IONSYS REMS Program

Risk Evaluation and Mitigation Strategy

Website Mockups
V8.0
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1. Footer

Footer is included on every web page. To reduce the length of the document, the screenshot is included once.
## 2. Home Page

IONSYS is a fentanyl iontophoretic transdermal system (fentanyl iontophoretic transdermal system) used in hospital settings. It is designed to manage the risks associated with the use of fentanyl in hospitals.

### Safe Use of IONSYS
- Hospitals must be certified in the IONSYS REMS Program to order, dispense, and administer IONSYS.
- IONSYS should only be used by patients in a hospital setting, must be discontinued prior to the patient leaving the hospital, and cannot be dispensed for use outside the hospital.
- Nurses and pharmacists must review key risk messages with patients using the IONSYS Medication Guide (included with each IONSYS).
  - Only the patient should administer doses from IONSYS.
  - The IONSYS hydrogel should not come into contact with the patient's fingers or mouth. Ingestion or contact with mucous membranes could lead to absorption of a potentially fatal dose of fentanyl.
  - Patients should immediately inform their nurse or pharmacist if IONSYS falls off or it starts keeping.
  - Patients should never leave the hospital with IONSYS.
  - Healthcare providers and those for whom IONSYS is not prescribed should avoid contact with the hydrogel.
  - Accidental exposure to an intact IONSYS or to the hydrogel component, especially by children, through contact with skin or contact with mucous membranes, can result in a fatal overdose of fentanyl.

### What is IONSYS?
IONSYS is an opioid analgesic that should only be used for the short-term management of acute postoperative pain severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate. IONSYS is a patient-controlled analgesia product that enables surgical patients to push a button to dispense fentanyl transdermally as needed for pain. Only the patient may activate IONSYS. Hospital pharmacies will not dispense IONSYS for outpatient use.

### Resources for Healthcare Providers
- IONSYS REMS Hospital Enrolment Form
- IONSYS REMS Safety Brochures: Guide for Nurses and Pharmacists
- IONSYS REMS Knowledge Assessment
- Dear Healthcare Provider Letter: Department Head: Surgery
- Dear Healthcare Provider Letter: Department Head: Anesthesia
- Dear Healthcare Provider Letter: Department Head: Nursing
- Dear Healthcare Provider Letter: Department Head: Obstetrics and Gynecology
- Dear Healthcare Provider Letter: Department Head: Orthopedics
- Dear Hospital Pharmacy Letter
- IONSYS Instructions for Use and Disposal
- Prescribing Information

### Resources for Patients
- IONSYS Medication Guide
3. **Home Page – Signed-In**

![IONSYS Risk Evaluation and Mitigation Strategy (REMS) Program](image)

**Safe Use of IONSYS**

- Hospitals must be certified in the IONSYS REMS Program to order, dispense, and administer IONSYS.
- IONSYS should only be used by patients in a hospital setting, must be discontinued prior to the patient leaving the hospital, and cannot be dispensed for use outside the hospital.
- Nurses and pharmacists must review key risk messages with patients using the IONSYS Medication Guide (included with each IONSYS):
  - Only the patient should administer doses from IONSYS.
  - The IONSYS hydrogel should not come into contact with the patient's fingers or mouth. Ingestion or contact with mucous membranes could lead to absorption of a potentially fatal dose of fentanyl.
  - Patients should immediately inform their nurse or pharmacist if IONSYS falls off or it starts leaking.
  - Patients should never leave the hospital with IONSYS.
- Healthcare providers and those for whom IONSYS is not prescribed should avoid contact with the hydrogel.
- Accidental exposure to an intact IONSYS or to the hydrogel component, especially by children, through contact with skin or contact with mucous membranes, can result in a fatal overdose of fentanyl.

**What is IONSYS?**

IONSYS is an opioid analgesic that should only be used for the short-term management of acute postoperative pain severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate. IONSYS is a patient-controlled analgesia product that enables surgical patients to push a button to dispense fentanyl transdermally, as needed for pain. Only the patient may activate IONSYS. Hospital pharmacies will not dispense IONSYS for outpatient use.

**Resources for Healthcare Providers**

- IONSYS REMS Hospital Enrollment Form
- IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists
- IONSYS REMS Knowledge Assessment
- Dear Healthcare Provider Letter - Department Head: Surgery
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- Dear Healthcare Provider Letter - Department Head: Orthopedics
- Dear Hospital Pharmacy Letter
- IONSYS Instructions for Use and Disposal
- Prescribing Information

**Resources for Patients**

- IONSYS Medication Guide
4. Patient Information

IONSYS Medication Guide

What is IONSYS?

IONSYS is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage acute postoperative pain, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed you are at risk for opioid addiction, abuse, and misuse that can lead to death.
- A patient-controlled medicine system that sticks to the skin. It will be applied by your healthcare provider on your upper outer arm or chest.

Please click on this link to see the IONSYS Medication Guide describing how to use IONSYS and important risk messages.

For additional information about the IONSYS REMS Program, please call 877-488-6835.
5. Hospital Certification

Hospital Certification

Steps for Hospital Certification

All hospitals must be certified in the IONSYS REMS Program in order to dispense and administer IONSYS. Certification requires the identification of an Authorized Representative for the hospital to complete the certification process.

- Hospitals will be notified that they have been certified in the IONSYS REMS Program.
- Hospitals must put processes and procedures in place to ensure that IONSYS is not dispensed for use outside of a certified hospital.
- The manufacturer will notify every year that the Authorized Representative is the current designated Authorized Representative.

Certification in the IONSYS REMS Program includes the following steps:

Designate

- Review the IONSYS REMS Program information and gather information on the hospital.
- Successfully complete the IONSYS REMS Hospital Certification Assessment. The certification must be renewed every three (3) years.

Examine

- Distribute Dear Healthcare Provider Letters along with IONSYS REMS Program education materials to the following hospital departments: Nursing, Anesthesia, Pain Management, Oncology, Gynecology, Orthopedics, and Pharmacy.
- Train all staff who dispense or administer IONSYS (nurses and pharmacists) and ensure they complete the IONSYS REMS Knowledge Assessment.

Assess

- Maintain the list of the healthcare providers trained in the IONSYS REMS Program.

