

COLLABORATIVE PRACTICE AGREEMENT:
LONG-ACTING INJECTABLE ANTIPSYCHOTICS

Effective October 1, 2010, Connecticut Senate Bill 428 (PA 10-117) expanded the opportunity for licensed pharmacists in the state to enter into a patient-specific collaborative drug therapy management agreement, or collaborative practice agreement, with physicians licensed in Connecticut to all settings and medical conditions. Therefore, licensed pharmacists in Connecticut may participate in the practice of monitoring, initiating, managing, modifying, and refilling drug therapy according to a written agreement with the physician(s) responsible for the patient's care.

The intent of this document is to describe the specific procedures that permit a licensed pharmacist to administer long-acting antipsychotic injections to patients under the care of a physician. No additional services delivered by the collaborating pharmacist will be permissible through this document. Expanding the collaborating pharmacist's clinical privileges will require either revision of this document, or the development of a new collaborative practice agreement.

The following collaborative practice agreement, between PHARMACIST, RPh and PHYSICIAN, MD, describes the clinical privileges granted to PHARMACIST, RPh in compliance with the Connecticut Pharmacy Practice Act. By signing this document, PHYSICIAN, MD enters into this agreement and PHARMACIST, RPh accepts the responsibilities of effectively carrying out the duties of this agreement. This written agreement outlines the process and procedures for collaborative patient care with long-acting injectable antipsychotic treatment.

This agreement will be reviewed annually by PHYSICIAN, MD and PHARMACIST, RPh.

COLLABORATIVE PRACTICE AGREEMENT APPROVED BY:

Pharmacist, RPh
Collaborating Pharmacist

Physician, MD
Collaborating Psychiatrist

DATE OF FIRST IMPLEMENTATION:

DATES OF ANNUAL REVIEW COMPLETED:

I. Purpose:

This document describes an agreement to formally authorize pharmacist-administered long-acting injectable antipsychotic (LAIA) therapy to patients requiring such treatment through a collaborative practice agreement with a collaborating physician. The goal of implementing LAIA administration services is to improve patient and provider access to these medications, and to optimize treatment outcomes for patients who may benefit from LAIA therapy. This document adheres to Section 20-631 of the Connecticut Comprehensive Drug Laws (published online April 2014; available at: http://www.ct.gov/dcp/lib/dcp/pdf/drug_control_pdf/drug_laws_4-15-14_web_june_2714.pdf)

II. Patient Population:

This collaborative practice agreement will apply to all patients referred to PHARMACIST, RPh by PHYSICIAN, MD. It will be understood that all such patients referred to PHARMACIST, RPh will have an established physician-patient relationship with PHYSICIAN, MD and that the referred patient requires LAIA treatment.

III. Training and Approval:

The State of Connecticut Department of Consumer Protection must approve each pharmacy site for patient safety and privacy. Collaborating pharmacists will complete necessary injection and disease state training before being permitted to provide LAIA administration services.

The collaborating pharmacist must have current certification and/or training in: 1) cardiopulmonary resuscitation, 2) first aid, 3) vaccine administration, 4) OSHA, and 5) blood-borne pathogen. Additionally, the collaborating pharmacist must have completed manufacturer specific training for each product and must complete a minimum of 2 hours of annual continuing education credits focused on antipsychotics and/or disease states that are FDA approved for the LAIA use (e.g., schizophrenia, bipolar disorder). The collaborating pharmacist will also be trained on the proper procedures for documentation and physician follow-up.

IV. General Provisions:

Specific procedures for all activities, including provider roles and responsibilities, are detailed in the protocol that follows. In order to improve access to LAIAs, and enhance patient care, PHARMACIST, RPh is given authority to administer approved LAIAs that have been prescribed for patients under the care of PHYSICIAN, MD.

