiries related to the use of collaborative drug therapy agreements (CDTAs). These inquiries have included:

- Whether a pharmacist may write a prescription and sign “on behalf of” a prescriber.
- Whether a pharmacist prescribing under a CDTA is exercising his or her own prescriptive authority or the prescriptive authority of the practitioner who signed the CDTA.
- Whether a prescriber must authenticate a prescription entered by a pharmacist on a practitioner’s behalf pursuant to a standing order or protocol.
- Whether a prescription completed by a pharmacist pursuant to a CDTA should be affixed with a label containing the pharmacist’s name or the patient’s treating practitioner.

This document attempts to provide some clarity to practitioners and facilities in ascertaining their regulatory obligations as it pertains to the use of CDTAs.

¹ RCW 18.64.005(1).

² See e.g. RCW 18.64.005(7).



The Basics of Collaborative Drug Therapy Agreements (CDTAs)

A CDTA is a set of written guidelines or protocols that establish the scope of prescriptive authority for a pharmacist. A pharmacist and a practitioner enter into a CDTA. When prescribing under a CDTA, a pharmacist is exercising his or her own prescriptive authority.

Since 1979, the legislature has authorized pharmacists to initiate or modify drug therapy in accordance with written guidelines or protocols previously established for their practice by a practitioner authorized to prescribe drugs.³ Since enactment of this provision, the phrase “collaborative drug therapy agreement” has referred to the written guidelines or protocols established by a pharmacist and practitioner.

A pharmacist may enter into a CDTA with a “practitioner.” A practitioner includes:

[a] physician, dentist, veterinarian, nurse⁴, or other person duly authorized by law or rule in the state of Washington to prescribe drugs.

RCW 18.64.011(29).

Once a CDTA is established, a pharmacist may prescribe drugs in accordance with the CDTA. Washington statute allows a CDTA to authorize a pharmacist to prescribe *any* legend drug,⁵ in addition to controlled substances.⁶ Washington statute does not provide *any* limit on what practice settings a CDTA may operate in, nor is there any affirmative statutory requirement for a pharmacist to communicate with the practitioner at a specific time.⁷ When a pharmacist provides health care services, including those provided under a CDTA, health plans are required to cover these health care services in the same manner as other health care providers, e.g. physicians.⁸

In implementing its duty to regulate the practice of pharmacy, the Commission has adopted rules around pharmacists exercising their prescriptive authority under a CDTA.⁹ The Commission has also provided guidance to the regulated community on the CDTA process.¹⁰ The Commission

³ Practice of Pharmacy – Requirements, Laws of 1979, ch. 90.

⁴ Currently this would include advanced registered nurse practitioners (ARNPs) and certified registered nurse anesthetist (See RCW 18.79.250 and RCW 18.79.240(r) respectively).

⁵ RCW 69.41.010(17).

⁶ RCW 69.50.101(II)(1) and (mm).

⁷ Instead, the CDTA should address issues relating to communication, drugs that can be prescribed, and practice setting (if applicable).

⁸ RCW 48.43.094.

⁹ WAC 246-945-350

¹⁰ See Pharmacy Quality Assurance Commission, *Collaborative Drug Therapy Agreement (CDTA) Process*, DOH 690-285 July, 2014. This can be found at: <https://www.doh.wa.gov/Portals/1/Documents/Pubs/690285.pdf> (last accessed July 18, 2018).



requires filing of all CDTAs with the Commission¹¹ and each CDTA is assigned a unique identifier.¹² In addition, the Commission's rule provides the minimum content of CDTAs:

(2) For purposes of pharmacist prescriptive authority under RCW 18.64.011(11), a written guideline or protocol is defined as an agreement in which any practitioner authorized to prescribe legend drugs delegates to a pharmacist or group of pharmacists authority to conduct specified prescribing functions. Any modification of the written guideline or protocol shall be treated as a new protocol. It shall include:

(a) A statement identifying the practitioner authorized to prescribe and the pharmacist(s) who are party to the agreement. The practitioner authorized to prescribe must be in active practice, and the authority granted must be within the scope of the practitioner's current practice.

(b) A time period not to exceed two years during which the written guideline or protocol will be in effect.