Certification

If you have been designated as your hospital’s Authorized Representative, please use the Start Certification button to start your certification today. You can also download the print version of the education resources and fax or mail your IONSYS REMS Hospital Certification Form and IONSYS REMS Knowledge Assessment to the IONSYS REMS Program at fax number 877-488-5621 or mail to IONSYS REMS Program PO Box 29242, Phoenix, AZ 85036-9240.

Start Certification
6. Hospital Certification – Signed-In

Hospital Certification

Steps for Hospital Certification

All hospitals must be certified in the IONSYS REMS Program in order to dispense and administer IONSYS. Certification requires the identification of an Authorized Representative for the hospital to complete the certification process.

- Hospitals will be notified that they have been certified in the IONSYS REMS Program.
- Hospitals must put processes and procedures in place to ensure that IONSYS is not dispensed for use outside of a certified hospital.
- The Medicines Company will verify every year that the Authorized Representative is the current designated Authorized Representative.

Certification in the IONSYS REMS Program includes the following steps:

- Designate an Authorized Representative for the hospital
- Review the IONSYS REMS Program
- Assess
- Educate
- Attent
- Distribute
- Train
- Maintain

- Complete the IONSYS REMS Program Assessment Form
- The certification must be renewed every three (3) years
- Distribute Dear Healthcare Provider Letters along with the following hospital department heads:
  - Surgery
  - Anesthesia
  - Nursing
  - Obstetrics
  - Ophthalmology
  - Pharmacy
- Train all staff who dispense or administer IONSYS (nurses and pharmacists) and ensure they complete the IONSYS REMS Program Assessment
- Maintain the list of the healthcare providers trained in the IONSYS REMS Program

Education Resources

- IONSYS REMS Hospital Enrollment Form
- IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists
- IONSYS REMS Knowledge Assessment
- Dear Healthcare Provider Letter - Department Head: Surgery
- Dear Healthcare Provider Letter - Department Head: Anesthesia
- Dear Healthcare Provider Letter - Department Head: Nursing
- Dear Healthcare Provider Letter - Department Head: Obstetrics/Gynecology
- Dear Healthcare Provider Letter - Department Head: Orthopedics
- Dear Hospital Pharmacy Letter
- IONSYS Instructions for Use and Disposal
- IONSYS Medication Guide
- Prescribing Information
7. **Nurses and Pharmacists – Not Signed-In**

What are the Roles of Nurses and Pharmacists in the Safe Use of IONSYS?

Hospital nurses play a critical role in ensuring the safe use of IONSYS. Before administering IONSYS, all nurses must be trained on its safe use, including its assembly, application, troubleshooting, and safe removal/disposal of IONSYS before each patient leaves the hospital. This also includes understanding that IONSYS can only be used in a hospital setting. Nurses should also be involved in educating the patient on how to use IONSYS in a safe manner, responding to alerts/notifications and alarms, ensuring proper adhesion of IONSYS, monitoring analgesic use from the digital display on the controller screen, and discontinuing/disposing IONSYS after patient use.

Pharmacists must also be trained since they will play an important role in the safe use of IONSYS. Pharmacists may be asked to take the lead in developing and implementing the processes and procedures necessary for their hospital to become certified by the IONSYS REMS Program. They may also be asked to assist in training other hospital staff in the safe use of IONSYS. Additionally, they could serve as a resource when IONSYS is implemented hospital-wide. Finally, pharmacists will order IONSYS from wholesalers, dispense them to the appropriate controlled storage locations on hospital floors, help with troubleshooting, and ensure that patients do not receive IONSYS as a medication when they leave the hospital.

Nurses and pharmacists must review this information and complete an IONSYS REMS Knowledge Assessment prior to dispensing or administering IONSYS for patient use. Hospitals will also be required to keep a record of all nurses and pharmacists who complete the Knowledge Assessment.

To complete the education and take the IONSYS REMS Knowledge Assessment, the following steps should be followed:

<table>
<thead>
<tr>
<th>Educate</th>
<th>Assess</th>
<th>Maintain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review the following IONSYS REMS Program education resources:</td>
<td>Successfully complete the IONSYS REMS Knowledge Assessment</td>
<td>Provide the Knowledge Assessment confirmation code (if completed online) or the completed Knowledge Assessment form to the Authorized Representative of your hospital for the training record.</td>
</tr>
<tr>
<td>IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists</td>
<td>IONSYS REMS Instructions for Use and Disposal</td>
<td>Prescribing Information</td>
</tr>
<tr>
<td>IONSYS REMS Medication Guide</td>
<td>Prescribing Information</td>
<td></td>
</tr>
</tbody>
</table>

Hospitals can choose whether nurses or pharmacists complete training online or on paper.

Please use the Start button to create an account, complete the education, and submit the IONSYS REMS Knowledge Assessment online. Once you have successfully completed your Knowledge Assessment, please provide the completed Knowledge Assessment confirmation code to your Authorized Representative of your Hospital for the training record.

Start
8. Nurses and Pharmacists – Signed-In

What are the Roles of Nurses and Pharmacists in the Safe Use of IONSYS?

Hospital nurses play a critical role in ensuring the safe use of IONSYS. Before administering IONSYS, all nurses must be trained on its safe use, including its assembly, application, troubleshooting, and safe removal/disposal of IONSYS before each patient leaves the hospital. This also includes understanding that IONSYS can only be used in a hospital setting. Nurses should also be involved in educating the patient on how to use IONSYS in a safe manner, responding to alerts/notifications and alarms, ensuring proper adhesion of IONSYS, monitoring analgesic use from the digital display on the controller screen, and discontinuing/disposing IONSYS after patient use.

Pharmacists must also be trained since they will play an important role in the safe use of IONSYS. Pharmacists may be asked to take the lead in developing and implementing the processes and procedures necessary for their hospital to become certified by the IONSYS REMS Program. They may also be asked to assist in training other hospital staff in the safe use of IONSYS. Additionally, they could serve as a resource when IONSYS is implemented hospital-wide. Finally, pharmacists will order IONSYS from wholesalers, dispense them to the appropriate controlled storage locations on hospital floors, help with troubleshooting, and ensure that patients do not receive IONSYS as a medication when they leave the hospital.

Nurses and pharmacists must review this information and complete an IONSYS REMS Knowledge Assessment prior to dispensing or administering IONSYS for patient use. Hospitals will also be required to keep a record of all nurses and pharmacists who complete the Knowledge Assessment.

