



June 6, 2018

The Honorable Bob Ferguson
Attorney General
State of Washington
PO Box 40100
Olympia, WA 98504

RECEIVED

JUN 08 2018

ATTORNEY GENERAL'S OFFICE
Solicitor General's Division

RECEIVED
PRCS

JUN 08 2018

ATTORNEY GENERAL
OF WASHINGTON

Dear Attorney General Ferguson:

As the Chair of the Medical Commission (Commission), I am seeking a formal opinion from your office to clarify provisions of Washington State law affording protections to Washington patients from health care practitioners who operate beyond the scope of their practice act, thus placing patients at risk of harm.

Healthcare professionals practice under their profession's respective legal authority. Allopathic physicians¹ and physician assistants practice pursuant to the requirements provided in Chapters 18.71 RCW and 18.71A, respectively. As relevant to our inquiry here, Washington law defines the practice of medicine broadly and includes situations where an individual:

Offers or undertakes to **diagnose**, cure, advise, or prescribe for any human disease, ailment, injury, infirmity, deformity, pain or other condition, physical or mental, real or imaginary, by any means or instrumentality[.]

RCW 18.71.011(1) (emphasis added)

One aspect of the practice of medicine is working with pharmacists to deliver drug therapy to patients. This coordination can take many forms, but the Commission's concern in this instance involves treating patients under what is commonly referred to as a collaborative drug therapy agreement (CDTA). These arrangements occur pursuant to a written agreement entered into by an individual physician or physician assistant and an individual pharmacist. On the Commission's side, there are no statutes or rules that govern a physician's or physician assistant's responsibilities under a CDTA.²

¹ The Commission's inquiry is limited to physicians credentialed under RCW 18.71 and physician assistants credentialed under RCW 18.71A.

² The Commission has, on at least one occasion, considered these issues. See In the Matter of the License to Practice as a Physician and Surgeon of Wayne W. Austin, MD, Department of Health Master case no. M2011-1365. A copy of the Stipulation to Informal Disposition is attached hereto as Exhibit A for your reference.



The pharmacy side of the equation is more complicated. Pharmacists operate under the authority granted to them in Chapter 18.64 RCW. Washington law defines the “practice of pharmacy” as:

the practice of and responsibility for: Interpreting prescription orders; the compounding, dispensing, labeling, administering, and distributing of drugs and devices; the monitoring of drug therapy and use; **the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs**; the participating in drug utilization reviews and drug product selection; the proper and safe storing and distributing of drugs and devices and maintenance of proper records thereof; the providing of information on legend drugs which may include, but is not limited to, the advising of therapeutic values, hazards, and the uses of drugs and devices.

RCW 18.64.011(28) (emphasis added)

In the pharmacy practice act, a “practitioner” is defined as a physician, dentist, veterinarian, nurse, or other person duly authorized by law or rule in the state of Washington to prescribe drugs. RCW 18.64.011(29).³

The Pharmacy Quality Assurance Commission has adopted a rule that governs CDTAs. Under this rule, if a pharmacist plans to “exercise prescriptive authority”⁴ in their practice by initiating or modifying drug therapy, the pharmacist must have on file at their place of practice a “properly prepared written guideline or protocol indicating approval has been granted by a practitioner authorized to prescribe.” WAC 246-863-100(2).

This rule further states that the 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

³ Under Washington law, both physicians and physician assistants are authorized to prescribe legend drugs and controlled substances. RCW 69.41.010(17) (a); RCW 69.50.101(kk) (1).

⁴ The use of the phrase “prescriptive authority” in this rule is confusing. The statutory citation is to the definition of “dispense” under RCW 18.64.011(11).



the authority granted must be within the scope of the practitioners' current practice.

(b) A time period not to exceed 2 years during which the written guideline or protocol will be in effect.

(c) A statement of the type of prescriptive authority decisions, which 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 logbook.

WAC 246-863-100(2).

Absent from both the statute and the rule is any reference to whether a pharmacist may diagnose or assess a patient's ailment. However, the Commission recently learned that the Washington State Pharmacy Association (WSPA) developed a program for patient care entitled the "Clinical Community Pharmacist (CCP)" that allows pharmacists to prescribe therapies for patients in acute situations to reduce urgent care and emergency room visits.

Under this program, a pharmacist can complete self-paced 20-hour curricula to learn how to identify illness, rule out complications and prescribe therapies for specified disease states. These disease states include:

Allergic rhinitis treatment

Anaphylaxis (treatment of acute condition, and refill epinephrine auto injectors)

Bronchospasm (treatment of acute conditions, and provision of fast acting beta agonist refill)

Burns

Headaches (Including prescribing triptans)



Human, canine and feline bite prophylaxis
Insulin refills
Oral fluoride
Herpes zoster treatment
Insect sting treatment
Swimmer's ear treatment
Urinary Tract Infection (UTI) treatment
Vaginal yeast Infection treatment

This training provides a “comprehensive review of a disease state, the differential diagnosis to rule out other causes of symptoms, and treatment recommendations.” These reviews last between 30 to 90 minutes. Once a pharmacist has completed this training, they receive a Clinical Pharmacist Certificate.⁵

Under one particular CDTA program by a pharmacy chain, CCPs can assess and prescribe treatment for these disease states. In their CCP protocol, this pharmacy chain lists “diagnosis” as one of the steps the CCP takes. For example, for insect stings they require the CCP to use a patient questionnaire, pharmacist evaluation form, a one-on-one consultation with the patient, and evaluation of the sting to decide appropriate treatment and/or referral. Another CDTA program run by a different pharmacy chain relies on a diagnostic “treatment algorithm” for the pharmacist to decide on the appropriate treatment for possible urinary tract infections.⁶

A third CDTA program run by a different pharmacy chain bars pharmacists from contacting their authorizing prescribers under a CDTA for immunizations:

“Collaborative Drug Therapy Agreement (CDTA)

- Collaborative Drug Therapy Agreement (CDTA) – The CDTA delegates prescriptive authority to the pharmacists for the immunization in the vaccine tables below.
- If the immunization is administered under the CDTA, the pharmacist must process the immunizations under their own name and NPI number.

⁵ A copy of the WSPA program description is available at <https://www.wsparx.org/general/custom.asp?page=CCP>. A copy of the program as described on the WSPA Web site on June 4, 2018 is attached to this request as Exhibit B.

⁶ A copy of the insect sting CDTA is attached to this request as Exhibit C. A copy of the urinary treatment infection CDTA is attached to this request as Exhibit D. Both of these CDTAs have been redacted to remove the name of the participating pharmacy. If that information is germane to responding to this request, please contact the Commission’s executive director and an unredacted copy will be provided.



• **The physician who has signed the CDTA should not be contacted under any circumstance.** The immunizations should not be processed under the name of the physician who signed the CDTA.”⁷ (emphasis added)

Based upon the CCP program as promoted by WSPA and the CDTA programs implemented by the respective pharmacy chains, I request a formal opinion on the following questions:

1. Does the phrase “the initiating or modifying of drug therapy in accordance with written guidelines or protocols previously established and approved for his or her practice by a practitioner authorized to prescribe drugs” include the act of diagnosing a patient’s condition?

2. If the answer to #1 above is yes, is there a statutory or administrative requirement for direct contact between the non-pharmacist practitioner and the patient?

3. May a physician licensed under RCW 18.71 delegate the diagnosis of a patient to a pharmacist licensed under RCW 18.64?

4. Does a pharmacist who diagnoses patients pursuant to a CDTA with a physician commit an act of unlicensed practice of medicine under RCW 18.130.190?

5. May a physician assistant licensed under RCW 18.71A delegate the diagnosis of a patient to a pharmacist licensed under RCW 18.64?

6. Does a pharmacist who diagnoses patients pursuant to a CDTA with a physician assistant commit an act of unlicensed practice as a physician assistant under RCW 18.130.190?

Sincerely,

Warren Howe, MD, Chair, Washington Medical Commission

Cc: Alden Roberts, MD, 1st Vice Chair, Washington Medical Commission
John Maldon, Public Member, 2nd Vice Chair, Washington Medical Commission
Melanie de Leon, Executive Director, Washington Medical Commission

⁷ A copy of the help page available to pharmacists operating under the CDTA is attached to this request as Exhibit E. This attachment has been similarly redacted.



Exhibit A – Stipulation to Informal Disposition, M2011-1365

Please see attached



STATE OF WASHINGTON
DEPARTMENT OF HEALTH
Olympia, Washington 98504

RE: Wayne W. Austin, MD
Master Case No.: M2011-1365
Document: Stipulation of Informal Disposition

Regarding your request for information about the above-named practitioner; attached is a true and correct copy of the document on file with the State of Washington, Department of Health, Adjudicative Clerk Office. These records are considered Certified by the Department of Health.

Certain information may have been withheld pursuant to Washington state laws. While those laws require that most records be disclosed on request, they also state that certain information should not be disclosed.

The following information has been withheld: **NONE**

If you have any questions or need additional information regarding the information that was withheld, please contact:

Customer Service Center
P.O. Box 47865
Olympia, WA 98504-7865
Phone: (360) 236-4700
Fax: (360) 586-2171

You may appeal the decision to withhold any information by writing to the Privacy Officer, Department of Health, P.O. Box 47890, Olympia, WA 98504-7890.

**STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION**

In the Matter of the License to Practice
as a Physician and Surgeon of:

WAYNE W. AUSTIN, MD
License No. MD00004528

Respondent

No. M2011-1365

**STIPULATION TO INFORMAL
DISPOSITION**

Pursuant to the Uniform Disciplinary Act, Chapter 18.130 RCW, the Medical Quality Assurance Commission (Commission) issued a Statement of Allegations and Summary of Evidence (Statement of Allegations) alleging the conduct described below. Respondent does not admit any of the *allegations*. This Stipulation to Informal Disposition (Stipulation) is not formal disciplinary action and shall not be construed as a finding of unprofessional conduct or inability to practice.

1. ALLEGATIONS

1.1 On July 15, 1954, the state of Washington issued Respondent a license to practice as a physician and surgeon. Respondent's license is currently active.

1.2 Respondent signed a two-year contract with Hoagland Pharmacy (Hoagland's) to supervise Hoagland's five pharmacists in a Collaborative Drug Therapy Agreement (CDTA). The contract is dated March 23, 2010. Through the CDTA, Respondent delegated his authority to Hoagland's pharmacists to provide immunizations to adults and adolescents. Respondent stated in the contract: "As the authorizing prescriber I will review the activities of the pharmacists administering vaccines as required."

1.3 Respondent signed a two-year contract with Rite Aid Pharmacies (Rite Aid) to supervise one hundred forty one (141) of Rite Aid's pharmacists in a CDTA. The contract is dated July 1, 2010. Through the CDTA, Respondent delegated his authority to Rite Aid's pharmacists to provide immunizations to infants, children and adults. Respondent stated in the contract: "As the authorizing prescriber I will, on a quarterly basis, review the activities of the pharmacists administering vaccines."

1.4 In a statement to the Commission's investigator, on May 2, 2011, Respondent said he did no actual monitoring of any of the pharmacists, although he believed the agreements were still in effect on that date.

1.5 In a letter to the Commission dated June 20, 2011, Respondent said that he had not remembered that he still had a contract with Rite Aid to supervise its pharmacists.

1.6 Respondent delegated to almost 150 pharmacists his authority to prescribe and provide immunizations, yet failed to do anything to assure that the pharmacists were using his delegated authority according to the established written protocols required by WAC 246-863-180(2). The protocols were submitted by the pharmacies to the Washington State Board of Pharmacy for approval. The protocols include provisions for recordkeeping, emergency procedures for patients' adverse reactions, screening for contraindications, documentation of informed consent, and adequate training of the pharmacists in how to administer immunizations and respond to adverse reactions.

2. STIPULATION

2.1 The Commission alleges that the conduct described above, if proven, would constitute a violation of RCW 18.130.180(14) (failure adequately to supervise auxiliary staff).

2.2 The parties wish to resolve this matter by means of a Stipulation to Informal Disposition (Stipulation) pursuant to RCW 18.130.172(1).

2.3 Respondent agrees to be bound by the terms and conditions of this Stipulation.

2.4 This Stipulation is of no force and effect and is not binding on the parties unless and until it is accepted by the Commission.

2.5 If the Commission accepts the Stipulation it will be reported to the Health Integrity and Protection Databank (HIPDB)(45 CFR Part 61), the Federation of State Medical Board's Physician Data Center, and elsewhere as required by law. HIPDB will report this Stipulation to the National Practitioner Data Bank (45 CFR Part 60).

2.6 The Statement of Allegations and this Stipulation are public documents. They will be placed on the Department of Health web site, disseminated via the

Commission's listserv, and disseminated according to the Uniform Disciplinary Act (Chapter 18.130 RCW). They are subject to disclosure under the Public Records Act, Chapter 42.56 RCW, and shall remain part of Respondent's file according to the state's records retention law and cannot be expunged.

2.7 The Commission agrees to forego further disciplinary proceedings concerning the allegations.

2.8 Respondent agrees to successfully comply with and complete the terms and conditions of this informal disposition.

2.9 A violation of the provisions of Section 3 of this Stipulation, if proved, would constitute grounds for discipline under RCW 18.130.180 and the imposition of sanctions under RCW 18.130.160.

3. INFORMAL DISPOSITION

The Commission and Respondent stipulate to the following terms.

3.1 **Practice Restriction**. Respondent may not enter into any Collaborative Drug Therapy Agreements with any pharmacies or pharmacists. This is a permanent practice restriction.

3.2 **Paper**. Within ninety (90) days of the effective date of this Stipulation to Informal Disposition, Respondent must submit for review and approval by the Commission, a typewritten paper of no less than one thousand (1,000) words, with citations to the applicable statutes and regulations, regarding the responsibilities of a physician in supervising pharmacists to whom the physician has delegated authority through a Collaborative Drug Therapy Agreement. The paper must discuss the reasons for and importance of the physician's role. Respondent agrees that his paper may be used by the Commission, in whole or in part, for education of physicians, pharmacists, and the public. Respondent will submit the paper to the Commission at the following address: Compliance Officer, Department of Health, Medical Quality Assurance Commission, PO Box 47866, Olympia, Washington 98504-7866.

3.3 **Cost Recovery**. Respondent agrees to pay one thousand dollars (\$1,000) to the Commission as partial reimbursement of some of the costs of investigating and processing this matter. Respondent must send a check payable to the Department of Health within 90 days of the effective date of this Stipulation. Respondent must send

payment to: Department of Health, Accounting Department, PO Box 1099, Olympia, Washington 98507-1099.

3.4 **Obey Laws.** Respondent must obey all federal, state and local laws and all administrative rules governing the practice of the profession in Washington.

3.5 **Costs.** Respondent must assume all costs of complying with this Stipulation.

3.6 **Violations.** If Respondent violates any provision of this Stipulation in any respect, the Commission may initiate further action against Respondent's license.

3.7 **Change of Address.** Respondent must inform the Commission and the Adjudicative Clerk Office in writing, of changes in his residential and/or business address within thirty (30) days of such change.

3.8 **Effective Date.** The effective date of this Stipulation to Informal Disposition is the date the Adjudicative Clerk Office places the signed Stipulation into the U.S. mail. If required, Respondent shall not submit any fees or compliance documents until after the effective date of this Stipulation.

4. COMPLIANCE WITH SANCTION RULES

4.1 The Commission applies the sanctions schedules in WAC 246-16-800, *et seq.* to determine appropriate sanctions. When the unprofessional conduct at issue is not described in one of the schedules, the rules require that the Commission use its judgment to determine appropriate sanctions, and explain that no sanction schedule applies. WAC 246-800(2)(d). There is no schedule within the sanctions rules that specifically applies to the failure to supervise staff. The Commission has therefore used its judgment to determine that the sanctions in this Stipulation Order are appropriate to protect the public.

4.2 The sanctions in this Stipulation include a permanent practice restriction, a paper addressing delegation of authority by a physician through Collaborative Drug Therapy Agreements, and partial cost recovery.

4.3 These sanctions are appropriate to address the allegations in this matter and will adequately protect the public.

//

//

5. RESPONDENT'S ACCEPTANCE

I, WAYNE W. AUSTIN, MD, Respondent, certify that I have read this Stipulation to Informal Disposition in its entirety; that my counsel of record, if any, has fully explained the legal significance and consequence of it; that I fully understand and agree to all of it; and that it may be presented to the Commission without my appearance. If the Commission accepts the Stipulation to Informal Disposition, I understand that I will receive a signed copy.

Wayne W. Austin MD 29 Dec 11
WAYNE W. AUSTIN, MD DATE
RESPONDENT

_____, WSBA # _____
ATTORNEY FOR RESPONDENT DATE

6. COMMISSION'S ACCEPTANCE

The Commission accepts this Stipulation to Informal Disposition. All parties shall be bound by its terms and conditions.

DATED: January 12, 2012.

STATE OF WASHINGTON
DEPARTMENT OF HEALTH
MEDICAL QUALITY ASSURANCE COMMISSION

Linda A. Ruiz
PANEL CHAIR

PRESENTED BY:

Suzanne L. Mager
SUZANNE L. MAGER, WSBA # 19284
DEPARTMENT OF HEALTH STAFF ATTORNEY



Exhibit B – WSPA Clinical Community Pharmacist program

Please see attached



CLINICAL COMMUNITY PHARMACIST

Share |

Clinical Community Pharmacist

Overview

The Clinical Community Pharmacist (CCP) is the newest patient care development for pharmacists practicing in community pharmacies. More than offering a screening, or recommending an OTC, this allows pharmacists to prescribe therapies for patients in acute situations to reduce urgent care and emergency room visits.

The Clinical Community Pharmacist Service is a tool to allow community pharmacists to meet the urgent needs of their communities. The clinical community pharmacist can provide after office hours and weekend care for their community, and care for their patients closer to home.

Disease states included in the Clinical Community Pharmacist Training

- Allergic rhinitis treatment
- Anaphylaxis (treatment of acute condition, and refill epinephrine autoinjectors)
- Bronchospasm (treatment of acute conditions, and provision of fast acting beta agonist refill)
- Burns
- Headaches (including prescribing triptans)
- Human, canine and feline bite prophylaxis
- Insulin refills
- Oral fluoride
- Herpes zoster treatment
- Insect sting treatment
- Swimmer's ear treatment
- Urinary Tract Infection (UTI) treatment
- Vaginal yeast Infection treatment

Training

In this self-paced training, approved for 20 CE hours, pharmacists will learn how to identify illness, rule out complications, and prescribe therapies. The Clinical Community Pharmacist training includes the required Fundamentals for the Clinical Community Pharmacist Module which prepares the pharmacist for establishing their own CCP Service, including developing a business and marketing plan, documentation, ethical considerations, and practical points. The Fundamentals Module is then supported by 14 clinical modules, which provide a comprehensive review of a disease state, the differential diagnosis to rule out other causes of symptoms, and treatment recommendations. The clinical modules were developed using practice guidelines and primary literature, contain citations to these sources, and have been peer reviewed to meet high standards.

