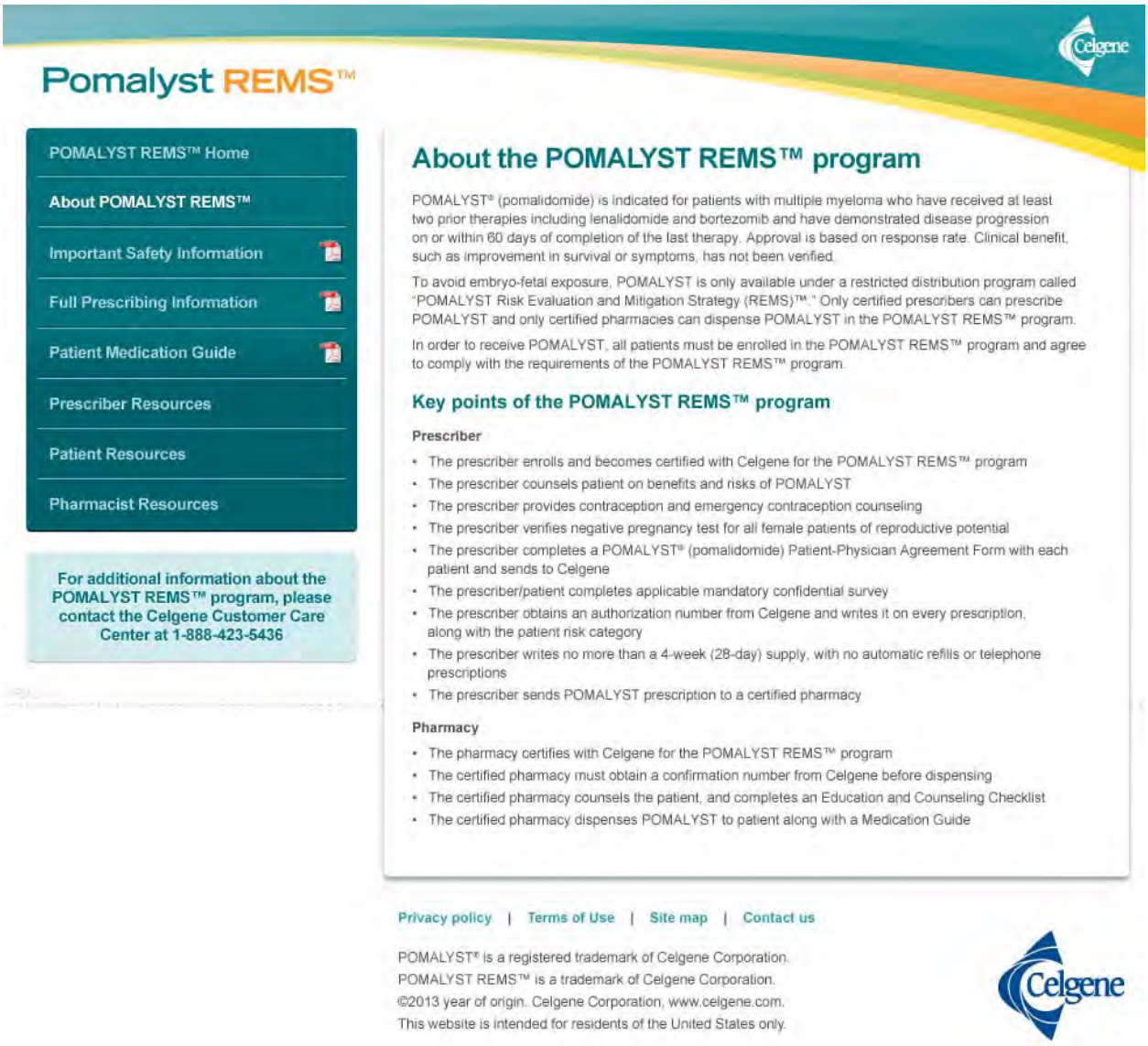
CelgeneRiskManagement.com

Login Page

Home Page (after prescriber logon)