The specific LAIAs that PHARMACIST, RPh is given authority to administer include, please check all that apply:

- Abilify Maintena® (aripiprazole monohydrate)
- Aristada® (aripiprazole)
- Aristada Initio® (aripiprazole)
- Invega Trinza® (paliperidone palmitate)
- Invega Sustenna® (paliperidone palmitate)
- Risperdal Consta® (risperidone)
- Haldol Decanoate® (haloperidol)
- Prolixin Decanoate® (fluphenazine)
- Zyprexa Relprevv® (olanzapine pamoate)

This agreement does NOT authorize PHARMACIST, RPh to: 1) initiate, manage, modify, monitor, refill, administer or discontinue any pharmacotherapy that is not described in this protocol, or 2)

order any laboratory tests for referred patients. PHARMACIST, RPh is also not authorized to change the LAIA dose unless directed to do so by the collaborating physician.

V. Specific Procedures:

A. New LAIA Patients, New LAIA Prescriptions:

PHARMACIST, RPh may administer LAIA therapy to patients for which there is a new prescription written by PHYSICIAN, MD for any of the approved protocol antipsychotics (p. 2; Appendix A). All new prescriptions will be written by the collaborating physician in a manner that makes them valid. In addition, the words “injections may be given by pharmacist” must be included in the “SIG” of the prescription. Prescriptions may be telephoned, faxed or sent electronically. The physician, or office staff for the physician, should obtain signed consent (Appendix B) from the patient and schedule an appointment for the patient to receive their first injection from the collaborating pharmacist. Also, a copy of the collaborative practice agreement will be kept in the patient’s medical record.

Once the patient has a scheduled LAIA appointment at the pharmacy, the collaborating pharmacist should make record of the appointment and keep pharmacy staff up-to-date regarding patients scheduled for LAIA administration appointments. On the patient’s appointment date, the following procedures should be followed when the patient arrives for their LAIA injection:

1. The patient is greeted by either the pharmacist, or a member of the pharmacy staff, and the patient’s identity is verified using both their first and last name, AND date of birth.
2. To insure patient privacy, the community pharmacy site must have a designated room available for injections. Each designated room will have two chairs and a table at a minimum. At the discretion of the PHYSICIAN, MD, the collaborating pharmacist may administer LAIA injections at places other than the pharmacy (e.g., an off-site clinic, a patient’s home, etc) provided that procedures in the collaborative practice agreement are adhered to and maintained.
3. Once the appointment and patient are verified, the patient is provided with patient information that is specific to the LAIA treatment that will be administered. [Note: it is the responsibility of the pharmacist to insure that the patient receives the most up-to-date information.] In addition, the patient must sign the LAIA patient encounter form (Appendix C) which provides consent to receive their LAIA injection from the pharmacist.
4. The patient’s prescription information is verified by the pharmacist, including medication administration due date. [Note: If the administration date of the LAIA dose falls outside of the manufacturer recommended dosing interval, the patient will not receive antipsychotic medication until the prescriber has been consulted. If applicable, the pharmacist should document any communication with the physician directly on the patient encounter form.
5. The pharmacist: cleans the injection preparation area using 70% isopropyl alcohol or disinfectant wipes; washes their hands using soap and water; inserts their hands into appropriately sized vinyl gloves and organizes the supplies necessary for the patient as required.
6. The pharmacist prepares the solution for injection by mixing the active ingredient and diluent according to the specific product prescribing information and instructions. [Note: When specified or recommended by the LAIA manufacturer, the pharmacist, or pharmacy staff, should remove any LAIA administration kits from refrigerated storage at least 30

minutes prior to reconstitution to allow sufficient time for the product to reach room temperature.