For a pharmacist to be certified as a Clinical Community Pharmacist, the pharmacist must complete the Fundamentals Module, plus at least one clinical module. The pharmacist can however, complete all the clinical modules, or pick the ones that best fit their practice setting. Once the pharmacist has completed their training

modules, they should, they should email askwspa@wsparx.org with the subject "CCP Certificate" so that WSPA Staff can issue their Clinical Community Pharmacist Certificate, which will list the modules the pharmacist completed.

Getting Started with Training

The CCP online training is hosted through the WSPA Education CCP Portal. The WSPA Education Portal requires learners to create a learner profile in this system. Pharmacists will first select and complete the Fundamentals Training, then they should complete the clinical modules of their choice.

Complete CCP Training:

Pharmacists may purchase the Complete CCP Training as a package through the WSPA Store, or Individuals can complete the trainings individually through the Educational Portal. The complete package is the best option for pharmacists who intend on completing 10 or more of the Clinical Modules. Once a pharmacist has purchased the Complete CCP Training through the WSPA they will receive an email with an Individual coupon code to be used to complete the trainings through the Educational Portal at no additional cost. WSPA members receive a discount on the Complete Training, but need to login as a WSPA member to get the discount.

Selective CCP Training:

Individuals who are interested in completing only a few of the trainings should access the WSPA Education CCP Portal directly. WSPA members should enter the WSPA members 50% off discount code for the Education Portal before paying for their trainings.

If you have any problems with the Educational Portal, the WSPA Store or coupons, please contact the WSPA Office at 428-228-7171 or askwspa@wsparx.org. Once you complete your clinical modules, email askwspa@wsparx.org with the subject "CCP Certificate" to have your Training Certificate released.

Adaptability

There is flexibility built into the Clinical Community Pharmacist Certificate. While Washington State Law allows for initiation, and modification of treatment, some states only allow for modification of therapies, and therefore the pharmacist would not be able to prescribe new therapy for an acute condition. The Clinical Community Pharmacist in these states will benefit from the modules addressing emergency refills for insulin, contraception, epinephrine auto-injectors, and bronchospasm.

Clinical Community Pharmacist Toolkit

To support implementation of the Clinical Community Pharmacist Service, WSPA has assembled a Clinical Community Pharmacist Toolkit complete with patient intake forms, pharmacist documentation forms, patient handouts, and collaborative drug therapy agreements to accompany each disease state. The documentation tool helps pharmacists capture key decision point information, guides therapy selection, and provides a format for documenting the outcome of the patient visit. The toolkit is available to pharmacies for a one-time, site-based fee. This fee will provide not only these tools, but also regular updates based on changing evidence based guidelines. All the documents in this toolkit are in editable form to allow the user to change the CDTA's to match their own or prescriber partner preferences, and to facilitate branding of the documents for the site.

Research

Pharmacists offering the Clinical Community Pharmacist Service are encouraged to join a study by the WSPA and University of Washington School of Pharmacy faculty funded by the Community Pharmacy Foundation to document the quality and safety of this service. For more information on joining the study, please contact Jenny Arnold at jenny@wsparx.org.

Supporters of CCP

Please visit the CCP Supporters Page to learn more of their contributions.

Prices

Clinical Community Pharmacist Training for pharmacists:

	WSPA Member	Non-Member*
Complete Clinical Community Pharmacist (20 CE hours)	\$375 (login to the WSPA website to get member discount)	\$575
A la cart: Fundamentals (4 CE hours) Clinical Module (0.5 - 1.5 CE hours)	\$150 \$17.50/module (to receive the WSPA member benefit - enter the 50% discount code at purchase)	\$250 \$35/module

*WSPA Membership is \$195 annually for pharmacists

Clinical Community Pharmacist Training for student pharmacists:

	WSPA Member	Non-Member*
Complete Clinical Community Pharmacist	\$75	\$95

*WSPA Membership is \$20 annually for student pharmacists

Toolkit

The toolkit and license to offer a Clinical Community Pharmacist Service is assessed for each licensed pharmacy site offering the service. The cost is a onetime fee of \$350 per site. See Large Scale Implementation for information for Chains and multiple independent sites.

Large Scale Implementation

WSPA is prepared to meet the needs of large scale partners who will have to implement a Clinical Community Pharmacist Service at multiple sites. We can assist with group access to the CE modules as well as offer discounted per location charge due to the ease of working with one individual for the chain as opposed to each site individually.

[Click here to visit the online store and your purchase of CCP CE.](#)

LATEST NEWS [MORE](#)

6/1/2018
June 7-8, Meeting Notice
- Rule Rewrite Project

5/21/2018
May 22nd PQAC
Webinar Cancelled

5/18/2018
Please Assist Eastern
WA Patients Displaced
by Flooding

CALENDAR [MORE](#)

6/5/2018
Webinar: HSA PQAC
Rules and New
Inspection Process.
Speaker: Cheryl Adams,
PQAC Commissioner

6/6/2018
Webinar: Compound
Your Wealth: Pharmacy
Accounting and Tax
Strategies

FEATURED JOBS

Retail Staff Pharmacist
Twisp, WA
Ulrich Valley Pharmacy

Director of Pharmacy
Tacoma, WA
Alliance South Sound Health

Pharmacist - Relocation Opportunity
Yakima, WA
Yakima Medical-Dental Clinic
[View All Jobs](#)

ONLINE SURVEYS

6/12/2018
Webinar: 2018 OSHA
Training - Bloodborne
Pathogens



Washington State Pharmacy Association
411 Williams Ave South
Renton, WA 98057

P: 425.228.7171

F: 425.277.3897

E: askwspa@wsparx.org

Home	Contact Us	Search
About WSPA	Advocate	Communicate
Connect	Educate	Membership
Pharmacy	Resources	Site Map
Practice		

Association Management Software Powered by YourMembership :: [Legal](#)



Exhibit C – Insect sting CDTA

Please see attached

Collaborative Drug Agreement for Insect Stings

Purpose:

pharmacist will assess and prescribe appropriate treatment in the case of suspected insect stings, where appropriate. are open 7 days a week, including weekday evenings, making access to care timely, accessible and, cost effective by avoiding an unnecessary trip to urgent care or the emergency room (ER). This treatment will be prescribed in a community pharmacy by a Clinical Community Pharmacist (CCP).

Background:

The insects that are responsible for the majority of serious sting-related reactions belong to the order Hymenoptera. The Hymenoptera families of medical interest include Apidae family honey bees and bumble bees, and the Vespidae family yellow jackets, yellow hornets, white-faced hornets, and paper wasps. A typical local reaction to a Hymenoptera sting is redness and painful swelling (1 to 5 cm) at the site of the sting, which develops within minutes and resolves within a few hours to a few days. Approximately 10 percent of individuals develop exaggerated redness and swelling at the site of the sting that gradually enlarges over a few days. This response is called large local reactions (LLR). LLRs peak at approximately 48 hours and then gradually resolve over 5 to 10 days. The area of swelling typically measures about 10 cm in diameter and can be quite painful. Yellow jackets in particular carry more bacteria on their exterior than other hymenoptera species, since they tend to scavenge around rotting food increasing the likelihood of the sting becoming infected, thus lack of proper evaluation and education could lead to complications. The CCP will assess patients, provide them adequate information on insect stings, and provide treatment or referral when appropriate.

Pharmacist Training:

Each pharmacist participating in this protocol must have completed the Washington State Pharmacy Association Clinical Community Pharmacist Certificate including the module on insect stings. The module includes home study materials to give the pharmacist a background on insect stings, clinical practice guidelines, diagnosis and management of patients with these bites, as well as appropriate measure to follow-up and refer patients.

Documentation:

All completed patient questionnaires, pharmacist assessment forms, follow-up forms, and/or records of prescriptions written under this protocol will be kept on file at the pharmacy in accordance with state law.

Policies and Procedures:

Any patient requesting an assessment or who presents to the pharmacy with an indication for treatment for an insect sting will be assessed by the CCP using the following procedures

- 1) A patient consent and release form (Appendix A) will be given to the patient that will include a questionnaire to gather patient-specific information and clinical signs and symptoms the patient is experiencing. Relevant health information, including, but not limited to allergies, medical conditions, and current medication history will be documented.
- 2) Patient must be ≥ 12 years of age. If younger than 12 years of age, the patient will be referred to an urgent care clinic or primary care provider (PCP).
- 3) The pharmacist will record the patient's temperature, blood pressure, heart rate, and description/location of the sting on the patient consent and release form.
- 4) The pharmacist will perform a visual and physical assessment (refer to differential diagnosis) of the sting and document the assessment on the Pharmacist Evaluation Form (Appendix B).
- 5) The CCP will utilize disease-state knowledge, current clinical guidelines, a one-on-one consultation, and the patient questionnaire in addition to a pharmacist evaluation form to make a differential diagnosis, and determine if the sting should be treated or referred to the appropriate healthcare provider.
- 6) An automatic referral is required for any patient meeting the criteria in Figure 1.
- 7) If treatment is appropriate, the pharmacist or technician will enter and prepare the prescription using the Bites Prescription Form (Appendix C)
- 8) In addition to the medication, patients will be provided with adequate information, both verbal and written, regarding the sign and symptoms of potential adverse reactions, as well as when and how to follow-up with the appropriate medical provider.
- 9) The patient will also be provided with information regarding insect stings, signs/symptoms of infection, guidance on when to seek medical care, as well as non-pharmacological options such as wound care to help prevent infection and reduce scarring or pain.
- 10) If treatment is provided, the patient's PCP will be notified of the CCP visit including any treatment, recommendations, or referrals provided to the patient using the Primary Care Provider Communication Form (Appendix D).
- 11) The pharmacist or technician will follow-up with the patient in 3-5 days and document the encounter in the patient's profile using the Insect stings Follow-up Form (Appendix E).
 - a. If there are any complications, questions, or concerns the pharmacist will work with the patient to decide the best course of action.
 - b. A minimum of 2 attempts to follow-up with the patient. All attempts shall be documented on Appendix E.