To complete the education and take the IONSYS REMS Knowledge Assessment, the following steps should be followed:

<table>
<thead>
<tr>
<th>Educate</th>
<th>Assess</th>
<th>Maintain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Review the following IONSYS REMS Program education resources: IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists, IONSYS Instructions for Use and Disposal, IONSYS Medication Guide, Prescribing Information</td>
<td>Successfully complete the IONSYS REMS Knowledge Assessment</td>
<td>Provide the Knowledge Assessment confirmation code (if completed online) or the completed Knowledge Assessment (if completed on paper) to the Authorized Representative of your hospital for the training record.</td>
</tr>
</tbody>
</table>
9. Create an Account

Create an Account

To create your web account for the IONSYS REMS Program, please complete the fields below. The Username you specify must be unique within the IONSYS REMS Program website. All fields below are required unless otherwise indicated.

First Name
Last Name
Email Address
Certification ID
Username
Password
Confirm Password

(If you were certified via fax, please enter your Certification ID)

Username
Check Username Availability
Use Email Address as Username

Submit
Cancel
10. Stakeholder Identification Page

Stakeholder Identification

Please select one of the following stakeholder types to ensure you are directed to the process that is appropriate to your role:

- **Hospital Authorized Representative** - The designated individual responsible for certifying their Hospital in the IONSYS REMS Program. This individual is responsible to attest to the program requirements and to oversee implementation and compliance with the IONSYS REMS Program. Hospital Authorized Representatives must be trained on the IONSYS REMS Program requirements and complete the **IONSYS REMS Program Knowledge Assessment** prior to attesting to the program requirements.

- **Nurses and Pharmacists** - Pharmacy and Nursing staff involved in dispensing or administering IONSYS must be trained on the IONSYS REMS Program requirements as described in the **IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists** (to which the **IONSYS Instructions for Use and Disposal** and the **IONSYS Medication Guide** are attached) and must complete and submit the **IONSYS REMS Program Knowledge Assessment** to the Authorized Representative of their hospital prior to dispensing or administering IONSYS for patient use.

Next
11. Hospital Intake

Hospital Intake

To certify your hospital in the IONSYS REMS Program, please complete the form below and submit. Once certified, you will receive a certification confirmation via your preferred method of communication. All fields below are required unless otherwise indicated.

Authorized Representative Intake

- First Name
- Last Name
- Title
- State License Number
- State License Type
- Phone
- Ext
- Fax
- Email Address
- Preferred Method of Communication: Email, Fax

Hospital Intake

- Hospital Name
- Hospital Address
- Hospital Address 2
- Hospital City
- Hospital State
- Hospital Zip
- State Hospital License Number
- State
- Hospital DEA Number
- DEA License Expiration
12. Nurses and Pharmacists Intake

Please complete the form below and submit. Once you have completed the Knowledge Assessment, you will receive a confirmation via your contact preference. All fields below are required unless otherwise indicated.
13. Hospital Lookup for Nurses and Pharmacists

Hospital Lookup for Nurses and Pharmacists
Please use the search function below to find the hospital in which you are affiliated. Linking to your affiliated hospital will allow your Authorized Representative to track the completion of your training and Knowledge Assessment.

[Search form with fields for Zip Code, City, State, and Search button]
14. Hospital Lookup for Nurses and Pharmacists with Search Result

Hospital Lookup for Nurses and Pharmacists

Please use the search function below to find the hospital in which you are affiliated. Linking to your affiliated hospital will allow your Authorized Representative to track the completion of your training and Knowledge Assessment.

[Input fields for Zip Code, City, State, Search button]

Table:

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>City</th>
<th>State</th>
<th>Zip Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>Floyd Valley Hospital</td>
<td>690 Main Street</td>
<td>New York</td>
<td>NY</td>
<td>10201</td>
</tr>
<tr>
<td>Health &amp; Hospita Corp of Marion Co</td>
<td>10 Park Avenue</td>
<td>New York</td>
<td>NY</td>
<td>10201</td>
</tr>
</tbody>
</table>

[Option to show 10 entries]

[Checkbox for I cannot find my hospital location]

[Next button]
15. Education Landing Page for Hospital

To review the tools for healthcare provider training and patient education for IONSYS please use the Start button when you are ready to begin.

Education Resources Overview

The following IONSYS REMS tools will be included within this online healthcare provider training:

- IONSYS REMS Safety Brochure; Guide for Nurses and Pharmacists
- IONSYS instructions for Use and Disposal

Click on the links below to review the following documents prior to starting the Knowledge Assessment:

- IONSYS Medication Guide
- Prescribing Information

Start

For additional information about the IONSYS REMS Program, please call 877-488-6835.
16. Education Landing Page for Nurses and Pharmacists

Education Resources Overview

The following IONSYS REMS tools will be included within this online healthcare provider training:

- IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists
- IONSYS instructions for Use and Disposal

Click on the links below to review the following documents prior to starting the Knowledge Assessment:

- IONSYS Medication Guide
- Prescribing Information

To review the tools for healthcare provider training and patient education for IONSYS please use the Start button when you are ready to begin.

17. Header of the Education Page and Knowledge Assessment for Hospital

- If Hospital Authorized Representative is taking the Education Program and Knowledge Assessment the **Hospital Certification** tab will be highlighted as shown below.

18. Header of the Education Page and Knowledge Assessment for Nurses and Pharmacists

- If Nurses and Pharmacists are taking the Education Program and Knowledge Assessment the **Healthcare Providers** tab will be highlighted as shown below.
Note: For the purpose of the mockup document, the header for Education page and Knowledge Assessment will display with Hospital Certification tab.

19. Education Page 1

IONSYS® REMS Safety Brochure: Guide For Nurses and Pharmacists

This guide is for pharmacists and nurses who dispense and/or administer IONSYS® (fentanyl iontophoretic transdermal system) for patient use. It includes information about the very important risk messages associated with the IONSYS Risk Evaluation and Mitigation Strategy (REMS) required by the Food and Drug Administration (FDA).

What is IONSYS?
IONSYS is an opioid analgesic that should only be used for the short-term management of acute postoperative pain severe enough to require an opioid analgesic in the hospital and for which alternative treatments are inadequate. IONSYS is a patient-controlled analgesia product that enables surgical patients to push a button to dispense fentanyl transdermally as needed for pain. Only the patient may activate IONSYS. Hospital pharmacies will not dispense IONSYS for outpatient use.