7. The pharmacist selects a needle length appropriate for the patient according to specifications provided by the manufacturer.
8. The pharmacist loads the LAIA dose into a syringe using an aseptic technique and as instructed in the LAIA prescribing information.
9. For deltoid administration, the pharmacist seats the patient in a chair that is perpendicular to the LAIA administering pharmacist's chair such that it enables the pharmacist to catch the patient in a fainting situation. For gluteal administration, the patient should be in a comfortable position (standing, sitting or reclined). Once in position, the patient should make the injection site accessible by moving their clothing appropriately. The pharmacist then makes an injection site determination in accordance with specific LAIA product prescribing information and incorporates the following:
 - Use of professional judgement and consideration of consumer privacy and comfort when more than one injection site option is available.
 - If clothing causes obstructed view of injection site, locate a private area for administration. Having a witness present during gluteal injections is preferred. If administration cannot be performed for any reason, the collaborating pharmacist should consult with the prescriber.
 - Rotate injection sites with each administration in accordance with specific LAIA product labeling. Expose the entire injection target area to permit an unobstructed view of the patient's injection site.
10. The pharmacist examines the patient's injection site for evidence of lesions and to establish that the site is pain free, and then wipes the injection site with an alcohol swab to remove oils and dirt from the site and allows the site to air dry.
11. The pharmacist grips the syringe and positions their hand according to desired preference and allowing for a darting motion to be generated in a trajectory toward the injection site.
12. The pharmacist compresses the muscle tissue using fingers of their opposite hand in order to stabilize the patient's injection site, makes a "C" with their ring finger and thumb and uses that as a target for the injection site. The pharmacist then inserts the needle into the skin at a 90 degree angle into the thickest part of the muscle all the way to the hub of the needle, injects the LAIA solution, and removes the needle.
13. The pharmacist then activates the safety syringe into a sharps container; then applies slight pressure to the injection site with a cotton ball for 30 seconds; then applies a bandage to the patient's injection site. The patient is then asked to wait in the pharmacy for 15 minutes in order to monitor for any possible adverse reactions.
14. During the 15 minute waiting period and prior to leaving, the pharmacist makes an appointment for the following LAIA injection and provides the patient with a written reminder about when the appointment is scheduled. Additionally, the pharmacist also documents information on the patient encounter form that provides details about the LAIA injection that the patient received. A copy of the patient encounter form is then sent to the collaborating physician; the original patient encounter form is then kept on file that is specific to the patient.

B. Adverse Reactions:

Following an intramuscular injection, it is common for patients to experience injection site pain and swelling. If the patient experiences an allergic reaction (i.e., sudden onset of itching, redness,

and hives within several minutes of LAIA administration; angioedema [swelling of lips, faces or throat], bronchospasm, or shock), the following procedures should be followed:

1. If itching and swelling are localized to the extremity in which the LAIA was administered, observe the patient closely for 30 minutes and observe the patient for generalized symptoms. If none occur, refer the patient for medical evaluation.
2. If symptoms are generalized, activate the emergency medical system (EMS) and call the prescribing physician for instructions. When possible, these phone calls should be made by another person in order to permit the collaborating pharmacist to remain with the patient.
3. Administer epinephrine (i.e., Epi-Pen) either subcutaneously or intramuscularly. The site of administration can be the anterior thigh, or deltoid.
4. Monitor the patient closely until EMS arrives. Perform CPR and maintain the patient's airway if necessary. Keep the patient in a supine position unless he/she is having difficulty breathing. If breathing is difficult, the patient's head may be elevated, provided their blood pressure is adequate to prevent loss of consciousness. Monitor the patient's vital signs frequently.
5. Repeat the epinephrine dose every 5–20 minutes, as the patient's symptoms require, until EMS arrives.
6. Refer the patient for medical evaluation, even if symptoms are completely resolved. Symptoms may recur after the epinephrine wears off, as much as 24 hours later.
7. Complete an adverse event form and submit to the FDA.

C. Patient Documentation and Physician Follow-up

After a patient has been administered their LAIA therapy, the collaborating pharmacist will document pertinent information on the patient encounter form (Appendix C) detailing specifics about the LAIA injection that the patient received. A copy of the patient encounter form is then sent to the collaborating physician as soon as possible and within 3 business days; the original patient encounter form is then kept on file in the pharmacy's patient record.

The frequency of pharmacist-physician communication will, in part, be determined by the LAIA dosing interval prescribed for the patient. The collaborating pharmacist will report to the collaborating physician, in aggregate, all LAIA administration services performed for each month.