12) If and when a patient is referred to their PCP, urgent care, or ER, the pharmacist or technician will do the following:

- a. Notify the PCP about the patient's current symptoms.
- b. If the patient does not have a PCP and the situation is not urgent, the patient will be referred to the nearest urgent care clinic or ER.
- c. If the patient's condition is urgent and requires immediate medical attention then contact the nearest urgent care clinic or ER to inform them of the patient's situation and arrange to have the patient transported.

Diagnosis:

The CCP will utilize the patient questionnaire, pharmacist evaluation form, a one-on-one consultation with the patient, and evaluation of the sting to decide appropriate treatment and/or referral.

1. Evaluation of the sting:

- A. Visual inspection of the sting
 - i. Signs of possible infection
 1. Redness, raised, and/or swollen wound
 2. Discharging pus from the wound
 3. Red streaks that extend out from the wound
- B. Physical examination
 - i. Signs of infection
 1. Fever and/or chills
 2. Warm or hot to the touch
 3. If applicable locate the lymph node closest to injury, palpate with 2-3 fingers and gently apply pressure to see if the lymph node is enlarged compared with the comparable node on the opposite side.
- C. Other factors
 - i. Time:
 1. Stings greater than 24 hours old with significant swelling and pain may be a candidate for prednisone therapy.
 2. Stings that are > 48 hours with significant redness, swelling, and pain, or have worsened should raise concern for infection.
 3. A sting, which initial reaction has subsided but develops a secondary reaction in 4-6 days, may be a result of delayed hypersensitivity which requires a different treatment than the initial reaction.
 - ii. Pain:
 1. Pain > 8 on the pain scale should be referred for further evaluation
 - iii. Location:
 1. Stings that involve the airway or oral region should be referred due to possible impairment of breathing.
 2. Stings that could possibly impair patients daily function should be referred.

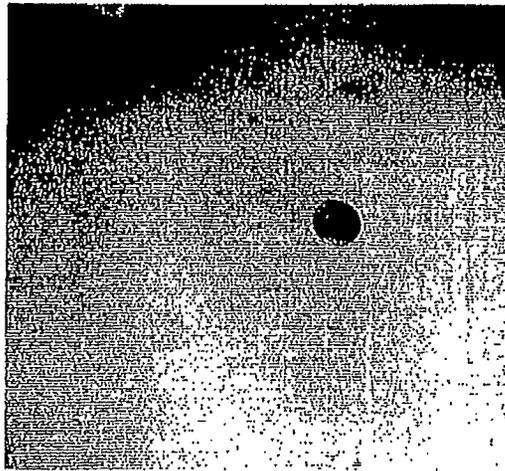


Figure 1: Uncomplicated local reactions from the sting of Hymenoptera insects usually consist of erythema and an area of painful swelling 1 to 2 cm in diameter surrounding the puncture site from the stinger. These reactions typically subside within a few hours.

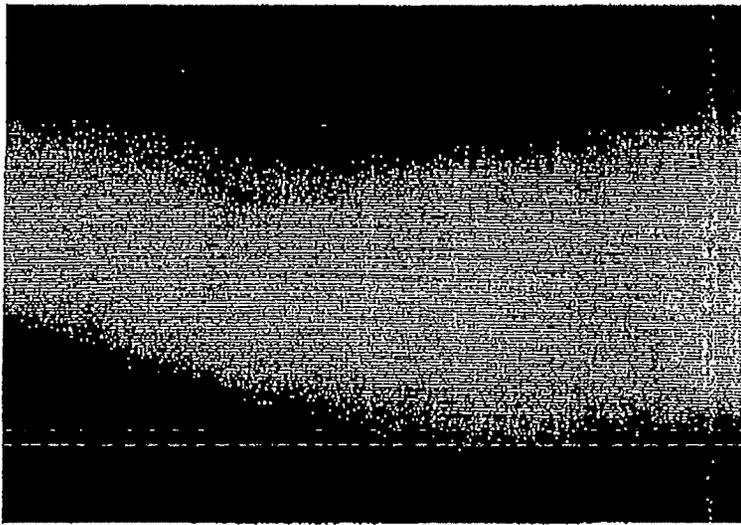


Figure 2: Large local reaction to insect sting

Exclusions:

Criteria Requiring Referral:

If the patient presents with any of the following, a referral to the appropriate healthcare provider is required for further evaluation:

- a. Stings that occurred > 48 hours ago
- b. Stings from other insects that are not bees, hornets, or wasps
- c. Stings inside the mouth or airway that may impair breathing
- d. Patient is <12 years of age
- e. Patient is < 18 years of age and requiring glucocorticoids treatment
- f. Patient presenting with several stings (use clinical judgement)
- g. Patient who presents with a generalized rash, swelling of face, throat or difficulty breathing
- h. Patient with documented allergy to bees or wasps
- i. Stings that have become infected or are suspected to be infected
- j. Stings that impair a patients daily function (i.e.: stings near an eye so patient cannot see well)
- k. Patient presents with a fever
- l. Patients who are pregnant

Treatment:

A patient specific treatment plan will be developed by the CCP and will include at least one of the following options: no therapy, over-the-counter therapy, pharmacist-prescribed therapy, or referral to another health care provider.

Prior to treatment being given the following steps will be taken:

- 1) Arrange for immediate emergency care if at any point the patient experience signs and symptoms of anaphylaxis
- 2) Remove the stinger by swiping the flat edge of a card or fingernail on the injection site. Stinger removal should be done within seconds of the sting in order to prevent more venom from being injected. However, after the first few seconds, no special technique (e.g., flicking to avoid compressing the venom sac) is necessary, since the venom should be fully expelled already [4]. Remaining stingers should be removed to promote proper healing and reduce risk of infection.
- 3) Remove jewelry from any areas of potential swelling
- 4) Wash the area with antibacterial soap (i.e.: Dial® soap, Hibiclens®) and water if patient has not already done so
- 5) Elevate the area of the sting, if possible

Over-the-counter therapy:

- 1) Cold compress: Apply cold compress for 10 minutes each application (reduces itching, redness, and swelling)
- 2) Oral analgesics:
 - a. Acetaminophen
 - i. Children (<50 kg): 10-15 mg/kg Q4-6H PRN for pain (max of 75 mg/kg/day), NTE 5 doses or 3,000 mg per 24 hours, whichever is less
 - ii. Children/Adolescents: (≥ 12-17 years old): 325 mg 1-2 T PO Q4-6H PRN for pain, NTE 3,000mg (9 tabs)/24hrs
 - iii. Adults (≥ 18 years old): 500 mg 1-2 T PO Q6H PRN for pain, NTE 3,000 mg (6 tabs)/24hrs
 - b. Ibuprofen
 - i. Children (< 50kg): 5-10 mg/kg Q6-8H, NTE 4 doses or 2,400 mg/24hrs, whichever is less
 - ii. Adults (≥ 12 years old): 400mg 1-2 T PO Q6-8H PRN for pain, NTE 3,200 mg
- 3) Oral anti-pruritic:
 - a. Diphenhydramine 25mg 1-2 tablets by mouth every 4-6 hours as needed for itching
 - b. Cetirizine 10mg 1 tablet by mouth every 24 hours as needed for itching
 - c. Ranitidine 150mg every 12 hours if secondary reaction occurs days after the sting.

Prescription Treatment Options:

1. Topical steroid:
 - a. Adults (≥ 18 years old):
 - i. Fluocinonide 0.05% cream or ointment-Apply a small thin layer to sting injury every 4 hours as needed for itching. (NOT for facial use)
 - ii. Clobetasol 0.05% cream or ointment - Apply a small thin layer to sting injury every 4 hours as needed for itching. (NOT for facial use)
 - iii. Triamcinolone cream 0.1% - Apply a thin layer to sting injury on face every 4 hours as needed for itching
 - b. Children (12 to 17 years):

- i. Mometasone 0.1% cream- Apply a small thin layer to sting injury every 4 hours as needed for itching. Do not apply to face or groin. Do not use longer than 2 weeks
- 2. Oral steroid:
 - a. Prednisone 20mg - Take one tablet by mouth every morning for 3 days

Symptoms	Recommended Treatment/Intervention
Mild erythema with 1-5 cm of painful swelling; starts to resolve within a few hours	Cold compress only
Pain, itching, redness, and swelling	Cold compress
Mild to Moderate pain	Acetaminophen 500mg Take 1-2 tabs PO Q4-6H PRN Pain, NTE 3,000mg/24hrs. OR Ibuprofen 400mg Take 1-2 tabs PO Q 6-8H PRN Pain, NTE 2400mg/24hrs
Pruritus (mild to moderate)	Diphenhydramine 25mg Take 1-2 tabs PO Q 6-8H PRN itching
Pruritus (moderate to severe)	Cetirizine 10mg Take 1 tab PO Q Day PRN itching. PLUS Fluocinonide 0.05% cream or ointment Apply a small thin layer to sting area Q 4H PRN itching. Do not apply to face or groin. Do not use longer than 2 weeks. OR Clobetasol 0.05% cream or ointment Apply a small thin layer to sting area Q 4H PRN itching. Do not apply to face or groin. Do not use longer than 2 weeks. OR Triamcinolone 0.1% Cream Apply thin layer to sting areas on face Q 4H prn itching.
Significant swelling > 4-10 cm and discomfort that evolved in the first 24-48 hours following the sting	Prednisone 20mg Take 1 tab PO QAM for 3 days

