

## Information for prescribers

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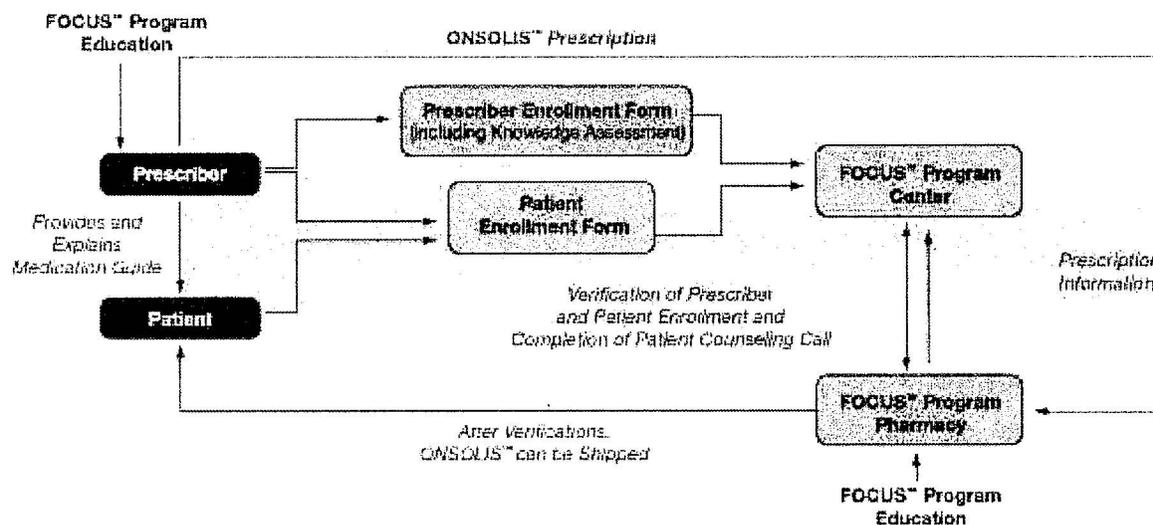
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### Overview of The FOCUS™ Program for ONSOLIS™



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### Overview of The FOCUS™ Program for ONSOLIS™, cont'd

The FOCUS™ Program for ONSOLIS™ is designed to provide facilitated, managed distribution with training and enrollment of all stakeholders involved. The purpose of this program is to mitigate the risk of ONSOLIS™ overdose, abuse, addiction, and serious complications due to medication errors. Every prescriber, patient, wholesaler/distributor, and FOCUS™ Program pharmacy is required to enroll in the program. As a result, any stakeholder involved in prescribing, dispensing, or receiving ONSOLIS™ will have been trained on its safe use conditions. This program may also minimize the risk of drug diversion and fraudulent prescriptions.

The key elements of this program are:

- Enrollment of all healthcare providers who will be prescribing ONSOLIS™;
- Enrollment of all patients prior to being prescribed ONSOLIS™; and
- Creation of a dispensing process that utilizes only enrolled pharmacies to assure safe dispensing of ONSOLIS™.

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### Overview of The FOCUS™ Program for ONSOLIS™, cont'd

#### Prescriber Enrollment

Prescriber education and enrollment process is comprised of the following 3 steps that must be completed prior to prescribing ONSOLIS™:

1. The prescriber reviews the educational materials (Website Educational Materials or Printed Educational Materials).
2. The prescriber completes and signs the Prescriber Enrollment Form (including Prescriber Knowledge Assessment) and faxes it to the FOCUS™ Program.
3. A FOCUS™ Program professional reviews the form, requests any missing or illegible information, and, when the necessary forms have been verified to be accurate and complete (including successful completion of the Prescriber Knowledge Assessment), the prescriber is notified of activation.

Prescribers will be re-educated (complete review of all educational materials) and re-enrolled (including Prescriber Knowledge Assessment) following substantial changes to the program or at least every 2 years.

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### Overview of The FOCUS™ Program for ONSOLIS™, cont'd Patient Enrollment

The patient (or legally authorized representative) counseling and enrollment process is comprised of the following 5 steps that must be completed prior to dispensing the patient's first prescription of ONSOLIS™.