What is a REMS?
A Risk Evaluation and Mitigation Strategy (REMS) is a strategy to manage known or potential serious risks associated with a drug and is required by the US Food and Drug Administration (FDA) to ensure that the benefits of the drug outweigh its risks. Treatment with fentanyl, the active component of IONSYS, may result in potentially life-threatening respiratory depression and death. The Medicine Company has worked with the FDA to develop the IONSYS REMS to prevent such respiratory depression resulting from accidental exposure to persons for whom it is not prescribed.

Educating nurses, pharmacists, and other healthcare providers about the risk of respiratory depression resulting from accidental exposure associated with IONSYS and ways this risk can be mitigated is an important part of this REMS. The IONSYS REMS also requires that hospitals be certified in the IONSYS REMS Program in order to dispense IONSYS.
20. Education Page 2

IONSYS® REMS Safety Brochure: Guide For Nurses and Pharmacists (continued)

What Are The Roles Of Nurses And Pharmacists In The Safe Use Of IONSYS?

Hospital nurses play a critical role in ensuring the safe use of IONSYS. Before administering IONSYS, all nurses must be trained on its safe use, including its assembly, application, trouble shooting, and safe removal/disposal of IONSYS before each patient leaves the hospital. This also includes understanding that IONSYS can only be used in a hospital setting. Nurses should also be involved in educating the patient on how to use IONSYS in a safe manner, responding to alerts/notifications and alarms, ensuring proper adhesion of IONSYS, monitoring anesthetic use from the digital display on the controller screen, and discontinuing/disposing IONSYS after patient use.

Pharmacists must also be trained since they will play an important role in the safe use of IONSYS. Pharmacists may be asked to take the lead in developing and implementing the processes and procedures necessary for their hospital to become certified by the IONSYS REMS Program. They may also be asked to assist in training other hospital staff in the safe use of IONSYS. Additionally, they could serve as a resource when IONSYS is implemented hospital-wide. Finally, pharmacists will order IONSYS from wholesalers, dispense them to the appropriate controlled storage locations on hospital floors, help with troubleshooting, and ensure that patients do not receive IONSYS as a medication when they leave the hospital.

Nurses and pharmacists must review this information and complete an IONSYS REMS Knowledge Assessment prior to dispensing or administering IONSYS for patient use. Hospitals will also be required to keep a record of all nurses and pharmacists who complete the knowledge assessment.
21. Education Page 3

IONSYS® REMS Safety Brochure: Guide For Nurses and Pharmacists (continued)

How Can IONSYS Be Used Safely?

- Hospitals must be certified in the IONSYS REMS Program to order, dispense, and administer IONSYS.
- IONSYS should only be used by patients in a hospital setting; must be discontinued prior to the patient leaving the hospital, and cannot be dispensed for use outside the hospital.
- Nurses and pharmacists must review key risk messages with patients using the IONSYS Medication Guide (included with each IONSYS).
  - Only the patient should administer doses from IONSYS.
  - The IONSYS hydrogels should not come into contact with the patient’s fingers or mouth. Ingestion or contact with mucous membranes could lead to absorption of a potentially fatal dose of fentanyl.
  - Patients should immediately inform their nurse or pharmacist if IONSYS falls off or it starts beeping.
  - Healthcare providers and those for whom IONSYS is not prescribed should avoid contact with the hydrogel.
- Accidental exposure to an intact IONSYS or to the hydrogel component, especially by children, through contact with skin or contact with mucous membranes, can result in a fatal overdose of fentanyl.
IONSYS® REMS Safety Brochure: Guide For Nurses and Pharmacists (continued)

Healthcare Provider Education And Training

It is important that healthcare providers within certified hospitals are aware of the risks associated with IONSYS® and that they are properly trained on the assembly and appropriate use of IONSYS®. It is also important to teach patients how to operate IONSYS® to self-administer doses of fentanyl as needed to manage their acute, short-term, postoperative pain. Tools for healthcare provider training and patient training include:

IONSYS REMS Materials


IONSYS® REMS Hospital Enrolment Form: IONSYS® can only be prescribed, dispensed, and administered in hospitals which are certified in the IONSYS® REMS Program. Among other requirements, the hospital Authorized Representative must ensure the institution has documented processes in place to ensure that IONSYS® is not dispensed for use outside of the certified hospital.

IONSYS® REMS Knowledge Assessment: This document tests healthcare providers’ knowledge of the appropriate assembly and use of IONSYS®, including important risk messages associated with the safe use of IONSYS®.

IONSYS® REMS Website: This guide, other educational materials, letters, the IONSYS® REMS Hospital Enrolment Form, and other important safety information are available on the IONSYS® REMS Website [www.IONSYSREMS.com](http://www.IONSYSREMS.com).

[Back] [Next]
23. Education Page 5

IONSYS® REMS Safety Brochure: Guide For Nurses and Pharmacists (continued)

Other IONSYS Materials

IONSYS Instructions for Use and Disposal (IFUD): This is a helpful guide that explains how to safely use and dispose of IONSYS. It also includes a section on how to troubleshoot any problems with IONSYS. This IFUD is included with each IONSYS and on the IONSYS REMS website.

IONSYS Guide for Patients: A quick reference guide for patients with patient-friendly text describing how to use IONSYS and important risk messages to review with patients to promote the safe use of IONSYS. This guide is included with each IONSYS and on the IONSYS REMS website.

Prescribing Information: This document provides the prescribing information for IONSYS (fentanyl iontophoretic transdermal system), which includes instructions for use and disposal. (It also includes the IONSYS Medication Guide as an attachment).

Adverse Event Reporting

- Healthcare providers should report all suspected adverse reactions associated with the use of IONSYS. Please contact The Medicines Company via the IONSYS REMS Program toll-free at 1-877-406-6835 or the FDA at 1-800-FDA-1088 or at http://www.fda.gov/medwatch.

Contact Information For The IONSYS REMS Program


For additional information about the IONSYS REMS Program, please call 877-488-6835.
24. Education Page 6

Instructions for Use and Disposal

IONSYS®

Fentanyl iontophoretic transdermal system, 40 mcg/activation

For single use only. Up to 24 hours or 60 doses, whichever comes first.