Symptoms	Recommended Treatment Approach for children/adolescents (12 to 17 years of age)
<p>Mild erythema with 1-5 cm of painful swelling; starts to resolve within a few hours</p> <p>Pain, itching, redness, and swelling</p> <p>Mild to Moderate pain</p>	<p>Cold compress only</p> <p>Cold compress</p> <p>Acetaminophen <i>Children (<60 kg): 10-15 mg/kg Q4-6H PRN for pain (max of 75 mg/kg/day), NTE 5 doses or 3,000 mg per 24 hours</i> <i>Children/Adolescents (12-17 years old): 325 mg 1-2 tabs PO Q4-6H PRN for pain, NTE 3,000 mg (9 tabs)/24hrs</i></p> <p>OR</p> <p>Ibuprofen <i>Children (<50kg): 5-10 mg/kg Q6-8H, NTE 4 doses or 1,200 mg/24hrs</i> <i>Children/Adolescent (12-17 years): 200 mg 1-2 tabs PO Q6-8H PRN for pain, NTE 3,200 mg</i></p>
<p>Pruritus (mild to moderate)</p>	<p>Diphenhydramine 25mg <i>Children (≥ 12 years): 1-2 tabs PO Q6-8H PRN itching</i></p>
<p>Pruritus (moderate to severe)</p>	<p>Cetirizine 10mg <i>Take 1 tab PO Q Day PRN itching</i></p> <p>PLUS</p> <p>Mometasone 0.1% cream <i>Apply a small thin layer to sting area Q4H PRN itching. Do not apply to face or groin. Do not use longer than 2 weeks</i></p>

Collaborative Drug Therapy Agreement Protocol for Insect Stings

As a licensed health care provider authorized to prescribe medications in the State of Washington, I authorize _____ (RPh/PharmD) of _____ and certified Interns (acting under the supervision of authorized pharmacists) employed at the _____ / to prescribe medications to patients ≥12 years of age or older for insect stings caused by bees, hornets, or wasps, in accordance with the laws (RCW 18.64.011) and regulations (WAC 246-863-100) of the State of Washington. The pharmacist named above has successfully completed the Washington State Pharmacy Association Clinical Community Pharmacist Certificate including the module on human, canine, and feline bites. In exercising this authority, the Pharmacists and Interns shall collect patient information, assess patients and make decisions about appropriate treatment. The Pharmacists or Interns will document all patient assessments performed and prescriptions written under this protocol. As the authorizing Prescriber I will, on quarterly basis, review all activities of the Pharmacists prescribing under this protocol.

This authorization will be in effect for two years, unless rescinded earlier in writing to the Washington State Board of Pharmacy by either the authorizing Prescriber or the Pharmacist. This protocol between the authorizing Physician and participating Pharmacist is valid only while the Pharmacist is working at a _____ or a _____ / authorized off-site clinic or function. Any significant changes to the protocol must be agreed upon by the participants and submitted to the Board.

Prescriber Name: _____

Prescriber Address: _____

Telephone: _____
Fax: _____

Prescriber Signature: _____ Date of Signature: 11/29/17

Pharmacist Name: _____ License #: _____

Pharmacist Signature: _____ Date of Signature: 11/07/17

Appendix B: Pharmacist Evaluation Form

Date: ___/___/___ Patient Name: _____ DOB: _____

Introduction

This document is designed to help you analyze the corresponding patient questionnaire and help you make a decision between whether to treat or refer. Questions or situations that advise you to refer are not always direct contraindications, but it may be in the patient's best interest to be referred to someone who knows that patient's particular disease state or situation better. This document should never replace your clinical judgement.

Patient Question	Pharmacist Evaluation	
1) Are you < 12 years of age?	YES	REFER
	NO	May be a candidate for treatment
2) Were you stung by an insect that was NOT a bee or wasp?	YES	REFER
	NO	May be a candidate for treatment
	UNKNOWN	May be a candidate -use clinical presentation and judgment
3) Are you experiencing any of the following: generalized rash, swelling of the face, lips, eyes or throat, or difficulty breathing?	YES	REFER immediately to the ER; follow protocol in P&P
	NO	May be a candidate for treatment
Do you have an allergy to bees or wasp?	YES	REFER
	NO	May be a candidate for treatment
Has the sting area worsened and become more red, painful or swollen since the incident?	YES	Swelling, redness and pain are normal reactions to a sting - but worsening conditions could indicate infection. Depending on the time since the sting, worsening of the condition of the sting area and the overall clinical sys the pharmacist should follow differential diagnosis criteria outlined in the P&P to determine if the patient would benefit from treatment or need a referral.
	NO	May be a candidate for treatment
Do you have a fever/chills?	YES	REFER
	NO	May be a candidate for treatment
4) Did the sting happen > 48 hours ago?	YES	REFER. If in 3-7 days no improvement or worsening of symptoms may be possible infection.
	NO	May be a candidate for treatment. If it has been < 24 hours and there is still significant pain, swelling & redness prednisone may be considered. If the

		sting just occurred in the last hour the swelling may continue or worsen.
5) Where on your body did the sting occur?	Stings inside the mouth or air ways may impair breathing. REFER. Evaluate if it is impairing their daily function if so. REFER.	
6) How many times were you stung?	Several Times	Multiple stings increase the risk for more severe reactions. Patient may need to be referred. Use clinical judgment.
	1 time	May be a candidate for treatment
7) On a scale of 0-10 rate your level of pain from the sting (0 = no pain & 10 worst pain ever felt)	8	REFER. Severe pain should be referred for further evaluation immediately.
	0-8	Use this to guide your recommendations for pain management covered in the protocol.
8) On a scale of 0-10 rate your level of itchiness of the sting area (0 = No itching & 10 Itchiest you have ever felt)	Use this answer to guide your recommendation for antihistamine and topical steroids use.	
9) FOR WOMEN: Is patient pregnant?	YES	REFER
	NO	May be a candidate for treatment

Decision to Treat

Are there any contraindications to outpatient treatment noted in patient assessment? YES: _____ NO: _____

If yes, then list below and refer patient to another primary care/urgent care/emergency care provider:

Prior to treatment being given the following steps will be taken:

- 1) Arrange for immediate emergency care if at any point the patient experience signs and symptoms of anaphylaxis
- 2) Remove the stinger by swiping the flat edge of a card or fingernail on the injection site. Stinger removal should be done within seconds of the sting in order to prevent more venom from being injected. However, after the first few seconds, no special technique (e.g., flicking to avoid compressing the venom sac) is necessary, since the venom should be fully expelled already [4]. Remaining stingers should be removed to promote proper healing and reduce risk of infection.
- 3) Remove jewelry from any areas of potential swelling
- 4) Wash the area with antibacterial soap (i.e.: Dial® soap, Hibiclens®) and water if patient has not already done so
- 5) Elevate the area of the sting, if possible

Additional Comments/Documentation:

Appendix C: Insect Stings Prescription Form

Date: / /	Patient Name:	DOB:
Intervention	Medication	Directions
Mild-Moderate Pain (≥18 years old) ICD-10 code W57	<input type="checkbox"/> Acetaminophen 500mg OR <input type="checkbox"/> Ibuprofen 400mg	<input type="checkbox"/> Take 1-2 tablet(s) PO every 4-6 hours PRN for pain. NTE 3,000mg per 24 hours Qty: _____ OR <input type="checkbox"/> Take 1-2 tablet(s) PO every 6-8 hours PRN for pain Qty: _____
Mild-Moderate Pain (12 to 17 years)	<input type="checkbox"/> Acetaminophen 325mg OR <input type="checkbox"/> Ibuprofen 200mg	<input type="checkbox"/> Children (<60 kg): 10-15 mg/kg every 4-6 hours PRN for pain (max of 75 mg/kg/day), NTE 5 doses or 3,000 mg per 24 hrs <input type="checkbox"/> Take 1-2 tablet(s) PO every 4-6 hours PRN for pain, NTE 3,000 mg (9 tabs)/24hrs Qty: _____ OR <input type="checkbox"/> Children (<50kg): 5-10 mg/kg every 6-8 hours, NTE 4 doses or 1,200 mg/24hrs <input type="checkbox"/> 200 mg 1-2 tabs PO every 6-8 hours PRN for pain, NTE 3,200 mg Qty: _____
Mild to Moderate Itching	Diphenhydramine 25mg	<input type="checkbox"/> Take 1-2 tablet(s) PO every 6-8 hours PRN for itching Qty: _____
Moderate to Severe Itching (≥18 years old)	<input type="checkbox"/> Cetirizine 10mg PLUS <input type="checkbox"/> Fluocinonide 0.05% cream or ointment OR <input type="checkbox"/> Clobetasol 0.05% cream or ointment OR <input type="checkbox"/> Triamcinolone 0.1% Cream	<input type="checkbox"/> Take 1 tablet PO once daily PRN for itching Qty: _____ PLUS <input type="checkbox"/> Apply a small thin layer to sting area Q 4H PRN itching. Do not apply to face or groin. Do not use longer than 2 weeks. Take one tablet PO BID for 3 days Qty: 15grams
Significant swelling > 5-10 cm (≥18 years old)	Prednisone 20mg	<input type="checkbox"/> Take 1 tablet PO once daily for 3 days Qty: 3 tabs
Moderate to Severe Itching (12 to 17 years old)	Cetirizine 10mg PLUS Mometasone 0.1% cream	<input type="checkbox"/> Take 1 tablet PO once daily as needed for itching Qty: _____ PLUS <input type="checkbox"/> Apply a small thin layer to sting area every 4 hours as needed for itching. Do not apply to face or groin. Do not use longer than 2 weeks Qty: 15 grams

Substitution Permitted (Pharmacist)

Dispense as Written (Pharmacist)

Appendix D: Primary Care Provider Communication Form

Dear Dr. _____

We are writing to inform you that our patient, _____ (DOB: _____) was recently seen by our clinical community pharmacist, _____ with an insect sting.