(c) A statement of the type of prescriptive authority decisions the pharmacist(s) is (are) authorized to make, which includes:

(i) **A statement of the types of diseases, drugs, or drug categories involved, and the type of prescriptive authority activity** (e.g., modification or initiation of drug therapy) authorized in each case.

(ii) A general statement of the procedures, decision criteria, or plan the pharmacist(s) is (are) to follow when making therapeutic decisions, particularly when modification or initiation of drug therapy is involved.

(d) A statement of the activities pharmacist(s) is (are) to follow in the course of exercising prescriptive authority, including documentation of decisions made, **and a plan for communication or feedback to the authorizing practitioner concerning specific decisions made.** Documentation may occur on the prescription record, patient drug profile, patient medical chart, or in a separate log book.

WAC 246-945-350(2)(c)(ii) (emphasis added).

¹¹ WAC 246-945-350 (2).

¹² *Supra* n. 18.



CDTAs, Standing Orders, and Protocols

Introduction

The Commission has become aware of the difficulty of identifying whether a document is a CDTA, a standing order, or a protocol. This section aims to provide guidance to people and facilities on whether a specific document is a CDTA, standing order, or protocol. The following table provides general definitions for those terms:

| Term | Definition |
|-----------------------|--|
| CDTA | As used by the Commission, a CDTA comprises written guidelines or protocols previously established and approved for a pharmacist’s practice by a practitioner authorized to prescribe drugs. The existence of a CDTA allows pharmacists to have <i>their own</i> prescriptive authority as outlined in the CDTA. ¹³ |
| Standing Order | Written care directives from an authorized provider delineating the circumstances and describing the parameters of specific situations under which another person may act to carry out specific medical orders. |
| Protocol | A series of actions (which may include a number of medications) that may be implemented to manage a patient’s clinical status. A protocol allows the application of specific interventions to be decided by a person based on the patient meeting certain criteria outlined in the protocol as long as the intervention is within the scope of practice of the person. A protocol includes alternative actions or “exceptions” to the prescriptive orders that allows for individual patient circumstance as assessed by the person. These “exceptions” are addressed by application of an algorithm that is a step-by-step procedure for solving a problem or accomplishing the intervention. ¹⁴ |

¹³ Although the term CDTA is not used in statute, the authority for the creation of a CDTA is found in statute (RCW 18.64.011(28)) and the Commission has promulgated rules providing of a CDTA’s minimum content and procedure for entry (WAC 246-945-350).

¹⁴ It should be noted that not all regulatory entities treat standing orders and protocols separately. For example, CMS frequently refers to standing orders and protocols collectively as standing orders. See <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/Survey-and-Cert-Letter-13-20.pdf> (last accessed March 27, 2018).



Distinguishing CDTAs from Protocols and Standing Orders

The diagrams below and accompanying explanation attempt to provide clear guidance to practitioners and facilities on how to distinguish CDTAs from other protocols and standing orders.

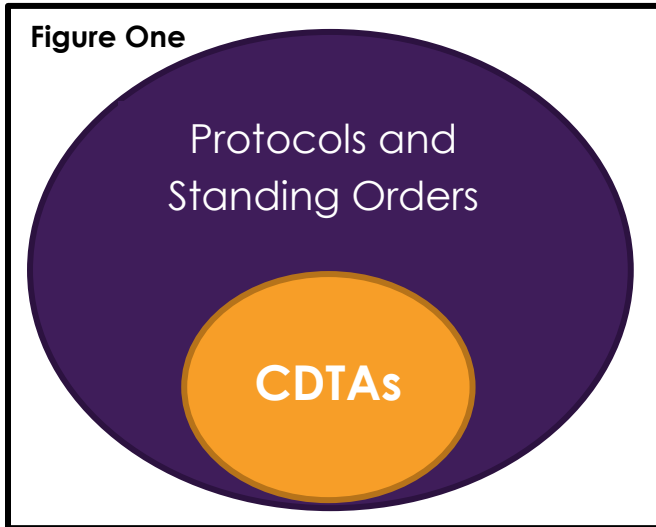
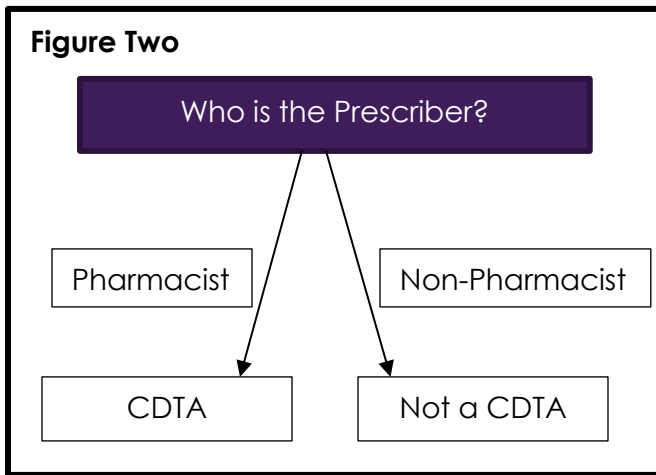


