



# Pomalidomide REMS Pharmacy Training

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# Pomalidomide REMS Pharmacy Training

Section 1: What is a REMS?

## In this section

- What is a REMS?
- Pharmacy Staff Knowledge Check

## What is a REMS?

- REMS stands for Risk Evaluation and Mitigation Strategies
- REMS programs are mandated by the US Food and Drug Administration (FDA)
- According to the FDA, a REMS program is:
  - A strategy to manage a known or potential serious risk associated with a drug or biological product
- The FDA determines if a REMS program is necessary to ensure that the benefits of the drug outweigh the risks

## Pomalidomide REMS

- **Risk:** If pomalidomide is used during pregnancy, it can cause serious birth defects or embryo-fetal death
- The goal of the Pomalidomide REMS is:
  - To prevent the risk of embryo-fetal exposure to pomalidomide
  - To inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for pomalidomide

## Pharmacy Staff Knowledge Check

- REMS stands for Risk Evaluation and Mitigation Strategies.
  - A. True
  - B. False

# Pharmacy Staff Knowledge Check

- REMS stands for Risk Evaluation and Mitigation Strategies.
  - A. True
  - B. False

Correct Answer: A. True

- REMS stands for **Risk Evaluation and Mitigation Strategies**
- A REMS is a strategy to manage a known or potential serious risk associated with a drug or biological product

## Pharmacy Staff Knowledge Check ( continued)

- Who mandates REMS programs?
  - A. The Pomalidomide REMS Manufacturers
  - B. The Food and Drug Administration (FDA)
  - C. The Environmental Protection Agency (EPA)

## Pharmacy Staff Knowledge Check ( continued)

- Who mandates REMS programs?
  - A. The Pomalidomide REMS Manufacturers
  - B. The FDA
  - C. The EPA

**Correct Answer: B. FDA**

- REMS programs are mandated by the FDA
- The FDA determines if a REMS program is necessary to ensure that the benefits of the drug outweigh the risks

## Pharmacy Staff Knowledge Check ( continued)

- The Pomalidomide REMS is mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for pomalidomide.
  - A. True
  - B. False

## Pharmacy Staff Knowledge Check ( continued)

- The Pomalidomide REMS is mandated to avoid embryo-fetal exposure and to inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for pomalidomide.
  - A. True
  - B. False

**Correct Answer: A. True**

- The goals of the Pomalidomide REMS are:
  - To prevent the risk of embryo-fetal exposure to these treatments
  - To inform prescribers, patients, and pharmacies on the serious risks and safe-use conditions for pomalidomide