Below is the description of the insect sting:

Date of sting: ____/____/____ Cause of sting: _____

Location of sting: _____

Based on signs/symptoms checked below:

Treatment

- Mild-moderate pain
- Mild itching
- Moderate-severe itching
- Mild to moderate localized swelling 1-5 cm
- Significant localized swelling > 5-10 cm
- Erythema
- Symptoms of possible anaphylaxis

Referral:

- Extreme pain
- Sting > 48 hours old
- Signs of infections
- Multiple stings
- Airway involvement
- Sting for other insect(s)
- Noted allergy to bees/wasps

Based on the signs and symptoms marked above we determined that it was appropriate to prescribe the following:

<i>Place copy of prescription label here</i>	<i>Place copy of prescription label here</i>
--	--

After a thorough assessment, our pharmacist found it appropriate to dispense the above medication(s). Our patient received a one-on-one consultation on the medication and when to seek further evaluation. Our pharmacy will follow-up with our patient and check for improvement and/or resolution of symptoms.

Thank you,

Clinical Community Pharmacist

Date: ____/____/____

Name of physician: _____

Address: _____

Phone #: _____ Fax #: _____

Communication form faxed to physician: Yes No

Date faxed: _____

Initials: _____

Appendix E: Insect Stings Follow-up Form (3-5 days post-visit)

Date: _____

Patient Name: _____

Date of birth: Last _____ First _____ Middle _____
Month/Day/Year Age: _____ Gender (circle): Male/Female

Pharmacist Name: _____

1. How are you feeling?
2. Are your symptoms getting better / worse / or the same?
Note: If the insect sting has not improved at the time of follow up, refer the patient the appropriate health care provider
3. Are you experiencing any signs of infection (e.g. fever, redness, swelling, pus, increased pain) or a rash?
4. What adverse reactions have you experienced, if any?
5. What questions/concerns do you have for me?

Additional comments about follow up phone call: _____

Unable to Contact/Attempts made:

1st Attempt (date/time): _____ Initials of caller: _____
2nd Attempt (date/time): _____ Initials of caller: _____



Exhibit D – Urinary tract infection CDTA

Please see attached

**PHARMACIST – UNCOMPLICATED URINARY TRACT
INFECTION
COLLABORATIVE DRUG THERAPY AGREEMENT**

Agreement Expires: 4-5-18

(Typically 2 years from date of signed protocol)

AUTHORIZING PRESCRIBER STATEMENT

I, _____ MD licensed in the State of Washington, do hereby authorize (RPh's listed below and/or on additional signature page), who are pharmacists licensed in the State of Washington and employed by _____, to prescribe medications for urinary tract infections in collaborative drug therapy agreement: 'Uncomplicated Urinary Tract Infection' to patients in accordance with the laws (RCW 18.64.011) and regulations (WAC 246-863-100) of the State of Washington. Prescriptions are to be written only to patients age 18 and older at _____ and off-site locations approved by the _____ Clinical Care Coordinator.

This authorization will be in effect for two years, unless rescinded earlier in writing to the Washington State Pharmacy Quality Assurance Commission by either party. Any significant changes in the protocol must be agreed upon by the participants and submitted to the Commission.

MD

Physician Signature: _____

License: _____ Date: 4/5/16

Pharmacists included in the protocol (may be included on a separate sheet)

	Name	Signature	License #	Date
1	[Handwritten Name]	[Handwritten Signature]	[Handwritten License #]	3-22-16
2	[Handwritten Name]	[Handwritten Signature]	[Handwritten License #]	3/22/16
3	[Handwritten Name]	[Handwritten Signature]	[Handwritten License #]	3/22/16
4	[Handwritten Name]	[Handwritten Signature]	[Handwritten License #]	3/22/16
5	[Handwritten Name]	[Handwritten Signature]	[Handwritten License #]	3/22/16
6	[Handwritten Name]	[Handwritten Signature]	[Handwritten License #]	3/22/16
7	[Handwritten Name]	[Handwritten Signature]	[Handwritten License #]	3-22-16
8	[Handwritten Name]	[Handwritten Signature]	[Handwritten License #]	3/22/16
9	[Handwritten Name]	[Handwritten Signature]	[Handwritten License #]	3/22/16

PHARMACIST – UNCOMPLICATED URINARY TRACT INFECTION

COLLABORATIVE DRUG THERAPY AGREEMENT

Purpose

To provide timely and accessible treatment of uncomplicated urinary tract infections. The pharmacist will ensure that patients receive adequate information regarding urinary tract infections and their treatment. This protocol will be utilized in the initiation of therapy. This treatment will be prescribed in a community pharmacy by a certified Clinical Community Pharmacist.

Procedure

When the patient requests, or there is indication of need for treatment of an uncomplicated urinary tract infection in female patients, the pharmacist will assess the patient. The pharmacist will integrate patient-specific information and disease-state knowledge to decide about treatment and/or referral to another provider for further assessment.

The pharmacist will refer the patient to a physician or other healthcare provider if the use of treatment for an uncomplicated urinary tract infection may not be appropriate for the patient or if any of the following conditions are present: fever, flank pain, shaking, chills, nausea, vomiting, vaginal discharge, urine flow obstruction, signs of a complicated infection, pregnant or breastfeeding, history of 3 or more episodes in previous 6 months or symptoms that are not consistent with previous UTI's. Patient will also be referred if they are male.

In addition to the medication, patients will be provided with both verbal and written information on the signs and symptoms of urinary tract infections, proper use of the medication, possible adverse effects and how to follow up.

Each prescription provided by a certified Clinical Community Pharmacist will be documented in a patient profile as required by law. If the patient has a primary care provider, that provider will be notified of the Clinical Community Pharmacist visit. The pharmacist will provide the patient with a prescription to be filled at a different pharmacy location if requested by the patient.

Medications to be Initiated

Antibiotic therapy to be Initiated

- Trimethoprim-sulfamethoxazole 160 mg-800 mg #6 — One tablet twice daily for three days.
- Nitrofurantoin monohydrate 100 mg #14 — One capsule twice daily for seven days.
- Ciprofloxacin 250 mg #14 — One tablet twice daily for seven days.

Analgesic therapy to be Initiated (If Indicated)

- Phenazopyridine 200 mg #6 — One tablet (three times daily after meals as needed for dysuria, NTE 2 days when used in combination with an antibiotic.

Documentation:

The completed patient questionnaires, pharmacist assessment forms, and/or records of prescriptions written under this protocol will be kept on file at the pharmacy in accordance with state law.

Pharmacist training:

Each pharmacist participating in this protocol must have completed the Washington State Pharmacy Association's Clinical Community Pharmacist Certificate, including the module on uncomplicated urinary tract infections.

**PHARMACIST – UNCOMPLICATED URINARY TRACT
INFECTION
COLLABORATIVE DRUG THERAPY AGREEMENT**

Protocol Review

For quality assurance, this protocol requires the Authorizing Prescriber to review periodically the activities of the pharmacists providing prescriptions and to provide feedback to the pharmacists when deemed necessary. A detailed report with the following information is available to the Authorizing Prescriber upon request.

- Patient Name
- Patient Date of Birth
- Prescription Name
- Prescription Date
- Pharmacist Name

The Clinical Care Coordinator will provide the Authorizing Prescriber this report upon request.