Refer to the Prescribing Information (PI) and the following educational materials for more information about IONSYS:

- IONSYS Medication Guide
- IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists

[Diagram of IONSYS drug unit and controller with label: "Drug Unit", "Controller", "Light", "Dosing Button", "Digital Display", "Barcode"]
25. Education Page 7

Instructions for Use and Disposal (continued)

1. Prepare Patient Site

⚠️ ONLY 1 IONSYS system should be applied at any given time.

a. Choose healthy, unbroken skin on the upper outer arm or chest ONLY
   (see Figure 1a).

b. Clip excessive hair if necessary. Do not shave—this irritates skin.

c. Clean with alcohol and let dry. Do not use soaps, lotions, or other agents.

d. When replacing an IONSYS system, the new system must be applied to a
   different site on the upper outer arm or chest.
26. Education Page 8

Instructions for Use and Disposal (continued)

2. Assemble IONSYS

- Always wear gloves when handling IONSYS.
- Complete this step before applying IONSYS to patient.
  a. Peel back tray lid (see Figure 2a). Remove foil pouch and the controller.
  b. Remove drug unit from foil pouch and place on a hard, flat surface
     (see Figure 2b).

Continued on next panel.
27. Education Page 9

Instructions for Use and Disposal (continued)

2. Assemble IONSYS (cont.)
   a. Align the matching shapes (see Figure 2c).
   b. Press on both ends of the device to ensure that snaps at both ends are fully engaged (see Figure 2d).
   c. Wait for system to complete self-test and the digital display to read "0" (see Figure 2e).

3. Train Patient on Proper Use of IONSYS
   A. Refer to the IONSYS Medication Guide to counsel your patient on the safe use of IONSYS.
Instructions for Use and Disposal (continued)

4. Apply IONSYS to Patient:
   - Always wear gloves when handling IONSYS.
   a. Peel off clear liner and apply IONSYS to the prepared site (see Figure 4a).
   b. Press and hold IONSYS onto patient for 15 seconds by pressing the edges
      with fingers (see Figure 4b). Do not press dosing button.
   c. If IONSYS is not securely adhered, see IONSYS Troubleshooting — Poor
      skin contact.

   NOTE: Ensure proper display orientation by reading "Doses Delivered" printed
   below the digital display.
Instructions for Use and Disposal (continued)

5. Verify Proper Use of IONSYS

- Remember that ONLY the patient should press the dosing button.
- Remove before MRI or radiographic procedures as medically necessary.
  - Patient will initiate a dose by pressing and releasing the button twice in 3 seconds
  - Each dose will be delivered over 10 minutes. During this time IONSYS is
    locked-out and will not respond to additional button presses
  - During the 10 minutes the light will blink green at a fast rate and the display will
    alternate between a walking circle and the number of doses delivered
    (see Figure 5)
6. Remove IONSYS from Patient and Dispose

- Follow your institution's procedures for handling narcotics or refer to the PI for more information.
- Always wear gloves when handling IONSYS.
- **Important**: If drug gel contacts your skin, thoroughly rinse area with water. **Do not use soap.**
  
  a. With gloves on, remove IONSYS from the patient (see Figure 6a).
  b. Pull the red tab to separate the red housing containing the drug (see Figure 6b).
  c. Fold the red housing in half and dispose per your institution's procedures or flush down the toilet (see Figure 6c).
  d. Hold down dosing button until display goes blank and dispose in waste designated for batteries.
31. Education Page 13

Instructions for Use and Disposal (continued)

IONSYS Troubleshooting

After successful assembly or anytime during use:

If you see or hear this:

- Blinking red for 15 seconds
- Beeping for 15 seconds
- Steady number
- IONSYS is not securely adhered
- Tape air is long edges

...then do this:

**Poor Skin Contact**

a. If IONSYS appears to be loose or lifting from skin, secure it to patient’s skin by pressing the edges with fingers or securing with nonallergenic tape.
b. If using tape, apply it along the long edges to secure IONSYS to patient’s skin.

**Do not cover the button or display.**
c. After tapping, if IONSYS beeps again, remove and dispose. Place a new IONSYS on a different skin site.
d. **Do not tap if evidence of blistered or broken skin.**

**No light**

- No beeps
- Blank display

**Low Battery or Defective System**

a. **Do not use the system.**
b. Dispose of IONSYS per instructions in section 6.
c. Place a new IONSYS on a different skin site.

**Blinking red**

- Beeping continuously
- Steady number

**System Error**

a. Remove from patient.
b. Hold down dosing button until beeping stops and display goes blank.
c. Dispose of IONSYS per instructions in section 6.
d. Place a new IONSYS on a different skin site.

**No light**

- No beeps
- Blinking number

**End-of-Use (80 doses or 24 hours)**

a. Remove from patient.
b. Hold down dosing button until display goes blank.
c. Dispose of IONSYS per instructions in section 6.
d. Place a new IONSYS on a different skin site.
32. Knowledge Assessment Landing Page

You are now going to review questions that will test your knowledge of the appropriate use of IONSYS® (fentanyl iontophoretic transdermal system) - including important risk messages associated with its safe use. To be certified in the IONSYS REMS Program you will need to answer ALL questions correctly. Please select the best option for each question.

You will have a maximum of six attempts to pass the assessment. After three unsuccessful attempts, the education resources are required to be reviewed again before relatching the Knowledge Assessment.

33. Knowledge Assessment #1

The IONSYS Risk Evaluation and Mitigation Strategy (REMS) is required by the Food and Drug Administration (FDA) to:

- A. Prevent respiratory depression resulting from accidental exposure to persons for whom it is not prescribed
- B. Educate healthcare providers about the risk of respiratory depression associated with IONSYS
- C. Ensure that IONSYS is dispensed and administered only within hospitals
- D. All of the above
34. **Knowledge Assessment #2**

Knowledge Assessment

**Question 2**

It is important that only healthcare providers are educated about the safe use of IONSYS.

- A. True
- B. False

Next

35. **Knowledge Assessment #3**

Knowledge Assessment

**Question 3**

IONSYS may be sent home with the patient upon leaving the hospital.