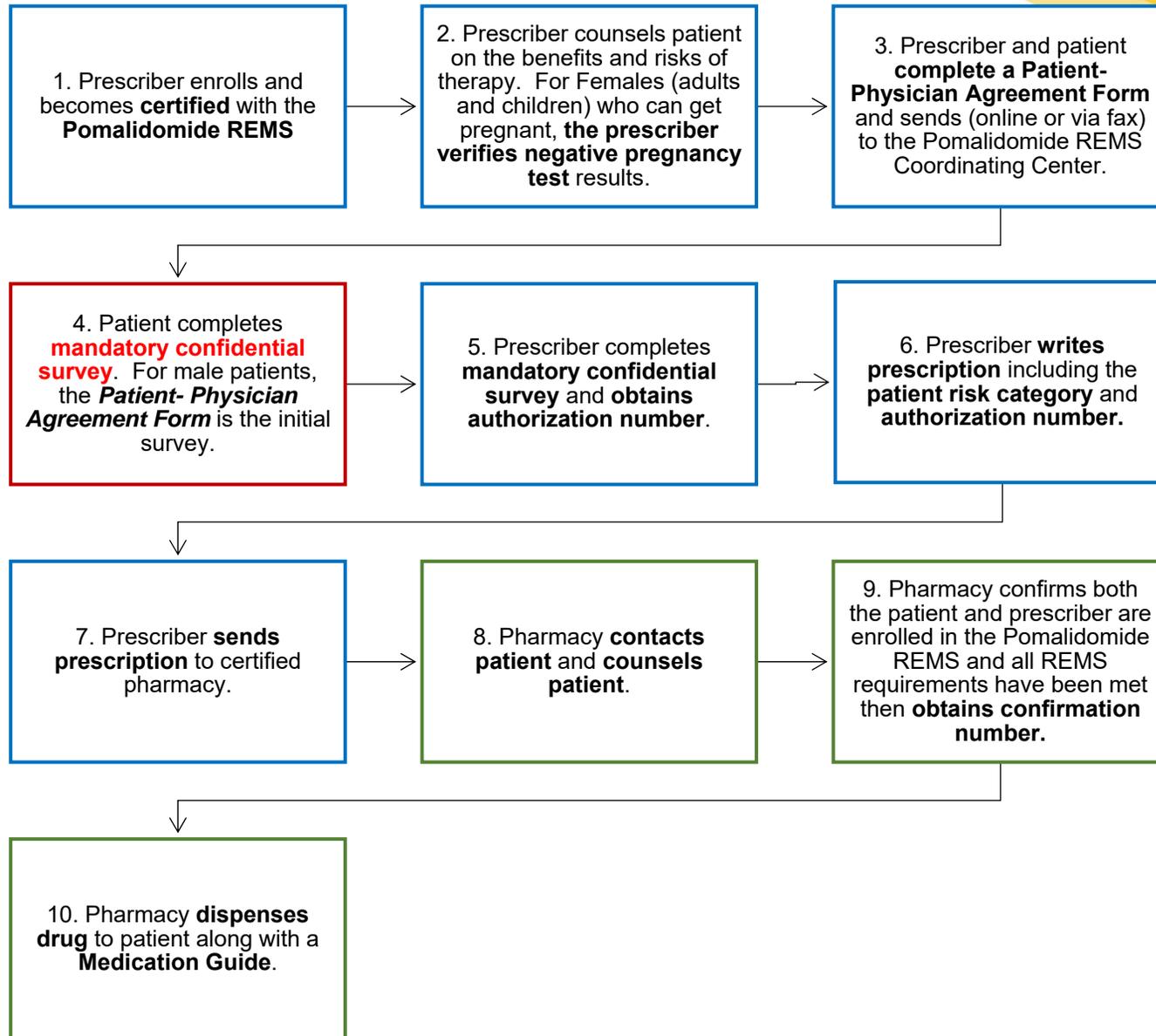
# Pomalidomide REMS Pharmacy Training

Section 2: Program Requirements  
for Patients and Prescribers

## In this section

- Program overview
- Certification and enrollment requirements for prescribers and patients
- Patient risk categories
- Contraception requirements
- Pregnancy test requirements
- Mandatory confidential surveys
- Pharmacy staff knowledge check

# Pomalidomide REMS Program Overview



## Certification and enrollment requirements for prescribers and patients

- Prescribers must be certified with the Pomalidomide REMS in order to prescribe pomalidomide for a patient
  - Prescribers must complete the Pomalidomide REMS **Prescriber Enrollment Form** and agree to comply with the program requirements
- Prescribers are required to enroll patients in the Pomalidomide REMS before starting a patient on a therapy
  - Patients must enroll in the Pomalidomide REMS by completing the **Patient-Physician Agreement Form** and agree to comply with the program requirements

## Patient risk categories

- There are 6 different patient risk categories for patients enrolled in Pomalidomide REMS:
  1. Adult female who can get pregnant
  2. Female child who can get pregnant
  3. Adult female who cannot get pregnant
  4. Female child who cannot get pregnant
  5. Adult male
  6. Male child

## Definition of females who can get pregnant

- **Females (adults and children) who can get pregnant** include all females who:
  - Are menstruating
  - Are amenorrheic from previous medical treatments
  - Are under 50 years of age
  - Are perimenopausal
  - Do not qualify for the females not of reproductive potential category
- The risk categories for **females who can get pregnant** are:
  - Adult Female who can get pregnant
  - Female child who can get pregnant

## Definition of females who cannot get pregnant

- **Females who cannot get pregnant** include females who:
  - Have been in natural menopause for at least 24 consecutive months
  - Have had a hysterectomy and/or bilateral oophorectomy
  - Have not started menstruating or shown signs of puberty
- The risk categories for **females who cannot get pregnant** are:
  - Adult female who cannot get pregnant
  - Female child who cannot get pregnant