WASHINGTON UNCOMPLICATED URINARY TRACT INFECTION PRESCRIPTION FORM

Name: _____ DOB: ____/____/____ Age: _____

Referral

- If patient is male, pregnant or breastfeeding
- ≥3 episodes in previous 6 months
- Urine flow obstruction is present
- No signs or symptoms consistent with UTI (painful burning sensation when urinating, urinary urgency/frequency, discomfort or pressure in lower abdomen, pain in pelvic area, cloudy and/or unpleasant smelling urine)
- If patient has ANY of the following symptoms
 - Fever _____
 - Nausea/vomiting
 - Flank pain (pain that runs along the back above waist level)
 - Shaking chills
 - Symptoms different from previous UTIs
 - Urine flow obstruction
- If patient has ANY of the following medical conditions
 - Previous complicated UTI
 - Ureteric or urethral stricture
 - Stones in the bladder, kidney, etc.
 - Urinary tract abnormalities
 - Indwelling urethral catheter
 - Nephrostomy tube
 - Intermittent catheterization
 - Cystocele (fallen bladder)
 - Vesicoureteral reflux (urine refluxes back into the upper urinary tracts)
 - Renal failure
 - Tumors of the urinary tract
 - Diverticulae
 - Renal cysts
 - Pelvic/lyceal obstruction
 - Ureteric stent
 - Invasive urological procedure
 - Neurogenic bladder
 - Ileal conduit procedure
 - Increased calcium in the kidneys
 - Medullary sponge kidney
 - Kidney transplant
- Other: _____

Note it is strongly recommended for patient to use Azo test strips to confirm the presence of leukocytes and nitrite in the urine. A positive result without any symptoms does not indicate a UTI. A negative result may represent a false negative and the patient should be referred. Directions are located on page 2

Medications Prescribed (May prescribe for a 3-7 day course, max visits 2/year)

Please refer to the Urinary Tract Infection Treatment Algorithm on page 3 before specific medication selection

P	R		
<input type="checkbox"/>		Nitrofurantoin monohydrate/macrocystals 100 mg 1 T PO BID X 5 days	# 10
<input type="checkbox"/>		Sulfamethoxazole-Trimethoprim DS 1 T PO BID X 3 days	# 6
<input checked="" type="checkbox"/>		Cephalexin 500mg 1 T PO Q12h X 7 days ***DO NOT USE***	# 14
<input type="checkbox"/>		Ciprofloxacin 250 mg 1 T PO BID X 3 days	# 6
<input type="checkbox"/>		Phenazopyridine 200 mg 1 Tab PO TID X 2 days PRN pain/dysuria	# 6
<input type="checkbox"/>		Phenazopyridine 97.5 mg 2 Tab PO TID X 2 days PRN pain/dysuria	# 12

Additional Comments/Documentation

- Symptoms patient presented with: _____

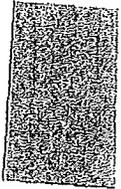
Note there is a chance symptoms could be due to something other than an uncomplicated urinary tract infection. Refer patient to PCP if you suspect other potential causes of symptoms and encourage patient to seek care promptly if symptoms change or don't improve.

Consultation Points

- Importance of finishing the entire course of antibiotics and future prevention even if their symptoms resolve.
- This is visit is not 100% diagnostic, and there is a chance they are experiencing something other than a UTI
- Side effects and instructions specific to each antibiotic.
- Proper use of phenazopyridine including only using for 2-3 days and then contacting their PCP if they are still symptomatic. Also counsel about the orange or red discoloration of body fluids and/or contact lenses.

_____ X _____
 RPH Substitution Permitted RPH DAW

 RPH Name Date



URINARY TRACT INFECTION ADDITIONAL INFORMATION FOR EVALUATION

- If the patient has had 3 or more episodes of UTI in the last 6 months, this may be a sign of recurrent UTI needing different treatment and follow up or of another disease, such as diabetes.
- There are other disorders that can have some of the same symptoms as an uncomplicated UTI. It is important to rule these out before treating. If you suspect that the patient has one of these illnesses instead, they should be referred to primary care.
 - **Vaginitis**
Symptoms: Dysuria, vaginal discharge or odor, pruritus or dyspareunia with absence of urinary frequency
 - **Urethritis**
Can mimic and present just like an uncomplicated UTI with its symptoms. Differing symptoms include: pain during sexual intercourse, severe pelvic or abdominal pain, urethral discharge or fever. Yet these may not occur all the time. Common causes of urethritis are sexually transmitted diseases (i.e., chlamydia, gonorrhea, and trichomoniasis). If you suspect urethritis without the presence of a UTI, you should ask the patient if they have had unprotected sexual intercourse with a different partner in the last 2-4 weeks.
- There are several other conditions that may mimic a UTI. Please see table 3 in the AAFP article from WSPA modules for more information. Summary of associated features included below:
 - **Acute Pyelonephritis:** Nausea, fever, flank pain, costovertebral angle tenderness, pyuria with casts
 - **Atrophic vaginitis:** Post-menopausal women, no infectious etiology
 - **Bladder cancer:** Frequency, urgency, hematuria
 - **Cystitis:** Frequency, urgency, pyuria, bacteriuria, urinary dipstick positive for nitrates
 - **Genital Herpes:** Dysuria, vulvar pain, grouped vesicles, tender inguinal adenopathy
 - **Interstitial cystitis:** Frequency, urgency, long standing symptoms, pain in bladder or urethra relieved by urination, negative urine cultures, ulcers or glomerulations (bladder hemorrhages) identified on cystoscopy
 - **Irritant cystitis:** Symptoms related to dietary intake, chemical irritant, or other exposures
 - **Overactive bladder:** Urgency, frequency, and possible incontinence, without dysuria
 - **Sexually transmitted disease:** Vaginal discharge, history of unprotected sexual intercourse

Azo Test Strip Instructions: See Clinical Ordering Guide for information on ordering Azo Test Strips.

Have patients urinate in the public restroom (they should NOT be utilizing our pharmacy restrooms) and interpret the results themselves. If needed, provide patient with Ziploc bag and have them bring the test strips back to the pharmacy for interpretation (note the 1-2 minute time limit).

Directions: After some urine has passed, wet one test strip by holding it in urine stream for 1-2 seconds. Make sure both test pads are wetted and immediately bring the edge of the test strip into contact with an absorbent material such as a paper towel to remove excess urine. Lay the test strip with the test pads facing upwards on the paper towel. Read the result at 1 minute for Nitrite and at 2 minutes for Leukocytes. Match the color of the test strip pads to the color blocks on the foil pouch. Any amount of uniform pink color on the nitrite test pad is positive, but pink spots or pink edges are not a positive result. A positive Leukocyte test will give a dark tan to purple color. Ignore any color change after you have read the test pad at 2 minutes.

Although most substances will not interfere with the test, some medication can affect the color of urine (phenazopyridine). For example, doses > 500mg of vitamin C in 24 hours and decreased urine pH due to cranberry juice or other dietary supplements can lead to a false negative nitrite result. Tetracycline may cause a false negative Leukocyte result.

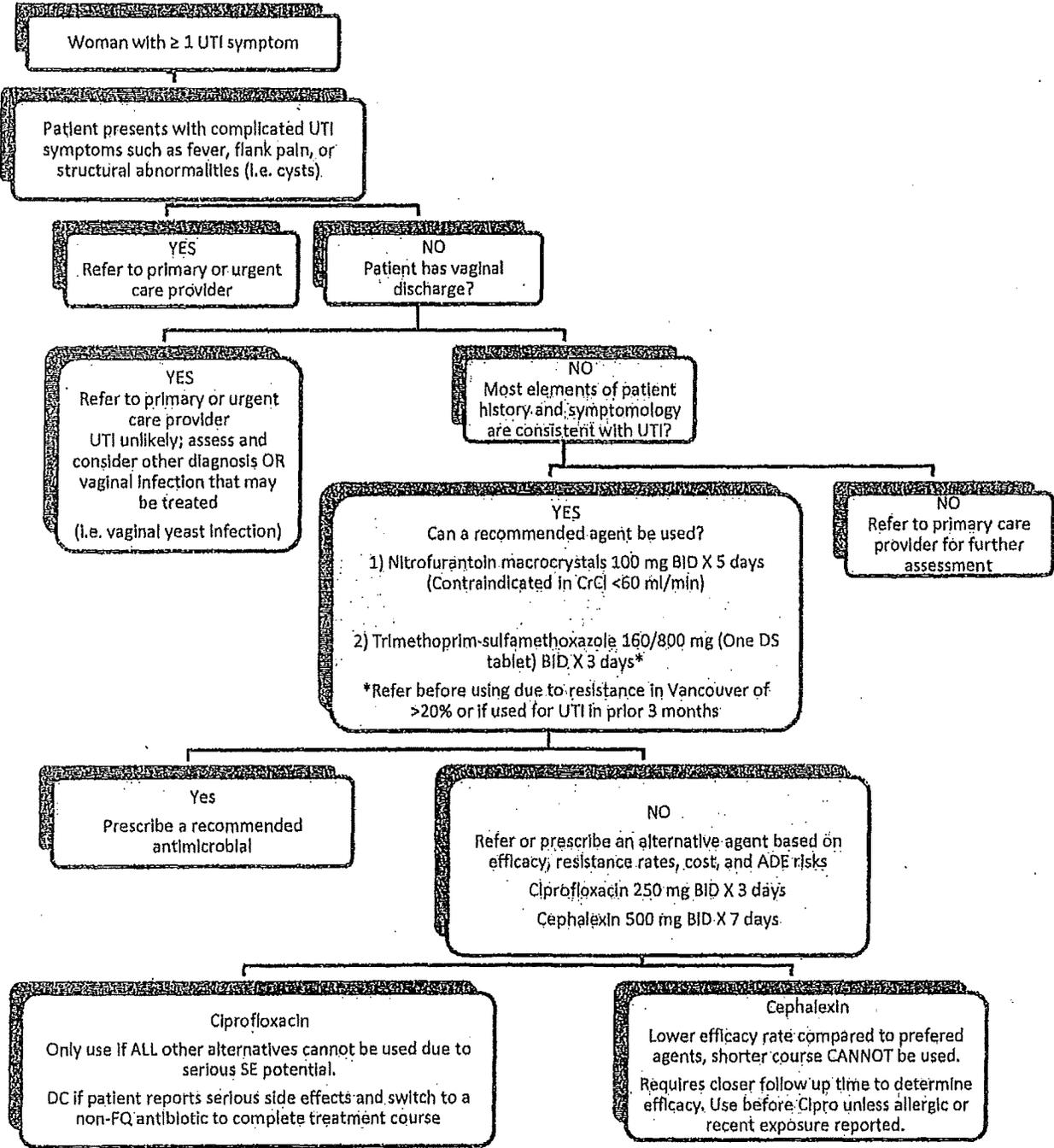
Some causes of a false negative nitrite result include infection by bacteria that does not change nitrate to nitrite, if diet does not include nitrates, or if the urine has not been held in the bladder long enough (at least 4 hours). Using Azo test strips during menstruation is not recommended because traces of menses can produce a false positive Leukocyte result.