D. Patient Misses an Appointment for Their Injection

If a patient fails to appear for their appointment, PHARMACIST, RPh will notify PHYSICIAN, MD, or collaborating physician's staff, on the same day. In addition, PHARMACIST, RPh and PHYSICIAN, MD will discuss an action specific to the individual patient. This may, or may not, require that PHARMACIST, RPh make attempts to contact the patient and provide PHYSICIAN, MD with pertinent information, on a timely basis, as it becomes available. Attention should be paid to the "allowable injection window" for the patient's LAIA therapy as described in the product label. The collaborating pharmacist should consult with the collaborating physician about any needed dose changes that will be required in these circumstances.

E. Follow-up Appointments for LAIA Injections:

PHARMACIST, RPh may administer follow-up LAIA therapy to patients for which there is a prescription with available refills written by PHYSICIAN, MD for any of the approved LAIAs. If there are no available refills, then the pharmacist must consult with the physician before being able to administer LAIA therapy to the patient. If the patient has valid refills on the appointment date, the pharmacist and pharmacy staff will follow the procedures outlined in section V.A.1-13 above. During the 15 minute post-injection waiting period, and prior to leaving, the collaborating

pharmacist will make an appointment for the following LAIA injection and provides the patient with a written reminder about when the appointment is scheduled.

F. Available for Inspection

A copy of this collaborative practice agreement will be available for inspection (e.g., by the Departments of Public Health and Consumer Protection) at the collaborating community pharmacy where LAIA administration services are being provided, and at the collaborating physician's office.

Appendix A:

Brand/ Generic	Indication	Dosages	Intervals	Product Label Comments
Abilify Maintena (aripiprazole monohydrate extended release injectable suspension)	Schizophrenia	200 mg 400 mg	q 4 wks q 4 wks	<ul style="list-style-type: none"> • Either dose may be administered in the deltoid or gluteal muscle • Prepare syringe according to manufacturer's recommendations. • Recommended starting dose is 400 mg IM q 4 weeks (26 days is the shortest interval between IM doses; • After the first Abilify Maintena injection, administer oral aripiprazole (10–20 mg) for the first 14 consecutive days to achieve therapeutic aripiprazole concentrations during initiation therapy; • If either the <u>2nd or 3rd dose is missed</u> and it has been more than 4 weeks and less than 5 weeks since the last injection, administer the next Abilify IM dose as soon as possible. If more than 5 weeks have elapsed since the previous injection, then re-start 14 days of concurrent oral aripiprazole with the next administered injection; • If the <u>4th or subsequent doses are missed</u> and if it has been between 4 weeks and 6 weeks since the previous injection, administer the next injection as soon as possible. If more than 6 weeks have elapsed since the previous injection, then re-start 14 days of concurrent oral aripiprazole with the next administered injection; • Lower doses are necessary for patients who are known CYP2D6 poor metabolizers or who are taking medications known to be clinically important CYP2D6 inhibitors (e.g., fluoxetine, paroxetine, duloxetine, bupropion) and/ or clinically important CYP3A4 inhibitors. See the Abilify Maintena product label for additional dose adjustments (Section 2.3; Table 1).
Aristada (aripiprazole lauroxil extended release injectable suspension)	Schizophrenia	441 mg 662 mg 882 mg 1064mg	q 4 wks q 4 wks q 4 or 6 wks q 6 wks	<ul style="list-style-type: none"> • Prepare syringe according to manufacturer's recommendations. • Only the 441 mg Aristada dose may be injected into the deltoid muscle; all four Aristada doses may be injected into the gluteal muscle; • Aristada doses are based on the patient's oral aripiprazole total daily dose: aripiprazole 10 mg/day = 441 mg of Aristada every 4 weeks; aripiprazole 15 mg/day = 662 mg Aristada every 4 weeks; aripiprazole 20 mg/day = 882 mg of Aristada every 4 weeks. • Upon first dose, you can either coadminister a loading dose of 675mg along with the maintenance dose and one 30mg oral dose OR continue taking the oral medication x 21 days and only give the maintenance dose on day 1. • Subsequent Aristada injections should not be given earlier than 14 days after the previous injection; • See Aristada product label (Section 2.2, Table 3) for specific recommendations about how to address missed Aristada injections; • Dose adjustments are required for 1) known CYP2D6 poor metabolizers and 2) for patients taking CYP3A4 inhibitors, CYP2D6 inhibitors, or CYP3A4 inducers for more than 2 weeks (Section 2.4, Table 4)