Pomalyst REMS module

www.POMALYSTREMS.com Web site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Full Prescribing Information
Patient Medication Guide
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For additional information about the POMALYST REMS™ program, please contact the Celgene Customer Care Center at 1-888-423-5436
About the POMALYST REMS™ program
POMALYST® (pomalidomide) is indicated for patients with multiple myeloma who have received at least two prior therapies including lenalidomide and bortezomib and have demonstrated disease progression on or within 60 days of completion of the last therapy. Approval is based on response rate. Clinical benefit, such as improvement in survival or symptoms, has not been verified.
To avoid embryo-fetal exposure, POMALYST is only available under a restricted distribution program called "POMALYST Risk Evaluation and Mitigation Strategy (REMS)™." Only certified prescribers can prescribe POMALYST and only certified pharmacies can dispense POMALYST in the POMALYST REMS™ program.
In order to receive POMALYST, all patients must be enrolled in the POMALYST REMS™ program and agree to comply with the requirements of the POMALYST REMS™ program.
Key points of the POMALYST REMS™ program
Prescriber
• The prescriber enrolls and becomes certified with Celgene for the POMALYST REMS™ program
• The prescriber counsels patient on benefits and risks of POMALYST
• The prescriber provides contraception and emergency contraception counseling
• The prescriber verifies negative pregnancy test for all female patients of reproductive potential
• The prescriber completes a POMALYST® (pomalidomide) Patient-Physician Agreement Form with each patient and sends to Celgene
• The prescriber/patient completes applicable mandatory confidential survey
• The prescriber obtains an authorization number from Celgene and writes it on every prescription, along with the patient risk category
• The prescriber writes no more than a 4-week (28-day) supply, with no automatic refills or telephone prescriptions
• The prescriber sends POMALYST prescription to a certified pharmacy
Pharmacy
• The pharmacy certifies with Celgene for the POMALYST REMS™ program
• The certified pharmacy must obtain a confirmation number from Celgene before dispensing
• The certified pharmacy counsels the patient, and completes an Education and Counseling Checklist
• The certified pharmacy dispenses POMALYST to patient along with a Medication Guide
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POMALYST REMS™ is a trademark of Celgene Corporation.
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This website is intended for residents of the United States only.
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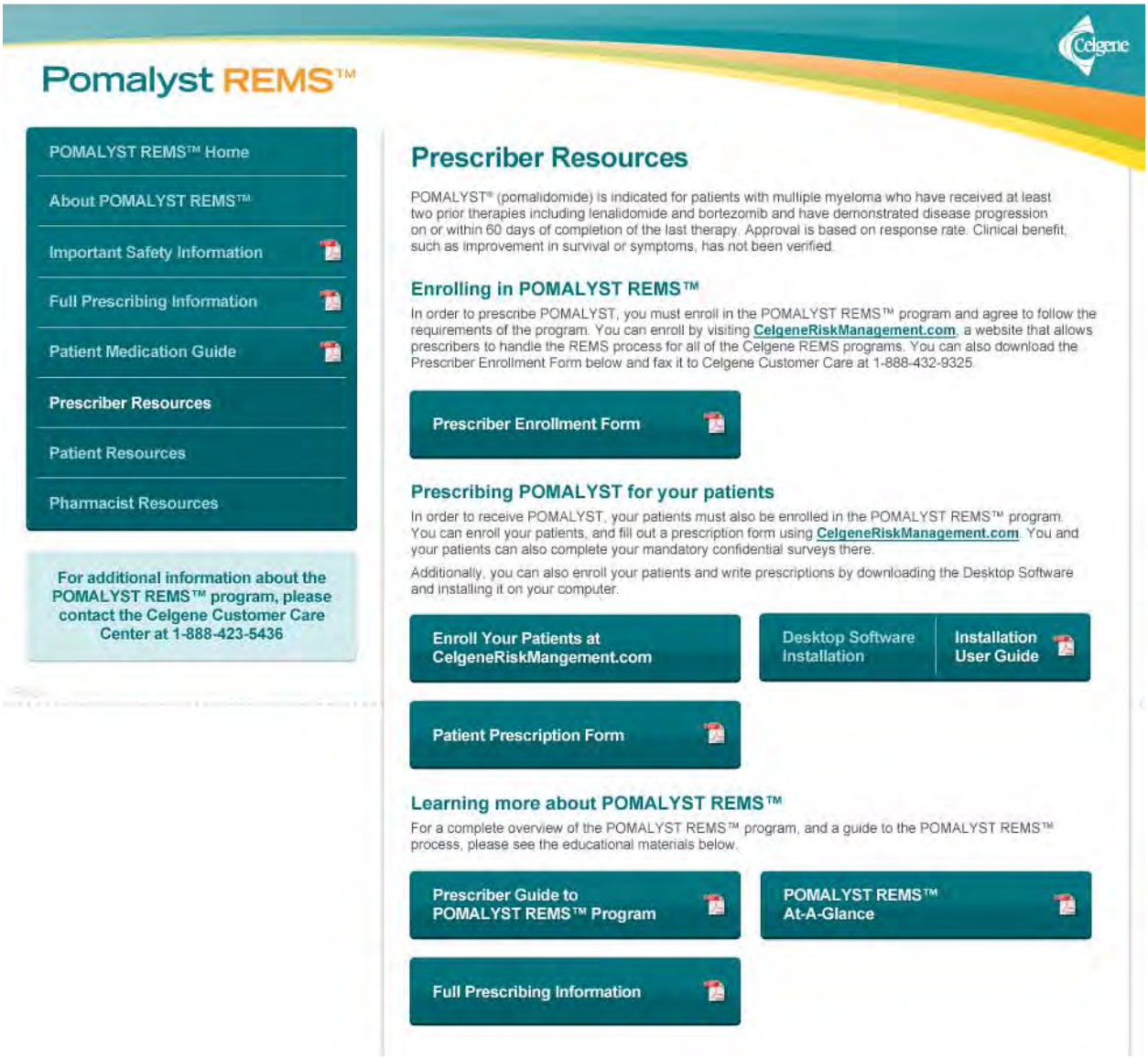