## Definition of males

- **Males** include adults and children (under 18 years of age)
- The risk categories for **males** are:
  - Adult Male
  - Male Child

## Contraception requirements: Females who can get pregnant

- Female patients (adults and children) who can get pregnant must either completely abstain from heterosexual sexual contact or must use 2 effective methods of contraception (at least one highly effective method and one effective method) at the same time
- The 2 effective contraceptive methods include using at the same time **at least 1 highly effective method** and **at least 1 additional method** of birth control every time they have sex with a male
- The 2 effective contraceptive methods must be started at least 4 weeks before therapy, during therapy (including dose interruptions), and for at least 4 weeks following discontinuation of therapy

### Highly Effective Methods

Tubal ligation

Intrauterine device (IUD)  
Hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants)

Partner's vasectomy

+

### Additional Effective Methods

Male latex or synthetic condom

Diaphragm

Cervical cap

Remind patients that not having any sexual intercourse is the only birth control method that is **100% effective**.

## Contraception requirements: Females who can get pregnant (continued)

- **Unacceptable contraception methods:**
  - Progesterone-only “mini-pills”
  - IUD Progesterone T
  - Female condoms
  - Natural family planning (rhythm method) or breastfeeding
  - Fertility awareness
  - Withdrawal
  - Cervical shield
    - A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception

## Contraception requirements: Males

- Male patients must use a latex or synthetic condom:
  - Every time they have sexual intercourse with a female of reproductive potential even if they have undergone a successful vasectomy
  - During therapy (including dose interruptions)
  - For 4 weeks after discontinuation of therapy

Remind patients that not having any sexual intercourse is the only birth control method that is **100% effective**.

## Pregnancy test requirements

- For females (adults and children) who can get pregnant: the prescriber must assess the patient's pregnancy status by ordering and confirming a negative test result at the following timeframes:
  - Before treatment initiation (first prescription):
    - 10-14 days prior to initiation of pomalidomide therapy
    - Within 24 hours of the initial prescription
  - During treatment:
    - Weekly during the first 4 weeks of use
    - Thereafter,
      - Every 4 weeks for female patients who can get pregnant with regular menstrual cycles
      - Every 2 weeks for female patients who can get pregnant with irregular menstrual cycles
- The pregnancy test must be sensitive to at least 50 mIU/mL

## Pregnancy test requirements (continued)

### If pregnancy does occur:

- Treatment must be **immediately** discontinued
- Any suspected embryo-fetal exposure must be reported **immediately** to the REMS Coordinating Center and reported to the FDA
  - Pomalidomide REMS Coordinating Center: 1-866-245-7925
  - FDA MedWatch number: 1-800-FDA-1088
- The patient should be referred to an obstetrician/gynecologist experienced in reproductive toxicity for further evaluation and counseling

## Mandatory confidential surveys

- All patients must complete brief mandatory confidential surveys in order to obtain treatment
- Surveys can be completed via [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com), or by calling the REMS Coordinating Center at 1-866-245-7925

### Patient Mandatory Confidential Survey Schedule for Adults and Children

Risk Category	Initial Prescription	Subsequent Prescriptions
Females who can get pregnant	Complete appropriate survey	Monthly survey
Females who cannot get pregnant	Complete appropriate survey	Child: Monthly survey Adult: Survey every 6 months
Males	Do not need to take initial survey	Monthly survey

## Pharmacy staff knowledge check

- How many patient risk categories are there in the Pomalidomide REMS?
  - A. 3
  - B. 5
  - C. 6

## Pharmacy staff knowledge check

- How many patient risk categories are there in the Pomalidomide REMS?
  - A. 3
  - B. 5
  - C. 6

**Correct Answer: C. 6**

<b>Pomalidomide REMS patient risk categories</b>	
<b>Adult</b>	<b>Child (under 18)</b>
Adult female who can get pregnant	Female child who can get pregnant
Adult female who cannot get pregnant	Female child who cannot get pregnant
Adult male	Male child