- A. True
- B. False

Next
36. Knowledge Assessment #4

**Knowledge Assessment**

**Question 4**

Healthcare providers (nurses and pharmacists) should avoid contact with the IONSYS hydrogel (i.e., wear gloves) when:

- [ ] A. Applying IONSYS
- [ ] B. Monitoring Patient Use of IONSYS
- [ ] C. Removing IONSYS
- [ ] D. Disposing of IONSYS
- [ ] E. All of the above

[Next]

37. Knowledge Assessment #5

**Knowledge Assessment**

**Question 5**

The IONSYS Medication Guide contains important information for the patient. Which one of the following statements is accurate?

- [ ] A. The IONSYS REMS Program will provide this guide to patients by mail after a patient has left from the hospital
- [ ] B. This guide only needs to be reviewed with the patient's caregiver before initiating treatment with IONSYS, because the patient may not be able to understand the instructions for use
- [ ] C. This guide should be reviewed with patients and caregivers before initiating treatment with IONSYS
- [ ] D. The IONSYS Medication Guide can only be obtained from hospital pharmacies

[Next]
38. Knowledge Assessment #6

Knowledge Assessment

Question 6
There is a risk of fatal overdose with inappropriate use or handling of IONSYS. Which of the following answers is most accurate?

- A. IONSYS can be fatal if misused by children
- B. IONSYS can be fatal if used by anyone for whom it is not prescribed
- C. IONSYS can be fatal if the hydrogels are ingested or if they come into contact with a healthcare provider’s or patient’s mucous membranes
- D. All of the above

Next

39. Knowledge Assessment #7

Knowledge Assessment

Question 7
Which of the following statements is accurate regarding safe disposal of IONSYS?

- A. IONSYS units should be removed using gloves - assuring both hydrogels remain with the unit
- B. The bottom housing containing the gels should be separated from the electronics (top housing) by pulling the red tab, and the bottom should be folded in half with the sticky side facing in. It should be disposed of flushing down the toilet or following institutional procedures
- C. Disposal of IONSYS should comply with hospital operating policies and procedures
- D. All of the above

Next
40. Knowledge Assessment #8

Knowledge Assessment

Question 8

Which of the following factors increases the risk of overdose of fentanyl from IONSYS?

- A. Instructing someone other than the patient to administer doses from IONSYS
- B. The patient must press the dose button twice within 3 seconds to administer a dose from IONSYS
- C. Applying only one IONSYS to a patient at any time
- D. IONSYS should only be applied to patients who can understand how to use IONSYS without help

Next

41. Knowledge Assessment #9

Knowledge Assessment

Question 9

What action is most likely to prevent IONSYS from being used outside of the hospital?

- A. Having inadequate record keeping of IONSYS dispensing
- B. Removing IONSYS from the patient prior to leaving the hospital
- C. Having inadequate hospital procedures for IONSYS disposal
- D. Applying IONSYS to the upper, outer arm, or chest

Submit
42. Knowledge Assessment – Success Page for Hospital

Knowledge Assessment Results

✅ Congratulations! You have now completed the assessment.

You answered all the questions correctly and have passed the assessment. Please press the Next button to complete your hospital's certification in the IONSYS REMS Program.

Knowledge Assessment Code: 1425-F545-S89P

QUESTION 1
The IONSYS Risk Evaluation and Mitigation Strategy (REMS) is required by the Food and Drug Administration (FDA) to:

✅ D. All of the above

QUESTION 2
It is important that only healthcare providers are educated about the safe use of IONSYS.

✅ B. False

QUESTION 3
IONSYS may be sent home with the patient upon leaving the hospital.

✅ B. False
43. Knowledge Assessment – Success Page for Nurses and Pharmacists

Knowledge Assessment Results

✓ Congratulations! You have now completed the assessment.

You answered all the questions correctly and have passed the assessment. Below is your IONSYS REMS Program Knowledge Assessment Code. You will also receive an email confirmation (if primary method of contact).

If you affiliated with a certified hospital, your successful completion of the training and Knowledge Assessment will be automatically uploaded to your Hospital Authorized Representative’s online dashboard along with them receiving confirmation by email (if applicable).

Knowledge Assessment Code: 1546-H454-P545

Question 1
The IONSYS Risk Evaluation and Mitigation Strategy (REMS) is required by the Food and Drug Administration (FDA) to:

✓ D. All of the above

Question 2
It is important that only healthcare providers are educated about the safe use of IONSYS.

✓ B. False

Question 3
IONSYS may be sent home with the patient upon leaving the hospital.

For additional information about the IONSYS REMS Program, please call 877-488-6835.
44. Knowledge Assessment – Failed Attempt Page

Note: For the purpose of the mockup document the header will display with Hospital Certification tab; however, depending on the stakeholder type the appropriate tab will be highlighted.

Knowledge Assessment Results

We’re sorry, you did not pass the Knowledge Assessment.

Below is a summary of your response. After three failed attempts, you must review the IONSYS REMS education resources before retaking the assessment. You have a maximum of six attempts to pass the assessment. Please use the Retake Assessment button below to correct your answers. Alternatively, you may revisit the IONSYS REMS education resources then take the assessment again.

**QUESTION 1**

The IONSYS Risk Evaluation and Mitigation Strategy (REMS) is required by the Food and Drug Administration (FDA) to:

- ✔ D. All of the above

**QUESTION 2**

It is important that only healthcare providers are educated about the safe use of IONSYS.

- ✗ B. True

**QUESTION 3**

IONSYS may be sent home with the patient upon leaving the hospital.

- ✔ B. False
45. Knowledge Assessment – Failed 3rd Attempts

Note: For the purpose of the mockup document the header will display with Hospital Certification tab; however, depending on the stakeholder type the appropriate tab will be highlighted.

Below is a summary of your response. You must review the IONSYS REMS education resources again before you attempt to retake the Knowledge Assessment. Please use the Education Resources button to review the education resources. Once your review is complete, you can retake the assessment again.

**QUESTION 1**
The IONSYS Risk Evaluation and Mitigation Strategy (REMS) is required by the Food and Drug Administration (FDA) to:

- ✓ D. All of the above

**QUESTION 2**
It is important that only healthcare providers are educated about the safe use of IONSYS.

- ✗ B. True

**QUESTION 3**
IONSYS may be sent home with the patient upon leaving the hospital.

- ✓ D. False
46. Knowledge Assessment – Failed 6th Attempts

Note: For the purpose of the mockup document the header will display with Hospital Certification tab; however, depending on the stakeholder type the appropriate tab will be highlighted.