Figure One attempts to illustrate that a CDTA is a subset of protocols and standing orders. In other words, while CDTAs can all be described as standing orders or protocols, not all standing orders and protocols can be described as a CDTA.



The key element in determining whether a particular protocol or standing order is a CDTA is the identity of the prescriber. If a pharmacist is the prescriber, then the protocol or standing order is a CDTA. If a non-pharmacist is a prescriber, then the protocol or standing order is not a CDTA. As an example, a pharmacist following a protocol for an immunization, who enters an order for an immunization under his or her own credentials, is operating under a CDTA.



Pharmacists Operating Under CDTAs – Regulatory Considerations

Introduction

A CDTA enables a pharmacist to act as a prescriber of legend drugs and/or controlled substances depending on the terms of the CDTA. The Legend Drug Act¹⁵ and the Uniform Controlled Substances Act support this interpretation.¹⁶ This interpretation also aligns with the Commission’s current rules that refer to a pharmacist’s “prescriptive authority.”¹⁷

Who should sign a prescription or order?

When prescribing under the terms of a CDTA, pharmacists should be writing a prescription in their own name and credentials, e.g. NPI and/or DEA registration number, and not the name and credentials of the practitioner authorizing the CDTA. A prescription written on behalf of a practitioner by a pharmacist may amount to unprofessional conduct under the Uniform Disciplinary Act.¹⁸

Is practitioner authentication necessary?

No, as the pharmacist is the prescriber under a CDTA there is no need for the practitioner to authenticate each individual prescription written under the CDTA by the pharmacist.

When a label is affixed to an outpatient prescription drug container, should the name of the pharmacist prescriber appear?

The Legend Drug Act¹⁹ provides, in relevant part, that:

To every box, bottle, jar, tube or other container of a legend drug [including controlled substances], which is dispensed by a practitioner authorized to prescribe legend drugs, there shall be affixed a label **bearing the name of the prescriber**, complete directions for use, the name of the drug either by the brand or generic name and strength per unit dose, name of patient and date: . . .

RCW 69.41.050(1).

That Pharmacists statute also provides. In relevant part, that:

To every box, bottle, jar, tube or other container of a prescription which is dispensed there **shall be fixed a label** bearing the name and address of the dispensing pharmacy, the prescription number, **the name of the prescriber**, the

¹⁵ RCW 69.41.010(17) and RCW 69.41.030(1).

¹⁶ RCW 69.50.101(kk)(1) and (ll).

¹⁷ WAC 246-945-350.

¹⁸ See e.g. RCW 18.130.180(13).

¹⁹ RCW 69.41.



prescriber's directions, the name and strength of the medication, the name of the patient, the date, and the expiration date. The security of the cover or cap on every bottle or jar shall meet safety standards adopted by the commission. . . .

RCW 18.64.246(1).

The statutory provisions cited above require the name of the prescriber to be included on any prescription label affixed to a container containing legend drugs, including controlled substances. If a pharmacist is prescribing under a CDTA, then the pharmacist is the prescriber. Consequently, the pharmacist's name should be on the label. If a person or facility wanted to add the name of the patient's treating practitioner, this would be permissible as long as all other labeling requirements have been complied with.

Will the Commission address "claims adjudication" issues encountered by pharmacists who prescribe under a CDTA?

No, claims adjudication issues are not within the jurisdiction of PQAC. Pharmacists or pharmacies using CDTAs should work with the patient and the authorizing practitioner on processes that support prescription filling that is in accordance with the patient's insurance provider. The commission cannot provide specific guidance on payer reimbursement processes.