Brand/ Generic	Indication	Dosages	Intervals	Product Label Comments
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<p>Invega Sustenna (paliperidone palmitate extended release injectable suspension)</p>	<p>Schizophrenia Schizoaffective Disorder</p>	<p>39 mg 78 mg 117 mg 156 mg 234 mg</p>	<p>q 4 wks (except at dose initiation - see Comments)</p>	<ul style="list-style-type: none"> • Prepare syringe according to manufacturer's recommendations. • Initiation dosing must be given in the deltoid muscle (234 mg on day 1 and 156 mg on day 8), subsequent doses may be given in either the deltoid or gluteal muscles; maximum monthly dose = 234 mg. (Section 2.2; Table 1) - needle size is specified by weight and location of the injection site - refer to product label. • If the patient misses the second dose of initiation treatment then the action plan is dependent upon the length of elapsed time from the first injection. (See Section 2.3, Table 2) • Following the two injections that serve as initiation dosing, the next injection is administered 5 weeks from the patient's first injection (or 4 weeks from the patient's second injection) • The recommended maintenance dose for the treatment of schizophrenia is 117 mg every 4 weeks. To decrease the risk of a missed dose, patients may be given a Invega Sustenna injection up to 7 days before or after the 4 week time point. • Consult the product label for information to support an action plan for managing missed maintenance doses. (see Section 2.3, Table 3) • Not recommended for patients with moderate or severe renal impairment. Co-administration with inducers of CYP3A4 and Pgp make require higher dose of Invega Sustenna.
<p>Invega Trinza</p>	<p>Schizophrenia</p>	<p>273 mg 410 mg 546 mg 819 mg</p>	<p>q 12 wks</p>	<ul style="list-style-type: none"> • Prepare syringe according to manufacturer's recommendations. • Invega Trinza is only indicated for patients who have been treated with Invega Sustenna for at least 4 months - it is recommended that the final two Invega Sustenna doses should be the same milligram dosage. Invega Trinza should be administered when the next Invega Sustenna dose is due • Dosing is once every 12 weeks using the following conversions guide: Invega Sustenna 78 mg = 273 mg Invega Trinza; Invega Sustenna 117 mg = 410 mg Invega Trinza; Invega Sustenna 156 mg = 546 mg Invega Trinza; Invega Sustenna 234 mg = 819 mg Invega Trinza • May be given either in the deltoid or gluteal muscle - needle size is specified by patient's body weight <u>and</u> location of the injection site - refer to product label. • To manage missed doses ranging from 4–9 months since last Invega Trinza dose, see Section 2.3, Table 2 in the product label. To decrease the risk of a missed dose, patients may be given an Invega Trinza injection up to 7 days before or after the 4 week time point. • Not recommended for patients with moderate or severe renal impairment.
<p>Risperdal Consta</p>	<p>Schizophrenia Bipolar I Disorder</p>	<p>12.5 mg 25 mg 37.5 mg 50 mg</p>	<p>q 2 wks</p>	<ul style="list-style-type: none"> • Remove dose pack from refrigeration for at least 30 minutes to get to room temperature before reconstituting. • Prepare syringe according to manufacturer's recommendations. • After the first Risperdal Consta injection, administer oral risperidone for the first 3 weeks to maintain therapeutic risperidone concentrations during initiation therapy - it should be discontinued after that point. After each injection of Risperdal Consta, there is only a small release of the drug (,1% of the dose), followed by a lag time of

						<p>3 weeks which is when the main release of the drug begins.</p> <ul style="list-style-type: none"> The recommended dose for the treatment of schizophrenia, and for Bipolar I disorder, is 25 mg IM every 2 weeks. Lower and higher doses are available to allow for individualized dosing of the patient. Caution is advised for Risperdal Consta in patients who are elderly, have renal or hepatic impairment or are taking CYP2D6 inhibitors or are known CYP2D6 poor metabolizers - each of these patient characteristics can cause risperidone accumulation. Adding a medication with known CYP3A4 inducing effects can reduce total levels of risperidone and can cause
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Information in two tables above is directly from the respective manufacturer's product label.