Sulfamethoxazole-Trimethoprim SW WA Resistance Information

Data for Jan 1- Dec 31, 2015 (Last referenced 1/13/2017)

- Peace Health Southwest Medical Center reported an E. coli susceptibility to Sulfamethoxazole- Trimethoprim of 80% (20% resistant).
 - Due to the high resistance rate in the SW WA area, Sulfamethoxazole- Trimethoprim is considered last-line therapy for the treatment of Urinary Tract Infections. Patients should be referred.
- Providence Health & Services- Olympia: reported an E. coli susceptibility to Sulfamethoxazole- Trimethoprim of 80% (20% resistant).
 - Due to the high resistance rate in the Central WA area, Sulfamethoxazole- Trimethoprim is considered last-line therapy for the treatment of Urinary Tract Infections. Patients should be referred.
- University of Washington and Harborview reported an E. coli susceptibility to Sulfamethoxazole- Trimethoprim of 62% (38% resistant)

URINARY TRACT INFECTION TREATMENT ALGORITHM



Patient Name: _____

DOB: ____/____/____

Age: _____

Pharmacist Name: _____

Date: _____

URINARY TRACT INFECTION FOLLOWUP: 3 DAYS AFTER VISIT

1. How are you feeling? Are your symptoms getting better / worse / the same?
 If symptoms not improving, refer to PCP for further evaluation.

2. Do you have any new symptoms?
 Remind patient if fever occurs within 3 days they should see their PCP

3. How have you been taking your medications for your UTI?

4. What adverse reactions have you experienced, if any?

5. What questions/concerns do you have for me?

Additional documentation:

Changes/updates to regimen:

- Referred to prescriber due to change in symptoms or other reason:

Unable to contact / attempts made:

**PHARMACIST- UNCOMPLICATED URINARY TRACT INFECTION
COLLABORATIVE DRUG THERAPY AGREEMENT**

UNCOMPLICATED URINARY TRACT INFECTION PATIENT EDUCATION

Definition	<ul style="list-style-type: none"> <input type="checkbox"/> A urinary tract infection (UTI) is an infection in any part of the urinary tract, but most commonly involves the lower urinary tract (bladder and urethra). UTIs are most common in young women but can also affect younger men after unprotected intercourse.
Symptoms	<ul style="list-style-type: none"> <input type="checkbox"/> Persistent urge to urinate. <input type="checkbox"/> Burning or painful sensation when urinating. <input type="checkbox"/> Passing frequent small amounts of urine. <input type="checkbox"/> Strong-smelling urine. <input type="checkbox"/> Pelvic pain (women), rectal pain (men).
Cause	<ul style="list-style-type: none"> <input type="checkbox"/> UTIs develop when bacteria enter the urinary tract through the urethra and multiply in the bladder. Infection of the bladder is usually caused by the bacteria <i>E. coli</i>, which is commonly found in the gastrointestinal tract. Sexual intercourse may move bacteria to the urinary tract, especially in women.
Prevention	<ul style="list-style-type: none"> <input type="checkbox"/> For women experiencing a UTI after sexual intercourse, bladder voiding immediately after intercourse and avoiding use of a diaphragm may be helpful. <input type="checkbox"/> Other steps to reduce the risks of UTI include: <ul style="list-style-type: none"> <input type="checkbox"/> Drinking plenty of fluids, especially water <input type="checkbox"/> Wiping from front to back <input type="checkbox"/> Avoiding potentially irritating feminine products
Treatments	<ul style="list-style-type: none"> <input type="checkbox"/> Drink at least 64 ounces of water in each 24 hour period. <input type="checkbox"/> Phenazopyridine (Azo) helps to relieve pain associated with UTIs. Take one tablet three times daily for no more than 2 days. <input type="checkbox"/> Oral antibiotics are used to eliminate bacterial infections. Note: some antibiotics may interfere with the effectiveness of oral contraceptives. Use a backup method of contraception.
Medication Information	<ul style="list-style-type: none"> <input type="checkbox"/> Nitrofurantoin macrocrystals side effects are abdominal pain, diarrhea, rash, and discoloration of urine to a dark brown color (this is normal). <input type="checkbox"/> Sulfamethoxazole – trimethoprim side effects are abdominal pain, diarrhea, increased sun sensitivity and sometimes a serious allergic reaction develops in which case, you should contact your physician right away. <input type="checkbox"/> Ciprofloxacin side effects are abdominal pain, nausea, vomiting, diarrhea and although rare, tendon pain/rupture is possible with this medication so contact your physician if you experience joint pain after taking your medication. <input type="checkbox"/> Cephalexin side effects include abdominal pain, diarrhea, and vomiting. <input type="checkbox"/> Phenazopyridine side effects are stomach cramps, headache, dizziness and discoloration of urine to a reddish color (this is normal).
See your provider if	<ul style="list-style-type: none"> <input type="checkbox"/> You are experiencing fever or chills. <input type="checkbox"/> You are experiencing nausea, vomiting, and rigid abdomen. <input type="checkbox"/> You have upper back and side (flank) pain. <input type="checkbox"/> You have impairment to urine flow or any known abnormalities in your urinary tract. <input type="checkbox"/> You are pregnant. <input type="checkbox"/> Pain persists or symptoms are not entirely resolved or you develop a fever in 3 days. <input type="checkbox"/> If you develop a rash or experience any serious side effects from your urinary tract infection medications. <input type="checkbox"/> You experience any serious side effects while taking ciprofloxacin such as tendon, joint and muscle pain, a "pins and needles" tingling or pricking sensation, confusion, and hallucinations.

PROVIDER NOTIFICATION FOR _____

STORE: _____

FAX: (____) _____

PHONE: (____) _____

INFORMATION ONLY: PRESCRIPTIONS PER _____ PROTOCOL

Patient Name: _____ DOB: ____/____/____

Physician Name: _____ Phone: (____) _____ Fax: (____) _____

This patient was seen at our pharmacy on ____/____/____ for an assessment by a trained clinical community pharmacist. The pharmacist integrated patient-specific information and disease-state knowledge to provide treatment and/or referral to another provider for further assessment. During this visit we carefully reviewed the patient's medical, prescription history, and lifestyle factors to ensure the safety of the patient and appropriateness of therapy.

The following prescription(s) were prescribed to our patient:

RX: _____ Quantity: _____ Refills: _____
Directions: _____

RX: _____ Quantity: _____ Refills: _____
Directions: _____

RX: _____ Quantity: _____ Refills: _____
Directions: _____

Upon review it was determined that the patient should be referred to their physician:

Reasons for provider referral for this patient include:

Pharmacist Signature: _____

Date: _____

Pharmacist Name (Print): _____

Please contact us if you have any questions about the care provided to our patient or if you would like to obtain additional information about our pharmacy's patient care services. Thank you!

CONFIDENTIALITY NOTICE:
SOME OF THE INFORMATION PRODUCED OR REPRODUCED ON THIS DOCUMENT CENTER MAY BE PRIVILEGED AND CONFIDENTIAL AND PROTECTED FROM DISCLOSURE. IF THE READER OF THIS INFORMATION IS NOT THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE READ ANY SUCH INFORMATION OR COMMUNICATION IN ERROR, PLEASE NOTIFY THE SENDER IMMEDIATELY.



Exhibit E – CDTA help page
Please see attached

Washington Immunization State-Specific Policies

Collaborative Drug Therapy Agreement (CDTA) New!

- [Collaborative Drug Therapy Agreement \(CDTA\)](#) – The CDTA delegates prescriptive authority to the pharmacists for the immunizations in the vaccine tables below.
- If the immunization is administered under the CDTA, the pharmacist must process immunizations under their own name and NPI number.
- The physician who has signed the CDTA should not be contacted under any circumstance. The immunization should not be processed under the name of the physician who signed the CDTA.

Vaccine Tables

- [Washington Vaccine Tables](#)
 - All pharmacy staff must print and read the vaccine tables for your state above.

Standing Order Prescription Templates

- Please [click here](#) to access the standing order prescription template for protocol.

Preservative Free Requirement

- Washington does not require the use of preservative free vaccines.

Required Reporting

- **Immunization Registry**
 - Walgreens currently reports all immunizations to the state Immunization Registry. Please click [here](#) for more information.
- **Physician Notification Letters (PNLs)**
 - Please click [here](#) for more information

Pharmacist Continuing Education Requirement

- There are no specific requirements that pharmacists participate in continuing education units or courses regarding vaccinations and immunizations.

Board of Pharmacy Application

- Washington does not require a specific Board of Pharmacy Application to administer vaccines.

Biomedical Waste Requirements

- Washington does not have any state-specific biomedical waste requirements outside of the federal and Walgreens' [biomedical waste requirements](#).

Can Pharmacy Interns Administer Vaccines?

- Per state law, pharmacy interns/externs can administer vaccinations in accordance with the [Walgreens Intern Details](#).

Sticker State Immunization Record Keeping

- Immunizations must be filed following standard practice of pharmacy therefore the record keeping sticker must be filed with the other prescriptions using [filing procedures for non-controlled prescriptions](#).

Updated: 11/3/15

Updated: 6/29/15

Updated: 9/18/14

Updated: 3/18/14