Action Taken by a Pharmacist issuing a prescription under the terms of a CDTA

The CDTA should provide guidance as to what preliminary steps are necessary before a pharmacist initiates or modifies drug therapy. Although an exhaustive list of preliminary steps would not be possible, a pharmacist must ensure that any action taken is within a pharmacist's scope of practice. For example:

Hypothetical No. 1: Patient A has been prescribed warfarin for many years and has been a patient of an anti-coagulation clinic during that time. Patient A has run out of refills for the warfarin prescription and needs a new prescription. Patient A meets with Pharmacist X to obtain a new prescription. Pursuant to a CDTA, Pharmacist X may prescribe Patient A the warfarin but only if new bloodwork is obtained. Pharmacist X orders the bloodwork for Patient A. Once the bloodwork results are obtained, Pharmacist X writes a new warfarin prescription for Patient A.

The preliminary steps in this hypothetical were: (i) assessment of the patient, and (ii) ordering and reviewing laboratory tests. A pharmacist's scope of practice includes the monitoring of drug therapy²⁰, which includes measuring and reviewing vital signs of a patient, and ordering and evaluating the results of laboratory tests relating to drug therapy.²¹ Consequently, these preliminary steps are within the scope of practice of a pharmacist and this exercise of prescriptive authority is appropriate.²² In this example, the pharmacist exercised independent decision making in evaluating the patient's therapy based upon laboratory results and the patient's clinical presentation in selecting a new dose of warfarin for the patient.

Hypothetical No. 2: Patient B has presented at a community pharmacy, complaining of nausea and abdominal pain. Patient B discloses not having been diagnosed with any medical condition and these symptoms have been present for about three days. The pharmacist does have a CDTA to prescribe certain medications and to provide immunizations. The pharmacist, based on the patient's presentation, engages in a differential diagnosis. The pharmacist conducts a physical examination of the patient, and orders multiple laboratory tests based on the patient's presentation. None of these preliminary steps are outlined in the CDTA. Based on the results, the pharmacist prescribes a medication not listed on the pharmacist's CDTA.

The preliminary steps in this hypothetical were: (i) examination of the patient, (ii) conducting a differential diagnosis, and (iii) ordering and reviewing laboratory tests. The concern in this hypothetical is the pharmacist providing services and prescribing a medication that is not contained in the CDTA. This amounts to practice beyond the scope of a pharmacist license.

²⁰ RCW 18.64.011(28).

²¹ WAC 246-945-355.

²² It is assumed for the purposes of this hypothetical that Pharmacist X complied with the terms of the CDTA when writing the prescription.



Pharmacists Operating under Protocols or Standing Orders relating to drug therapy that are not CDTAs – Regulatory Considerations

Overview

The Commission understands pharmacists regularly operate under a protocol or standing order relating to drug therapy. Examples include a pharmacist operating under a health system's P&T approved protocol, and a community pharmacist working pursuant to a protocol with a specific practitioner. The Commission has identified the following recurring issues as they pertain to pharmacists operating under protocols or standing orders relating to drug therapy:

- If a pharmacist operating under a protocol or standing order issues a new prescription for a practitioner, must the pharmacist's name appear on the prescription or drug container label?
- If a pharmacist operating under a protocol or standing order issues a new prescription in the name of a practitioner, must the practitioner authenticate the prescription?

Who is the prescriber?

If the pharmacist is the prescriber under a CDTA, then the pharmacist's name (and credentials if applicable) must appear on the prescription and drug container label. If a pharmacist is operating under a standing order or protocol and *is not* the prescriber, the pharmacist's name (and credentials), *do not* need to appear on the prescription or drug container label. Instead, the prescriber's name (and credentials) should appear on the prescription and drug container label.

Authentication Requirements for Prescriptions written pursuant to a Protocol or Standing Order that is not a CDTA.

Controlled Substances

The Commission would require a pharmacist to obtain prescriber authentication for a controlled substance prescription written pursuant to a protocol or standing order that is not a CDTA.