Abilify® Maintena (aripiprazole mono- hydrate)	No	N/A	Either	0.8–2.0 mL	q 4 wks	<ul style="list-style-type: none"> 26–34 days since last injection Shake vigorously for 20 sec Inject slowly; injected product should be milky white / opaque
Aristada (aripiprazole lauroxil)	No	N/A	441 mg: deltoid or gluteal; 662/ 882/ 1064mg mg: <u>glute</u> <u>al</u> <u>only</u>	1.6–3.2 mL	q 4 wks for lowest three doses; <u>q 6 wks</u> <u>for</u> <u>1064m</u> <u>g</u>	<ul style="list-style-type: none"> 441 mg q 4 wks: 2–6 wks since last injection; 662–882 mg q 4 wks: 2–8 wks since last injection; 1064 mg given q 6 wks: 2–8 wks since last injection Beyond the upper time limits above, injections must be accompanied by oral aripiprazole supplementation - see product label for specifics Tap 10 times, then shake for 30 sec Inject in a rapid, continuous manner (< 10 sec); injected product should be a white, uniform aqueous suspension
Invega® Sustenna (paliperidone palmitate)	No	N/A	Either	0.25– 1.5 mL	q 4 wks	<ul style="list-style-type: none"> 4–6 wks since last injection Shake vigorously for 10 sec Inject slowly
Invega® Trinza (paliperidone palmitate)	No	N/A	Either	0.875– 2.625 mL	q <u>12</u> wks	<ul style="list-style-type: none"> 10–14 wks since last injection; if btwn 14-16 wks - admin same dose with MD approval Shake vigorously for 15 sec w/ in 5 minutes prior to injection Inject slowly; injected product should be uniformly milky white
Risperdal® Consta (risperidone)	Yes	30 min	Either	2.0 mL	q 2 wks	<ul style="list-style-type: none"> 3 days +/- due date Shake vigorously for 10 sec Inject slowly; injected product should be uniformly milky white

modified from C. DiMattia, PharmD, Genoa-QOL and individual product labels

Brand/ Generic	Indication	Dosage	Intervals	Product Label Comments
Haldol Decanoate (haloperidol decanoate)	Schizophrenia	10-20x oral dose	q month	<ul style="list-style-type: none"> • Product comes in 50mg/mL and 100mg/mL ampules • Maximum dose is 450mg q month • Give as an IM injection using 21G needle - do not administer more than 3mL at one time • See package insert for details on administration
Prolixin Decanoate (fluphenazine decanoate)	Schizophrenia	1.25x oral dose	q 4-6 weeks	<ul style="list-style-type: none"> • Start at 12.5mg and titrate up to 1.25x the oral dose. • Maximum dose is 100mg q 3 weeks • Can administer IM or SQ with a needle \geq 21G needle • See package insert for details on administration
Zyprexa Relprevv (olanzapine)	Schizophrenia	150-405mg	q 2-4 weeks	<ul style="list-style-type: none"> • Doses can include 2 week intervals for the 150mg and 300mg dosage or 4 week intervals for the 300mg and 405mg doses • Given as IM injection with 1.5 inch 19G needs (may use 2 inch needle if obese). • Follow package insert instructions when diluting and administering carefully. See package insert for additional details on administration.

Appendix B:

Consent for Long-Acting Antipsychotic Injections by a Community Pharmacist

I am aware that Dr. XXX, psychiatrist, has entered into a Collaborative Practice Agreement with YYY, community pharmacist, to administer long-acting antipsychotic injections for his/her patients. I understand that each of these health care practitioners are licensed in the state of Connecticut.