1. The prescriber counsels the patient on the Medication Guide for ONSOLIS™
2. The prescriber and patient complete and sign the Patient Enrollment Form and the prescriber faxes it to the FOCUS™ Program.
3. A FOCUS™ Program professional reviews the form and requests any missing or illegible information.
4. The FOCUS™ Program counseling call to the patient is completed.
5. When the previous steps have been successfully completed, the prescriber and pharmacy are notified of patient activation.

Patients will be re-counseled (complete review of the current Medication Guide for ONSOLIS™) and re-enrolled following substantial changes to the program or at least every 2 years. If an active patient transfers to another active prescriber, the patient and new prescriber must complete a new Patient Enrollment Form.

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### Overview of The FOCUS™ Program for ONSOLIS™, cont'd **Pharmacy Enrollment**

The FOCUS™ Pharmacy education and enrollment process is comprised of the following 3 steps that must be completed prior to receiving ONSOLIS™ inventory for dispensing:

1. The Pharmacist-In-Charge reviews the educational materials (Website Educational Materials or Printed Educational Materials).
2. The Pharmacist-In-Charge completes and signs the Pharmacy Enrollment Form and faxes it to the FOCUS™ Program.
3. A FOCUS™ Program professional reviews the form, requests any missing or illegible information, and, when the form has been verified to be accurate and successfully completed, the pharmacy is notified of activation.

FOCUS™ pharmacies will be re-educated (complete review of all educational materials) and re-enrolled following substantial changes to the program or at least every 2 years.

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### Overview of The FOCUS™ Program for ONSOLIS™, cont'd

#### ***Prescription Processes***

#### ***Process for Initial Prescription***

The first prescription for ONSOLIS™ is processed by the FOCUS™ pharmacy according to the following 2 steps:

1. Prescriber faxes the initial prescription for ONSOLIS™ to the FOCUS™ Program to start the verification process. Prescriber sends the original, hardcopy prescription via a secure, traceable courier to an active FOCUS™ pharmacy. The original, hardcopy prescription must be received by the FOCUS™ pharmacy before dispensing ONSOLIS™.
2. Prior to dispensing, the FOCUS™ pharmacy verifies (via receipt of a unique FOCUS™ Program database authorization number) the following:
  - a. Prescriber is active in the FOCUS™ Program,
  - b. Patient is active in the FOCUS™ Program through the current prescriber, and
  - c. Patient has successfully completed a FOCUS™ Program counseling call to review the safe use conditions and to ensure that their prescriber has performed the following steps prior to dispensing ONSOLIS™:

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- i. counseled the patient (or legally authorized representative) that they must be regularly using another opioid pain medicine for their constant pain and their body must be used to this medicine (opioid tolerant),
- ii. counseled the patient (or legally authorized representative) on appropriate product use and contraindications, and
- iii. provided a Medication Guide for ONSOLIS™ to the patient (or legally authorized representative) and reviewed it with them.

Once all of the above conditions are met, ONSOLIS™ can be dispensed by a FOCUS™ pharmacy via a secure, traceable courier (with proof of delivery and adult signature required) to an address specified by the patient.

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### Overview of The FOCUS™ Program for ONSOLIS™, cont'd

#### ***Process for Subsequent Prescriptions***

Subsequent prescriptions for ONSOLIS™ by the same prescriber for the same patient are processed according to the following 2 steps:

1. Prescriber sends the original, hardcopy prescription for ONSOLIS™ via a secure, traceable courier to an active FOCUS™ pharmacy. The original, hardcopy prescription must be received by the FOCUS™ pharmacy before dispensing ONSOLIS™.
2. Prior to dispensing, the FOCUS™ pharmacy verifies (via receipt of a unique FOCUS™ Program database authorization number) the following:
  - a. Prescriber is active in the FOCUS™ Program,
  - b. Patient is active in the FOCUS™ Program through the current prescriber, and
  - c. Patient has previously received a prescription for ONSOLIS™ and successfully completed a FOCUS™ Program counseling call.

Once all of the above conditions are met, ONSOLIS™ can be dispensed by a FOCUS™ pharmacy via a secure, traceable courier (with proof of delivery and adult signature required) to an address specified by the patient.

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