Knowledge Assessment Results

We're sorry, you did not pass the Knowledge Assessment.

Because this was your sixth failed attempt at the Knowledge Assessment your ability to take the Knowledge Assessment has been suspended. In order to reset your Knowledge Assessment attempts you must contact the IONSYS REMS Program at 877-488-6836.
47. Hospital Attestation

Hospital Attestation

To complete the certification for Health & Hospital Corp of Marion Co into the IONSYS REMS Program online, please review the attestation section below to provide your acknowledgment along with signature and signature date.

Alternatively, you may print your online enrollment form and fax it to the IONSYS REMS Program at 877-488-6835.

As an Authorized Representative, responsible for the hospital, Frank Adam, attest to the following IONSYS REMS Program requirements:

I understand that IONSYS is only available through the IONSYS REMS Program. As the designated Authorized Representative, I must comply with the following program requirements for hospitals to ensure that IONSYS is only ordered, prescribed, dispensed, and administered in certified hospitals. I acknowledge that:

1. I am the Authorized Representative designated by my hospital to complete certification on behalf of the hospital and oversee implementation and compliance with the IONSYS REMS Program.
2. I attest that this hospital provides acute care, treats patients in the hospital, and offers post-operative pain management.
3. I have reviewed the IONSYS Prescribing Information, IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists (to which the IONSYS Instructions for Use and Disposal and the IONSYS Medication Guide are attached), and have successfully completed the IONSYS REMS Knowledge Assessment.
4. I understand the benefits and risks associated with IONSYS and the requirements of the IONSYS REMS Program.
5. I will ensure all staff, including pharmacy and nursing staff, involved in dispensing or administering IONSYS have been trained on the IONSYS REMS Program requirements as described in the IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists (to which the IONSYS Instructions for Use and Disposal and the IONSYS Medication Guide are attached) and have successfully completed the IONSYS REMS Knowledge Assessment. This training will be documented.
6. I will establish or oversee the processes, procedures, systems, order sets, protocols, and/or other measures to help ensure compliance with the requirements of the IONSYS REMS Program. These processes, procedures, systems, order sets, protocols, and/or other measures will be documented.
7. I understand that the hospital will not sell, lease, or transfer IONSYS inventory to any other pharmacy, institution, distributor, or prescriber.
8. I will ensure that the certified hospital involved in the prescribing, dispensing, and administration of IONSYS is informed of rates of respiratory depression and the elements of the IONSYS REMS by distributing the Dear Healthcare Provider Letters and Dear Hospital Pharmacy Letter within 3 weeks of receiving notification of certification in the IONSYS REMS Program.
9. I understand that the hospital pharmacy is not to dispense IONSYS for use outside the hospital.
10. I understand that IONSYS must be removed from the patient prior to the patient leaving the hospital.
11. I will report any adverse events suggestive of respiratory depression resulting from accidental exposure associated with the use of IONSYS to The Medicines Company or the FDA.
12. I will comply with requests to be audited by The Medicines Company to ensure that all processes and procedures are in place and are being followed for the IONSYS REMS Program and appropriate documentation is available upon request.
13. I will renew this hospital’s certification in the IONSYS REMS Program every 3 years after initial certification.
14. I understand this hospital must have a new Authorized Representative complete an IONSYS REMS Hospital Enrollment Form and successfully complete the IONSYS REMS Knowledge Assessment within 4 weeks of the hospital designating a new Authorized Representative.

By checking this box, I agree to the responsibility outlined above and hereby state that all of the information I have submitted is true and accurate.

Signature: [Signature]
Signature Date: [Signature Date]

For additional information about the IONSYS REMS Program, please call 877-488-6835.
48. My Dashboard – View Hospitals

My Dashboard
Welcome to your IONSYS REMS Program dashboard.

View Hospitals  View Nurses and Pharmacists

Below is/are your Hospital location(s) certification details. Please use the Add Hospital button to add a new hospital location.

<table>
<thead>
<tr>
<th>Name</th>
<th>Address</th>
<th>Certification ID</th>
<th>Certification Status</th>
<th>Certified Date</th>
<th>Expiration Date</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Health &amp; Hospital Corp of Marion Co</td>
<td>15 Park Avenue, New York NY 10201</td>
<td>FAC94952209</td>
<td>Certified</td>
<td>03/15/2015</td>
<td>03/15/2015</td>
<td>View</td>
</tr>
<tr>
<td>Floyd Valley Hospital</td>
<td>600 Main Street, Phoenix AZ 84747</td>
<td>FAC94952288</td>
<td>incomplete</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Western State Hospital</td>
<td>212 77th Street, Los Angeles CA 90037</td>
<td>FAC845866555</td>
<td>Deactivated</td>
<td>03/15/2015</td>
<td>07/27/2015</td>
<td>Re-certify</td>
</tr>
</tbody>
</table>

1 - 3 of 3 Items

Add Hospital
49. My Dashboard – View Nurses and Pharmacists

![My Dashboard Image]

Welcome to your IONSYS REMS Program dashboard.

View Hospitals  View Nurses and Pharmacists

Below are the nurses and pharmacists associated with your Hospital location(s) along with their Knowledge Assessment status.

<table>
<thead>
<tr>
<th>Name</th>
<th>Hospital Name</th>
<th>Hospital Address</th>
<th>Status</th>
<th>Knowledge Assessment Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>John Doe</td>
<td>Health &amp; Hospital Corp of Man</td>
<td>15 Park Avenue, New York</td>
<td>Complete</td>
<td></td>
</tr>
<tr>
<td>John Smith</td>
<td>Floyd Valley Hospital</td>
<td>620 Main Street, Phoenix</td>
<td>Incomplete</td>
<td></td>
</tr>
</tbody>
</table>

1 - 2 of 2 Items

Show [10] entries
50. Hospital Certification Progress – Certified

**Health & Hospital Corp of Marion Co**

From the table below you can view and track your certification progress for the hospital.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Progress</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Account Registration</td>
<td>✓</td>
<td>Completed</td>
</tr>
<tr>
<td>Enrollment Form</td>
<td>✓</td>
<td>Completed</td>
</tr>
<tr>
<td>Education Resources</td>
<td>✓</td>
<td>Download Education Resources</td>
</tr>
<tr>
<td>Knowledge Assessment</td>
<td>✓</td>
<td>Completed</td>
</tr>
<tr>
<td>Certification Attestation</td>
<td>✓</td>
<td>Print Confirmation</td>
</tr>
<tr>
<td>My Profile</td>
<td>✓</td>
<td>Available</td>
</tr>
</tbody>
</table>