The purpose of this Collaborative Practice Agreement is to increase the availability of effective antipsychotic treatments, to improve the control of psychiatric symptoms, and to reduce the risk of re-hospitalization.

Once I have signed this consent form, I understand that Dr. XXX and pharmacist YYY have agreed upon the following procedures:

- 1.
2. Dr. XXX will send an order for services (medication, dose, route, date of first injection, and frequency) to the community pharmacist;
3. The community pharmacist will confirm Dr. XXX's order for services;
4. I will be contacted by a pharmacy staff member 1-2 days before my scheduled appointment as a reminder;
5. YYY community pharmacist is authorized to:
 - a. Obtain appropriate demographic and medical history information from myself and/or from my caregivers and/or Healthcare Power of Attorney.
 - b. Administer injections of approved long-acting antipsychotic medication as ordered by Dr. XXX;
 - c. Confidentially report information about my symptoms and/or side effects to Dr. XXX;
 - d. Provide me with education about my medication.

I understand that it is my choice to receive these services and that I may withdraw my consent at anytime by notifying either the community pharmacist or Dr. XXX. I hereby authorize Dr. XXX to refer me to YYY community pharmacist for long-acting antipsychotic injections and I consent to receive such services.

Patient's name (please print)

Name of Person Authorizing (please print)
(If Applicable)

Patient's signature

Authorizing Person's signature
(If Applicable)

Date

Relationship to Patient
(If Applicable)

START TIME:

END TIME:

Notes on Injection Clinical Encounter (NICE) Form

Patient Name: _____		Date: _____	
Long Acting Injectable Medication/Dose: _____ / _____		Refills: _____	
Injection Details	injection site ___ Rt ___ Lft Delt _____ Glut _____ (Previous site: ___ Rt ___ Lft Delt _____ Glut _____)	Lot# _____ Exp: _____ / _____	
Vital Signs	B/P: _____ Pulse: _____ Respiration: _____	Weight: _____ lbs. Last weight: _____ lbs. Change _____	
Individual Patient Symptoms: Observations & Brief Interview			
Appearance (Observe)	Affect (Observe)	Interaction (Observe)	Sleep & Appetite (Interview)
___ Appropriately dressed ___ Disheveled ___ Good Hygiene ___ Poor Hygiene ___ Relaxed posture ___ Agitated	___ Anxious ___ Pre-occupied ___ Restlessness ___ Blunted/flat affect ___ Suspiciousness ___ Talking to self ___ Normal	___ Makes eye contact ___ Avoids eye contact ___ Initiates conversation ___ Socially withdrawn ___ Engaging conversation ___ One word answers ___ Clear/thoughtful Speech ___ Disorganized/ Fast speech	___ Sleeping well ___ Not sleeping ___ Good appetite ___ Poor appetite
Other: _____ _____			
Comment on Patient's Mood: Describe: _____ _____			
Any New Complaints of Side effects? ___ No ___ Yes			
___ Blurred Vision	___ Tremor	___ Dry Mouth	___ Constipation
___ Stiffness	___ Heartburn	___ Nausea/vomiting	___ Diarrhea
___ Weight gain	___ Weight loss	___ Fatigue	___ Overmedicated
___ Signs of TD Duration/Other: _____ _____			
Any New Habits/Behaviors? ___ Patient denies any new habits/behaviors			
_____ _____			
Clinical Notes ___ Nursing ___ Pharmacist Injection tolerated Yes ___ No ___			
_____ _____			
Needs New Rx? Y N	Next Appt: ___ / ___ / ___	Next Injection needed by: ___ / ___ / ___	Faxed <input type="checkbox"/>
Nurse Signature: _____		OR Pharmacist Signature: _____	

*** NICE Form should be saved in patient's records & faxed to prescriber's office***

Template provided by Connecticut Pharmacy Direct Specialty Solutions; if used outside of the study please contact Sharon Spicer at sspicer@ctpharmacydirect.com