## Pharmacy staff knowledge check (continued)

- For the Pomalidomide REMS, female patients (adults and children) who can get pregnant must take:
  - A. Only one pregnancy test 10-14 days before first prescription
  - B. Only one pregnancy test within 24 hours before first prescription
  - C. Two pregnancy test: 10-14 days before and within 24 hours prior to first prescription

## Pharmacy staff knowledge check (continued)

- For the Pomalidomide REMS, female patients (adults and children) who can get pregnant must take:
  - A. Only one pregnancy test 10-14 days before first prescription
  - B. Only one pregnancy test within 24 hours before first prescription
  - C. Two pregnancy test: 10-14 days before and within 24 hours prior to first prescription

### **Correct Answer:**

**C. Two pregnancy test: 10-14 days before and within 24 hours prior to first prescription**

- Prescribers must obtain 2 negative pregnancy tests before the first prescription for females who can get pregnant:
  - 10 to 14 days before an initial prescription
  - Within 24 hours before an initial prescription

## Pharmacy staff knowledge check (continued)

- Which is a **highly effective** method of contraception?
  - A. Male latex or synthetic condom
  - B. IUD
  - C. Female condom

## Pharmacy staff knowledge check (continued)

- Which is a **highly effective** method of contraception?
  - A. Male latex or synthetic condom
  - B. IUD
  - C. Female condom

**Correct Answer: B. IUD**

<b>Highly Effective Methods</b>	<b>Additional Effective Methods</b>
Tubal ligation	Male latex or synthetic condom
Intrauterine device (IUD)	Diaphragm
Hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants)	Cervical cap
Partner's vasectomy	



# Pomalidomide REMS Pharmacy Training

Section 3: Program Requirements for  
Pharmacies

## In this section

- Training and certification requirements
- Pharmacy compliance
- Pharmacy staff knowledge check

## Training and certification requirements

- Pomalidomide REMS counselors must:
  - Be licensed healthcare professionals
  - Complete the Pomalidomide REMS training **annually** and pass certification exam **with 100% accuracy**
  - Educate patient by telephone or in person before treatment can be dispensed
  - Understand and counsel patients on the potential for birth defects or death to an unborn baby
  - Counsel patients on possible side effects
- Other pharmacy staff involved in dispensing treatment must:
  - Be educated on the guidelines for dispensing

## Pharmacy compliance

- Pharmacy manager responsibilities
  - Educate all staff regarding dispensing guidelines
  - Includes floater pharmacists, pharmacy technicians, or anyone else handling the product
  - Complete and return all documentation that pertains to non-compliance

**Did you know?** Pharmacy managers can call the REMS Coordinating Center at **1-866-245-7925** with questions.

## Pharmacy compliance (continued)

- Pharmacy deviations
  - The pharmacy will be required to investigate and correct conditions that lead to deviations from Pomalidomide REMS
  - The Pomalidomide REMS Coordinating Center will work with the pharmacy to implement appropriate corrective actions and a timeframe for those actions
  - If corrective actions are not successful, the Pomalidomide REMS may take additional action, up to and including deactivation of the pharmacy

## Pharmacy compliance (continued)

- A High Risk Deviation is:
  - Any action taken by the pharmacy that is inconsistent or non-compliant with the Pomalidomide REMS that increases the risk of embryo-fetal exposure
  - Any action that occurs on a consistent basis that shows a pharmacy's negligent or willful disregard to the Pomalidomide REMS program requirements
  - For any additional occurrence of a High Risk Deviation beyond 2 High Risk Deviations, the pharmacy may be deactivated and no longer permitted to dispense product

## Pharmacy staff knowledge check

- Pomalidomide REMS program certified counselors must complete the training:
  - A. Annually
  - B. Every 6 months
  - C. Every 2 years

## Pharmacy staff knowledge check

- Pomalidomide REMS program certified counselors must complete the training:
  - A. Annually
  - B. Every 6 months
  - C. Every 2 years

**Correct Answer: A. Annually**

- Counselors must complete training annually

## Pharmacy staff knowledge check (continued)

- All counselors must pass the certification test with an accuracy of:
  - A. 100%
  - B. 90%
  - C. 95%

## Pharmacy staff knowledge check (continued)

- All counselors must pass the certification test with an accuracy of:
  - A. 100%
  - B. 90%
  - C. 95%