The Commission's position is consistent with that of the U.S. Drug Enforcement Administration (DEA). The DEA has provided interpretive guidance that practitioners may not delegate their own personal prescriptive authority to others because it is the sole responsibility of a practitioner to ensure a prescription for a controlled substance is for a legitimate medical



purpose.²³ In addition, the DEA provided the following question and answer for its rules on electronic prescriptions for controlled substances:

Q. Is a practitioner required to review a prescription before signing it?

A. All controlled substances must be reviewed by the prescribing practitioner. The practitioner must affirmatively indicate those prescriptions that are ready to be signed. A practitioner has the same responsibility when issuing an electronic prescription as when issuing a paper prescription to ensure that the prescription conforms in all respects with the requirements of the Controlled Substances Act and DEA regulations. This responsibility applies with equal force regardless of whether the prescription information is entered by the practitioner or a member of his staff.²⁴

Non-Controlled Legend Drugs

The Commission would not require a pharmacist obtain prescriber authentication for a non-controlled legend drug prescription written pursuant to a protocol or standing order that is not a CDTA.²⁵

The Legend Drug Act provides the following requirements for a valid prescription:

A prescription, in order to be effective in legalizing the possession of legend drugs, must be issued for a legitimate medical purpose by one authorized to prescribe the use of such legend drugs. Except as provided in RCW 69.41.095, an order purporting to be a prescription issued to a drug abuser or habitual user of legend drugs, not in the course of professional treatment, is not a prescription within the meaning and intent of this section; and the person who knows or should know that he or she is filling such an order, as well as the person issuing it, may be charged with violation of this chapter. A legitimate medical purpose shall include use in the course of a bona fide research program in conjunction with a hospital or university.

RCW 69.41.040(1).

The Commission does not interpret this provision to require prescriber authentication for prescriptions/orders written by a pharmacist pursuant to a protocol or standing order that is not a CDTA. [Note: A pharmacist should always use professional judgment based on

²³ 21 C.F.R. § 1306.04(a).

²⁴ See https://www.dea diversion.usdoj.gov/ecom/e_rx/faq/practitioners.htm (last accessed September 18,2018).

²⁵ This would not prevent other state licensing boards or commissions from requiring licensees under their jurisdiction to authenticate prescriptions written on their behalf by another individual. Practitioners should verify whether authentication is necessary in this situation with their own licensing authority. Additionally, this position of the Commission should not be considered the opinion of a federal regulatory agency, e.g. U.S. Drug Enforcement Administration and U.S. Food and Drug Administration.



their patient assessment, drug utilization review, or in the course of patient counseling to determine if further consultation with the prescriber is necessary.]