51. Hospital Certification Progress – Incomplete Certification

**Floyd Valley Hospital**

From the table below you can view and track your certification progress for the hospital.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Progress</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Account Registration</td>
<td>✓</td>
<td>Completed</td>
</tr>
<tr>
<td>Enrollment Form</td>
<td></td>
<td>Incomplete</td>
</tr>
<tr>
<td>Education Resources</td>
<td></td>
<td>Start Education Program</td>
</tr>
<tr>
<td>Knowledge Assessment</td>
<td></td>
<td>Incomplete</td>
</tr>
<tr>
<td>Certification Attestation</td>
<td></td>
<td>Incomplete</td>
</tr>
<tr>
<td>My Profile</td>
<td>✓</td>
<td>Available</td>
</tr>
</tbody>
</table>
52. Nurses and Pharmacists Progress – KA Incomplete

Frank Adam

From the table below you can view and track your progress.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Progress</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Account Registration</td>
<td>Completed</td>
<td></td>
</tr>
<tr>
<td>Education Resources</td>
<td>Incomplete</td>
<td>Start Education Program</td>
</tr>
<tr>
<td>Knowledge Assessment</td>
<td>Incomplete</td>
<td></td>
</tr>
</tbody>
</table>

53. Nurses and Pharmacists Progress – KA Completed

Frank Adam

From the table below you can view and track your progress.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Progress</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Account Registration</td>
<td>Completed</td>
<td></td>
</tr>
<tr>
<td>Education Resources</td>
<td>Completed</td>
<td>Download Education Resources</td>
</tr>
<tr>
<td>Knowledge Assessment</td>
<td>Completed</td>
<td>Print Confirmation</td>
</tr>
</tbody>
</table>
54. Hospital Certification Confirmation

Congratulations! Your hospital is now certified in the IONSYS REMS Program.

Below is your IONSYS REMS Program Certification ID. Please retain this information for your records.

Certification ID: FAC84747474

You may now:
- Manage your hospitals
- View your profile
55. Authorized Representative Profile

Your profile information is displayed below. If you need to make any changes to your profile please contact the IONSYS REMS Program at 877-489-5635. To go back to your Dashboard please use the My Dashboard button in the top right corner of this website.

Name: <First and Last Name>
Title: Nurse
Phone: 898-938-9464
Ext: 8558
Fax: 585-383-3838
Email: <email address>
Preferred Method of Communication: Email
56. Forms & Resources

Forms & Resources

Forms

IONSYS REMS Hospital Enrollment Form

Resources

IONSYS REMS Safety Brochure: Guide for Nurses and Pharmacists
IONSYS REMS Knowledge Assessment
Dear Healthcare Provider Letter - Department Head: Surgery
Dear Healthcare Provider Letter - Department Head: Anesthesia
Dear Healthcare Provider Letter - Department Head: Nursing
Dear Healthcare Provider Letter - Department Head: Obstetrics and Gynecology
Dear Healthcare Provider Letter - Department Head: Orthopedics
Dear Hospital Pharmacy Letter
IONSYS Instructions for Use and Disposal
IONSYS Medication Guide
Prescribing Information
57. Request Username

Please enter your credentials in the spaces provided below. Your username will be sent to your registered email address with the IONSYS REMS Program.

First Name
Last Name
Email Address

Submit
58. Request Password

Please enter the username and email address you used to register in the IONSYS REMS Program below. You will receive an email with a temporary password. Please follow the instructions in the email to reset your password.

Username: 
Email Address: 
Submit

59. Change Password

To change your password, please use the fields below. Your new password must be at least eight (8) characters in length and contain at least one letter and one number. Passwords are case sensitive.

Current Password: 
New Password: 
Confirm New Password: 
Submit
60. Contact Us

Contact Us

If you have any questions or require additional information, please contact the IONSYS REMS Program utilizing the information provided below:

Phone Number
877-488-4635

Fax Number
877-488-8601

Mailing Address
IONSYS REMS Program
P.O. BOX 26242
PHOENIX, AZ 85038-9242
61. Certification Deactivated Message – **Program Opt Out, Hospital Closed, AR Not Confirmed, Expired** – My Dashboard

![Certification Deactivated Message]

Based on the information provided, we have determined that your certification was deactivated for the following reason: AR Not Confirmed. If you wish to begin the re-certification process, please click on the **Start Re-Certification** button or use the **My Dashboard** button to stay on your My Dashboard page. Please contact the IONSYS REMS Program at **877-488-6835** if you need any further assistance.

My Dashboard

62. Certification Cancelled Message – **6-Month Incomplete Certification** – My Dashboard

![Certification Cancelled Message]

Based on the information provided, we have determined that your certification was cancelled for the following reason: 6-month Incomplete Certification. Please click the **OK** button to start your certification.

Please contact the IONSYS REMS Program at **877-488-6835** for further assistance.

OK
63. **Certification Cancelled Message – Suspension, Non Compliant – My Dashboard**

![Certification Deactivated](image_url)

Based on the information provided, we have determined that your certification was deactivated for the following reason: Suspended.

Please contact the IONSYS REMS Program at **877-488-6835** if you need to re-certify.

My Dashboard

64. **Identifier Validation Message – DEA #/Identifier Could Not Be Validated – Hospital and AR Website Certification**

![Identifier Validation Issue](image_url)

Based on the information provided, the DEA number could not be validated. You may select *Modify Identifiers* to correct the issue now or select *Continue* to proceed with certification at this time.

**NOTE:** As part of the IONSYS REMS Program certification process the identifier must be successfully validated. If you choose not to correct the identifier issue and move forward through the certification process, your certification will be considered incomplete until all required fields have been validated.

If you need assistance with this process, or are not sure what the problem might be, please contact the IONSYS REMS Program at **877-488-6835**.

Modify Identifiers  Continue
65. **Identifier Validation Message – May Already Be Certified – Hospital and AR Website Certification**

![Identifier Validation Message](image)

66. **User ID Already Exists – Website Certification**

![User ID Form](image)
This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

JUDITH A RACOOSIN
10/03/2018