**Correct Answer: A. 100%**

- Counselors must pass the certification exam with 100% accuracy

## Pharmacy staff knowledge check (continued)

- The Pomalidomide REMS may deactivate pharmacies for deviations.
  - A. True
  - B. False

## Pharmacy staff knowledge check (continued)

- The Pomalidomide REMS may deactivate pharmacies for deviations.
  - A. True
  - B. False

**Correct Answer: A. True**

- The pharmacy will be required to investigate and correct conditions that lead to deviations from the Pomalidomide REMS
- If corrective actions are not successful, the Pomalidomide REMS may take additional action, up to and including deactivation of the pharmacy



# Pomalidomide REMS Pharmacy Training

## Section 4: Guidelines for Counseling

## In this section

- Counseling for female patients who can get pregnant
- Counseling for female patients who cannot get pregnant
- Counseling for male patients
- Additional counseling for all patients taking pomalidomide
- Pharmacy staff knowledge check

### POMALIDOMIDE REMS

#### Education and Counseling Checklist for Pharmacies

PHARMACY INFORMATION			
Pharmacy Name:			
Pharmacy Address:	City:	State:	ZIP Code:
Counselor Name:	Work Phone Number:		
PATIENT INFORMATION			
Patient Name:	Date of Birth:		
REMS CONFIRMATION			
Prescription Confirmation Number:		Confirmation Date:	
Patient Risk Category: <input type="checkbox"/> Adult Female Who Can Get Pregnant <input type="checkbox"/> Female Child Who Can Get Pregnant <input type="checkbox"/> Adult Male Who Can Not Get Pregnant <input type="checkbox"/> Male Child <input type="checkbox"/> Female Child Who Can Not Get Pregnant <input type="checkbox"/> Adult Male			
Confirmation Date:		Confirmation Prescriber is Certified, Patient is Enrolled and Not Pregnant (if applicable) and the Confirmation Number Provided by the Prescriber is Valid. <input type="checkbox"/> Yes <input type="checkbox"/> No	
Authorization Code:			
Checklist for Female Patients of Reproductive Potential			
<input type="checkbox"/> I will make sure that patients are aware that they will receive the Medication Guide along with their prescription			
I COUNSELED ADULTS AND CHILDREN ON:			
<input type="checkbox"/> Potential embryo-fetal toxicity			
<input type="checkbox"/> Not taking pomalidomide if pregnant or breastfeeding			
<input type="checkbox"/> Using at the same time at least 1 highly effective method—tubal ligation, IUD, hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy—and at least 1 additional effective method of birth control—male latex or synthetic condom, diaphragm, or cervical cap—every time they have sex with a male, or abstaining from sex with a male			
<input type="checkbox"/> Continuing to use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control beginning at least 4 weeks before taking pomalidomide, while taking pomalidomide, during dose interruptions, and for at least 4 weeks after stopping pomalidomide every time they have sex with a male, or abstaining from sex with a male			
<input type="checkbox"/> Unacceptable methods of birth control are progesterone-only "mini-pills", IUD Progesterone T, female condoms, natural family planning (rhythm method) or breastfeeding, fertility awareness, withdrawal, and cervical shield (A cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception).			
<input type="checkbox"/> Obtaining a pregnancy test—performed by their healthcare provider—weekly during the first 4 weeks of use. Thereafter, pregnancy testing should be repeated every 4 weeks during the rest of their treatment in females with regular menstrual cycles or no cycle at all. If menstrual cycles are irregular, the pregnancy testing should occur every 2 weeks			
<input type="checkbox"/> The need to stop taking pomalidomide right away in the event of becoming pregnant, or if they think for any reason they may be pregnant, and to call their healthcare provider immediately			
<input type="checkbox"/> Possible side effects include deep vein thrombosis, pulmonary embolism, myocardial infarction and stroke			
<input type="checkbox"/> Not sharing pomalidomide capsules with anyone- especially with females who can get pregnant			
<input type="checkbox"/> Not donating blood while taking pomalidomide (including dose interruptions) and for 4 weeks after stopping pomalidomide			
<input type="checkbox"/> Not breaking, chewing, or opening pomalidomide capsules			
<input type="checkbox"/> Instructions on pomalidomide dose and administration			
Milligram (mg) Strength: _____		Number of Capsules Dispensed: _____	
FEMALE CHILDREN (<18 YEARS OF AGE):			
<input type="checkbox"/> Parent or legal guardian must have read the Pomalidomide REMS educational material and agreed to ensure compliance			

Page 1 of 2

Phone: 1-XXX-XXX-XXXX

www.PomalidomideREMSProgram.com

Fax: 1-XXX-XXX-XXXX

The sequence of this section is based on the [Education and Counseling Checklist for Pharmacies](#).