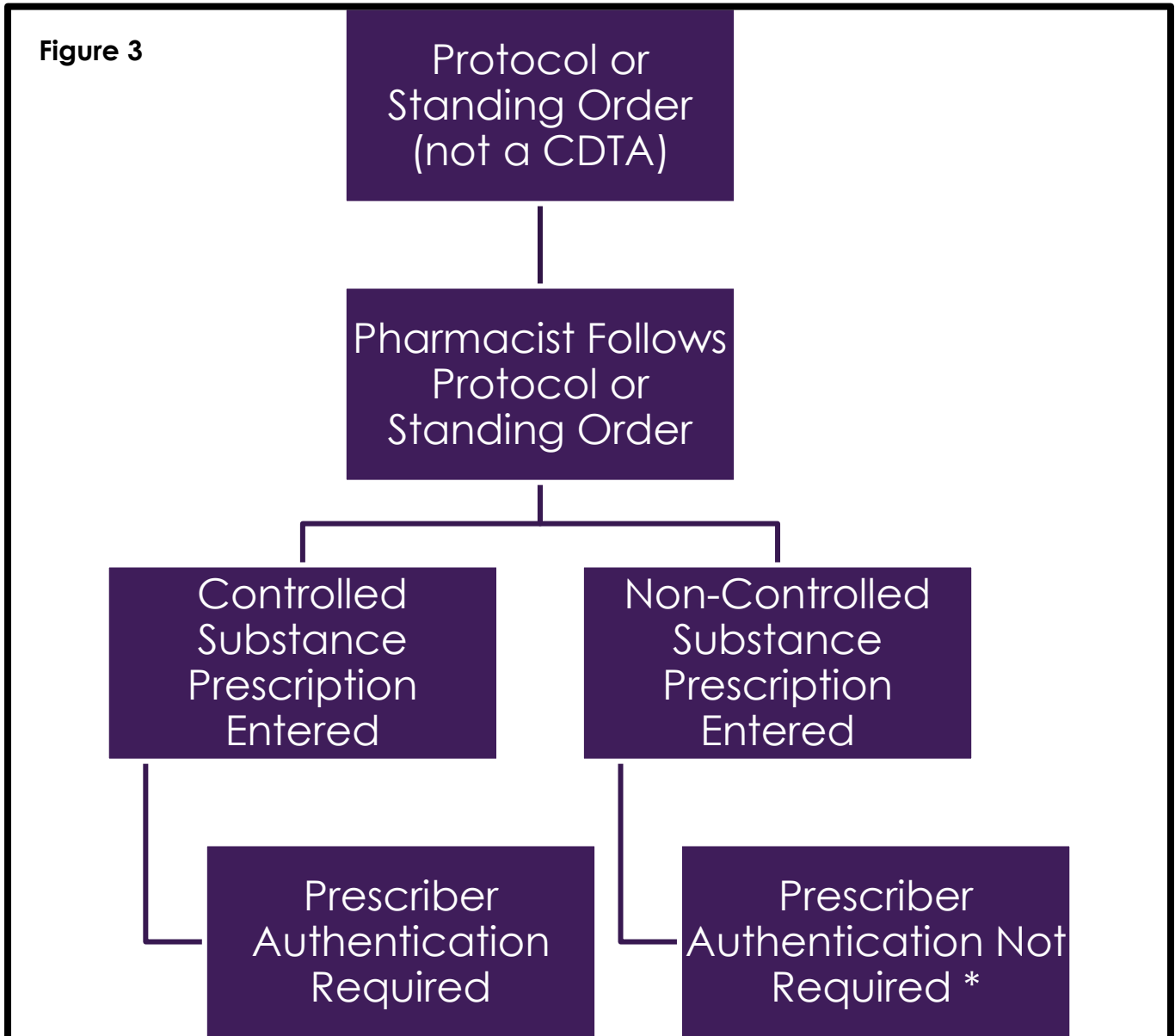
Hypothetical No. 1: A pharmacist working in a refill center using a protocol to authorize a prescription refill receives a request for a controlled substance. The pharmacist reviews the patient's information that may include non-discretionary parameters such as patient report of pain score, time since last refill, and review of Prescription Monitoring Program, and determines the prescription can be refilled. The pharmacist in this situation would communicate to the prescriber the prescription should be refilled and request the prescriber issue a refill. In this example, the prescriber would need to issue the prescription refill or authenticate a refill request submitted by the pharmacist. The pharmacist's name would not appear on the prescription, as this is a protocol (not a CDTA.)

Hypothetical No. 2: A pharmacist working in a refill center using a protocol to authorize a prescription refill receives a request for a non-controlled substance used to treat diabetes (e.g., metformin). The pharmacist reviews the patient's A1c and asks whether the patient is experiencing any side effects pursuant to a protocol. Based on this, the pharmacist authorizes a refill for this patient. The pharmacist uses a specific criterion without discretionary decision-making to evaluate the patient's therapy. In this case, if the A1c is less than 7 and there are no reported side effects or adverse drug reactions, the protocol allows the same medication and dose to be refilled. The original prescription was issued by a prescriber for a legitimate medical condition. The refill would be issued under the prescriber's name, and authentication by the prescriber would not be required.

In both of the above hypothetical examples, the pharmacist authorizing the refill is not operating under a non-CDTA protocol. This protocol is not a CDTA because the pharmacist is issuing a prescription in the name of a different practitioner. A protocol is classified as a CDTA only when the pharmacist is exercising his or her own prescriptive authority.



Figure Three (below) attempts to distill the Commission's position and interpretation of relevant requirements as they pertain to authentication of a prescription entered by a pharmacist pursuant to a protocol or standing order that is not a CDTA.



* [Note: Pharmacists should always use their professional judgment based on their patient assessment, drug use review or the course of patient counseling to determine if further consultation with the prescriber is necessary.]



Appendix 1: CDTA Decision Tree



* This includes all types of drug or preventative therapy performed under the terms of a CDTA e.g. immunizations.