Please report adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST to Celgene using any of the following methods:

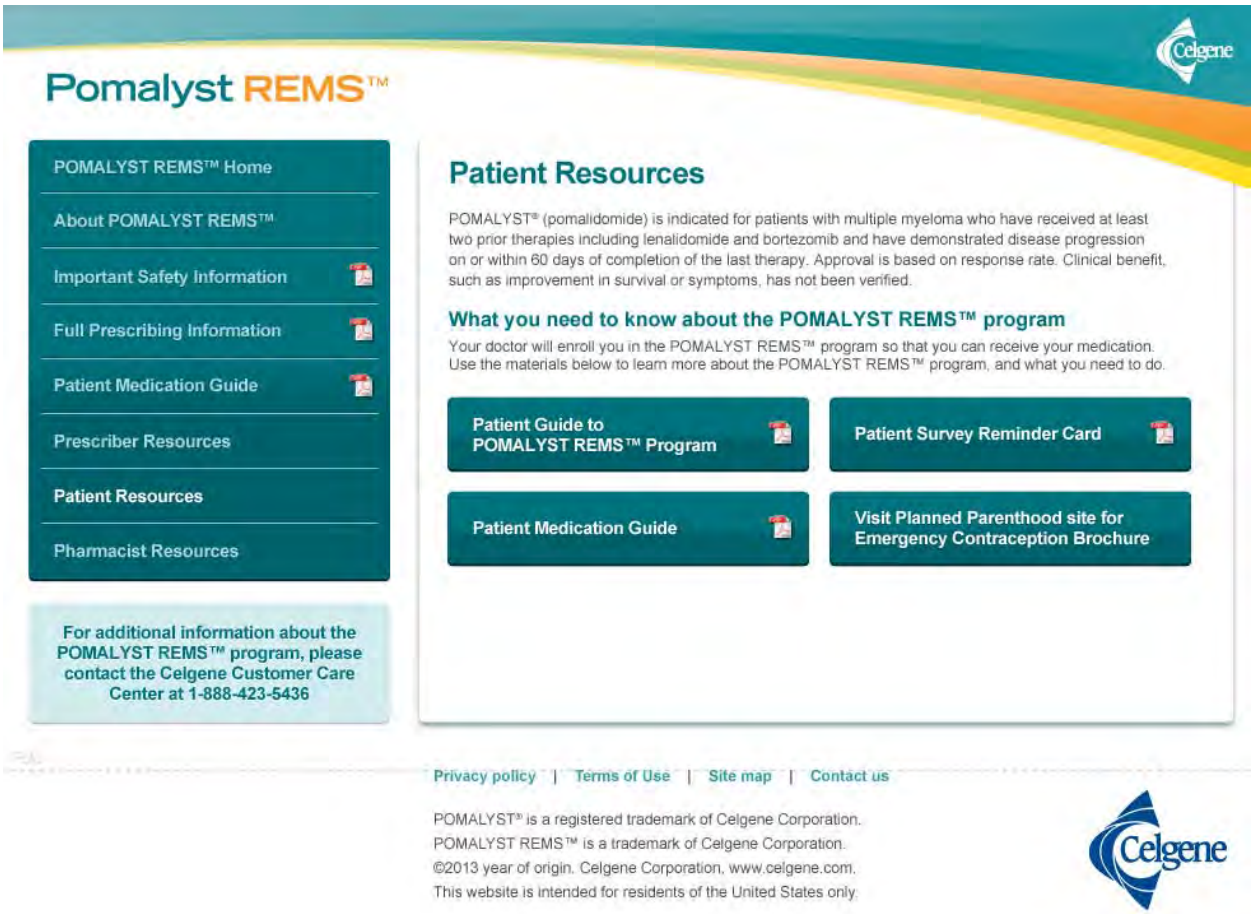
REPORTING TO CELGENE

Email:	drugsafety@celgene.com
Telephone:	1-908-673-9667
Toll-free:	1-800-640-7854 (Global Drug Safety & Risk Management) or 1-888-423-5436 (Celgene Customer Care Center)
Fax:	1-908-673-9115
Mail to:	Global Drug Safety & Risk Management Celgene Corporation 300 Connell Dr. Suite 6000 Berkeley Heights, NJ 07922

REPORTING TO THE FDA

Adverse drug experiences that are suspected to be associated with the use of POMALYST and any suspected pregnancy occurring during the treatment with POMALYST may also be reported to the FDA MedWatch Reporting System using any of the following methods:

Online:	https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm
Telephone:	1-800-332-1088
Fax:	1-800-332-0178
Mail to:	MedWatch 5600 Fishers Lane Rockville, MD 20852-9787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What you need to know about the POMALYST REMS™ program
Your doctor will enroll you in the POMALYST REMS™ program so that you can receive your medication. Use the materials below to learn more about the POMALYST REMS™ program, and what you need to do.
Patient Guide to POMALYST REMS™ Program
Patient Survey Reminder Card
Patient Medication Guide
Visit Planned Parenthood site for Emergency Contraception Brochure
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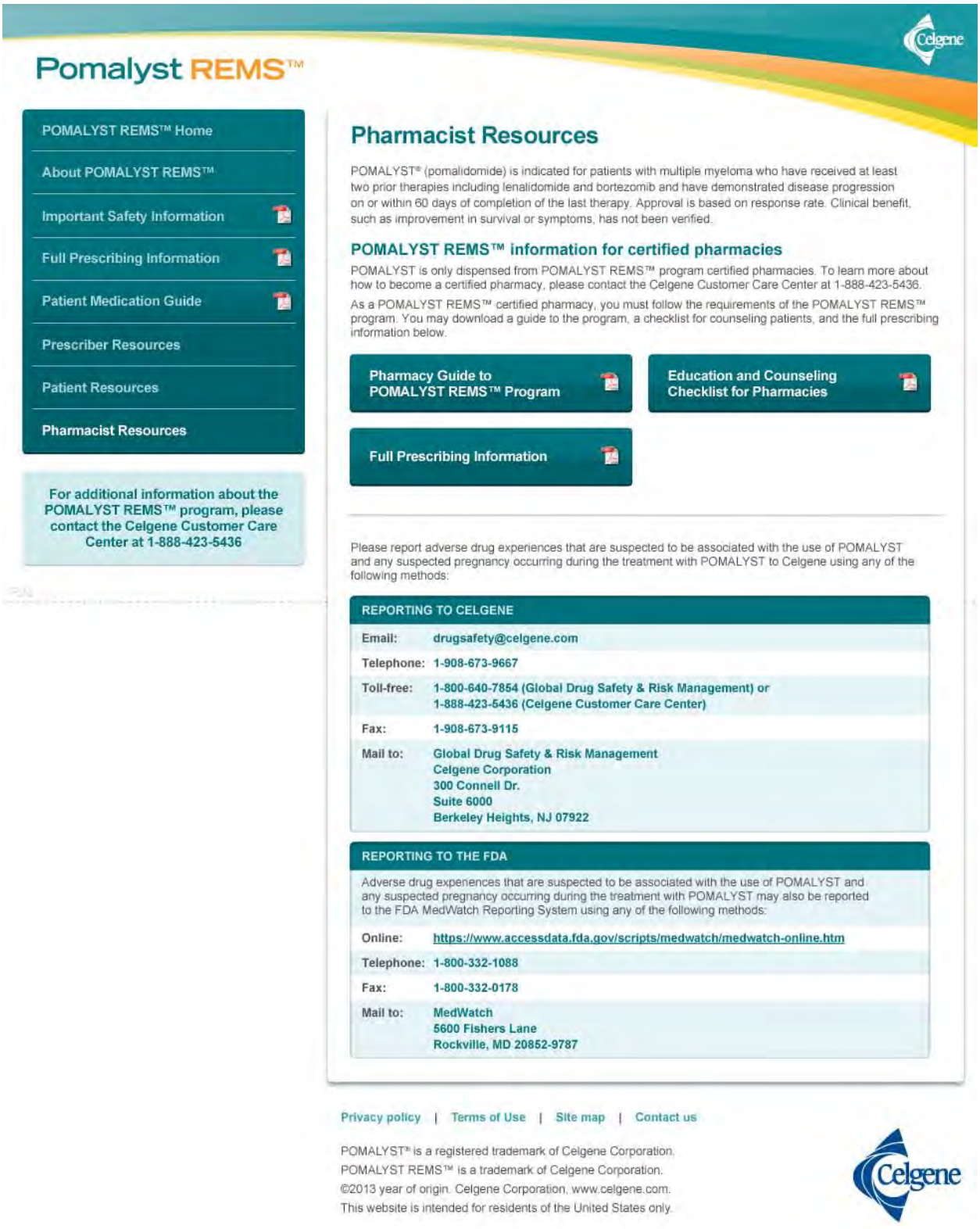

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POMALYST REMS™ information for certified pharmacies

POMALYST is only dispensed from POMALYST REMS™ program certified pharmacies. To learn more about how to become a certified pharmacy, please contact the Celgene Customer Care Center at 1-888-423-5436.

As a POMALYST REMS™ certified pharmacy, you must follow the requirements of the POMALYST REMS™ program. You may download a guide to the program, a checklist for counseling patients, and the full prescribing information below.

- Pharmacy Guide to POMALYST REMS™ Program
- Education and Counseling Checklist for Pharmacies
- Full Prescribing Information

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Mail to:	MedWatch 5600 Fishers Lane Rockville, MD 20852-9787

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