**Remember to fill out this checklist for every patient for every prescription.**

## Counseling for females who can get pregnant

- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

### **COUNSEL ADULTS AND CHILDREN ON:**

- Potential embryo-fetal toxicity
- Not taking treatment if pregnant or breastfeeding
- Using **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control **every time they have sex with a male**, or abstaining from sex with a male
  - **Highly effective** methods of contraception: Tubal ligation, intrauterine device (IUD), hormonal (birth control pills, hormonal patches, injections, vaginal rings, or implants), or partner's vasectomy
  - **Additional effective** methods of contraception: Male latex or synthetic condom, diaphragm, or cervical cap

## Counseling for females who can get pregnant (continued)

### **COUNSEL ADULTS AND CHILDREN ON:**

- Unacceptable methods of birth control are:
  - Progesterone-only “mini-pills”
  - IUD Progesterone T
  - Female condoms
  - Natural family planning (rhythm method) or breastfeeding
  - Fertility awareness
  - Withdrawal
  - Cervical shield (a cervical shield should not be confused with a cervical cap, which is an effective secondary form of contraception)

## Counseling for females who can get pregnant (continued)

- **COUNSEL ADULTS AND CHILDREN ON:**
  - Continuing to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control:
    - Beginning at least 4 weeks before treatment
    - During treatment
    - During dose interruptions
    - For at least 4 weeks after stopping treatment
    - **Every time they have sex with a male**, or abstaining from sex with a male

## Counseling for females who can get pregnant (continued)

- **COUNSEL ADULTS AND CHILDREN ON:**
  - Obtaining a pregnancy test—performed by their healthcare provider during the following timeframes:
    - Before treatment initiation (first prescription):
      - 10-14 days prior to initiation of pomalidomide therapy
      - Within 24 hours of the initial prescription
    - During treatment:
      - Weekly during the first 4 weeks of use
      - Thereafter,
        - Every 4 weeks for female patients who can get pregnant with regular menstrual cycles
        - Every 2 weeks for female patients who can get pregnant with irregular menstrual cycles
  - The need to stop treatment right away **in the event of becoming pregnant, or if they think for any reason they may be pregnant,** and to call their healthcare provider immediately

# Counseling for females who can get pregnant (continued)

## COUNSEL ADULTS AND CHILDREN ON:

- Not sharing capsules with anyone
- Not donating blood during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Keeping pomalidomide prescription out of the reach of children
- Instructions on dose and administration
  - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist
- Returning any unused pomalidomide capsules for disposal to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide.

## FOR FEMALE CHILDREN (<18 YEARS OF AGE):

- Parent or legal guardian must have read the Pomalidomide REMS education material and agreed to ensure compliance
- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

## Counseling for females who cannot get pregnant

### **COUNSEL ADULTS AND CHILDREN ON:**

- Not sharing capsules with anyone
- Not donating blood during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Keeping pomalidomide prescription out of the reach of children
- Instructions on dose and administration
  - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist
- Returning any unused pomalidomide capsules for disposal to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide.

## Counseling for females who cannot get pregnant (continued)

- **FOR FEMALE CHILDREN (<18 YEARS OF AGE):**
- Parent or legal guardian must have read the Pomalidomide REMS education material and agreed to ensure compliance
- Parent or legal guardian must inform the child's doctor when the child begins menses or shows signs of puberty

## Counseling for male patients

- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription

### **COUNSEL ADULTS AND CHILDREN ON:**

- Potential embryo-fetal toxicity and contraception
  - Wearing a latex or synthetic condom every time when engaging in sexual intercourse with a female who can get pregnant, even if they have undergone a successful vasectomy
- Female partners of males receiving treatment must call their healthcare provider right away if they get pregnant

## Counseling for male patients (continued)

### **COUNSEL ADULTS AND CHILDREN ON:**

- Not sharing capsules with anyone
- Not donating blood or sperm during treatment (including dose interruptions) and for 4 weeks after stopping treatment
- Not breaking, chewing, or opening capsules
- Keeping pomalidomide prescription out of the reach of children
- Instructions on dose and administration
  - It is required that the milligram strength and number of capsules dispensed be recorded on the patient checklist
- Returning any unused pomalidomide capsules for disposal to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide.

### **FOR MALE CHILDREN (<18 YEARS OF AGE):**

- Parent or legal guardian must have read the Pomalidomide REMS education material and agreed to ensure compliance

## Additional counseling for all patients taking pomalidomide

### **COUNSEL ADULTS AND CHILDREN ON:**

- Possible side effects include deep vein thrombosis, pulmonary embolism, myocardial infarction and stroke

## Pharmacy staff knowledge check

- Which of these is **not** something patients need to be counseled on?
  - A. Not sharing capsules
  - B. Not breaking, chewing, or opening capsules
  - C. Wearing gloves while taking capsules

## Pharmacy staff knowledge check

- Which of these is **not** something patients need to be counseled on?
  - A. Not sharing capsules
  - B. Not breaking, chewing, or opening capsules
  - C. Wearing gloves while taking capsules

**Correct Answer: C. Wearing gloves while taking capsules.**

- Patients must be counseled on:
  - Not sharing capsules with anyone
  - Not breaking, chewing, or opening capsules
  - Keeping pomalidomide prescription out of the reach of children
  - Not donating blood while taking pomalidomide, during breaks (dose interruptions), and for 4 weeks after stopping pomalidomide
  - Returning any unused pomalidomide capsules for disposal to the Pomalidomide REMS, their prescriber, or the pharmacy that dispensed their pomalidomide

## Pharmacy staff knowledge check (continued)

- Females who can get pregnant must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control for 4 weeks after stopping treatment.
  - A. True
  - B. False

## Pharmacy staff knowledge check (continued)

- Females who can get pregnant must use at the same time at least 1 highly effective method and at least 1 additional effective method of birth control for 4 weeks after stopping treatment.
  - A. True
  - B. False

**Correct Answer: A. True**

- Females who can get pregnant must continue to use **at the same time** at least 1 highly effective method and at least 1 additional effective method of birth control:
  - Beginning at least 4 weeks before treatment
  - During treatment
  - During dose interruptions
  - For at least 4 weeks after stopping treatment
  - **Every time they have sex with a male**, or abstaining from sex with a male

## Pharmacy staff knowledge check (continued)

- All patients must receive a **Medication Guide** along with their prescription.
  - A. True
  - B. False

## Pharmacy staff knowledge check (continued)

- All patients must receive a **Medication Guide** along with their prescription.
  - A. True
  - B. False

**Correct Answer: A. True**

- Make sure that patients are aware that they will receive the **Medication Guide** along with their prescription



# Pomalidomide REMS Pharmacy Training

Section 5: Guidelines for Dispensing

## In this section

- Pharmacy and prescription requirements
- Dispensing guidelines
- Steps for dispensing
- Pharmacy staff knowledge check

## Pharmacy and prescription requirements

- Dispensing pharmacies **must be certified in the Pomalidomide REMS** by completing the ***Pharmacy Enrollment Form*** and must be educated on the **REMS requirements and on dispensing procedures for the treatment**
- Pharmacy must ensure that every prescription includes:
  - Patient and prescriber demographics and contact information
  - Dosing information and instructions
  - Prescriber signature
  - Patient Risk Category
  - Valid Authorization Number
- Authorization numbers are valid for **7 days** from the date of last pregnancy test for female patients who can get pregnant and **30 days** from the date it is issued for all other patients
- No automatic refills or telephone prescriptions are permitted
- Faxed prescriptions are permissible depending on state laws

## Dispensing guidelines

- Dispense **no more than a 4-week (28-day) supply** with the **Medication Guide**. A new prescription is required for further dispensing
- **Dispense subsequent prescriptions only if there are 7 days or less remaining of therapy on the existing prescription**
- Dispense or ship the product within 24 hours of obtaining and recording the confirmation number
- For females who can get pregnant, product **must be shipped the same day** confirmation number is obtained **or picked-up within 24 hours** of obtaining confirmation number
- Pharmacy is required to **cancel** the confirmation number if product is not provided to the patient within the required time frame
- Pharmacy must obtain a new confirmation number by accessing the Pomalidomide REMS Pharmacy Portal or by calling the Pomalidomide REMS Coordinating Center at 1-866-245-7925 when ready to ship or have the product picked up

## Dispensing guidelines (continued)

- When shipping, pharmacy must require a signature confirming receipt
- Pharmacy shall keep an inventory log for the drug, by strength, reflecting its on-hand inventory at all times
- Do not distribute, transfer, loan, or sell pomalidomide, except with the permission of the Pomalidomide REMS
- Accept unused capsules (previously dispensed) from a patient or patient caregiver for proper disposal

# Steps for dispensing

## Review incoming prescriptions

- Only accept prescriptions with all of the following information:
  - Patient and prescriber demographics and contact information
  - Dosing information and instructions
  - Prescriber signature
  - Patient Risk Category
  - Valid Authorization Number
- Make sure the prescription is signed and dated
- Confirm the prescription is written for a 4-week (28-day) supply or less
- For subsequent prescriptions, verify there are 7 days or less of therapy remaining on the existing prescription

## Steps for dispensing (continued)

### Counsel patient

- Patients must receive counseling from a Pomalidomide REMS certified pharmacy counselor
- Complete the corresponding section (based on the patient risk category) of the Education and Counseling Checklist
  - Make sure form is signed and dated by the counselor and appropriate boxes are checked off
  - Keep a copy of the checklist and the associated prescription
- Please report adverse drug experiences that are suspected to be associated with the use of the drug and any suspected pregnancy occurring during the treatment

## Steps for dispensing (continued)

- **Obtain confirmation number from the Pomalidomide REMS Pharmacy Portal**
- Prior to each prescription, access the Pomalidomide REMS Pharmacy Portal or contact the Pomalidomide REMS Coordinating Center at 1-866-245-7925, available 8:00AM- 8:00PM, Monday- Friday.
  1. Search Certified Prescriber (name and National Provider Identifier (NPI))
  2. Search Enrolled Patient (name and date of birth)
  3. Enter Authorization Number
  4. Enter Number of Capsules and Milligram Strength
  5. Generate Confirmation Number
  6. Document Confirmation Number
- If you do not obtain a confirmation number, you are not permitted to dispense the product to the patient
- If you have questions about the validity of the prescribers authorization or pharmacy confirmation numbers, call the Pomalidomide REMS Coordinating Center.

## Steps for dispensing (continued)

- **Dispense prescription**
  - Include a **Medication Guide** with each prescription
  - Document the dispense date on either the shipping receipt or pharmacy dispensing log
  - Dispense or ship the product within 24 hours of obtaining and recording the confirmation number
  - For females who can get pregnant, product **must be shipped the same day** confirmation number is obtained **or handed to the patient within 24 hours**

## Pharmacy staff knowledge check

- An confirmation number is valid for:
  - A. 24 hours
  - B. 7 days
  - C. 30 days

## Pharmacy staff knowledge check

- An confirmation number is valid for:
  - A. 24 hours
  - B. 7 days
  - C. 30 days

**Correct Answer: A. 24 hours**

- The confirmation number is **only valid for 24 hours**
- Pharmacy is required to **cancel** the confirmation number if product is not provided to the patient within the required time frame

## Pomalidomide REMS (continued)

- For more information on the Pomalidomide REMS:
  - Call the Pomalidomide REMS Coordinating Center at 1-866-245-7925
  - Visit the Pomalidomide REMS Website at [www.PomalidomideREMSProgram.com](http://www.PomalidomideREMSProgram.com)

### **Did you know?**

The Pomalidomide REMS Coordinating Center has Specialists to educate and train pharmacy staff on the Pomalidomide REMS program guidelines and compliance.