

Bosentan REMS Transition Q/A

All Stakeholders:

- 1. When will the transition take place?
 - The Bosentan REMS will transition to the new REMS Administrator on Monday, June 27, 2022
- 2. Will the Bosentan REMS Contact Center and Website be available during the system transition weekend?
 - The Bosentan REMS Contact Center and Website will be **unavailable** during the system transition weekend, beginning 8:00pm ET Friday, June 24, 2022.
 - The Bosentan REMS Contact Center and Website will be **available** following the system transition, beginning 8:00am ET Monday, June 27, 2022.
 - Contact information for the Bosentan REMS will remain the same
 - o Website: www.BosentanREMSProgram.com
 - Phone Number: 1-866-359-2612Fax Number: 1-800-730-8231
- 3. Where can I learn more about this system transition?
 - A pre-recorded webinar can be viewed at <u>www.BosentanREMSwebinars.com</u>.
- 4. Will my current login work on Monday, June 27, 2022, post-transition?
 - As part of the transition, all information, except for your password, will be migrated to the new REMS Administrator. If you have not reset your password via the link provided to your email on Sunday, June 26, 2022, you will be prompted to create a new password at initial login to the Bosentan REMS Website following the transition.

O Prescribers:

1. Will need to verify your Certification ID and NPI number, along with your email address.

O Pharmacy AR's:

1. Will need to verify your Enrollment ID and NPI, NCPDP, or DEA, along with your email address.

O Pharmacy Staff:

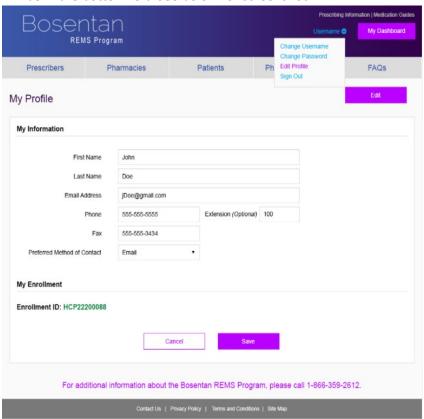
- 1. Will need to verify your Enrollment ID and NPI, NCPDP, or DEA, along with your email address.
- 5. Will patients experience any changes?
 - No, patient requirements remain the same in the Bosentan REMS. However, since
 pharmacies cannot obtain a PDA during transition weekend, bosentan cannot be
 dispensed via an outpatient or specialty pharmacy between 8:00pm ET Friday, June 24,
 2022, until 8:00am ET Monday, June 27, 2022.

- 6. How do I know if the pharmacy uses the REMS Pharmacy Network (pharmacy switch) when obtaining a PDA?
 - Pharmacies that currently utilize the "switch" receive the Pre-Dispense Authorization (PDA) determination through their pharmacy network claim adjudication software and requires no outside processing. Non-"switch" pharmacy users utilize the www.BosentanREMSProgram.com website or call the Bosentan REMS Contact Center to obtain a PDA. If you are still unsure how your pharmacy is classified, we recommend reaching out to your Authorized Representative for the pharmacy in question or calling the Bosentan REMS Contact Center.

All Pharmacy and Staff:

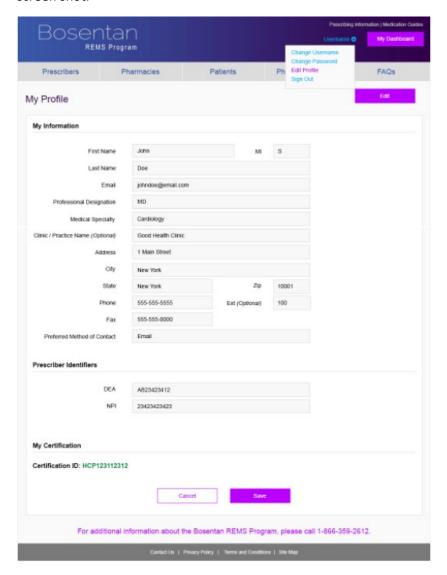
- 1. Will I or my pharmacy need to recertify/re-enroll in the Bosentan REMS?
 - All currently certified pharmacies and the associated Authorized Representative and enrolled Pharmacy will remain certified/enrolled in the Bosentan REMS following the transition.
 - All pharmacy locations for chain pharmacies will transfer to the new REMS
 Administrator and no action specific to recertifying or reenrolling is needed prior to or
 after the transition by the Authorized Representative.
- 2. How should pharmacy staff prepare for the transition?
 - Currently enrolled Pharmacy Staff should ensure that they are able to log into the Bosentan REMS Website, update their email address (if necessary), and note their Enrollment IDs.
 - Pharmacy Staff that support a pharmacy currently using the REMS Pharmacy Network "Switch" should create a user ID if they do not already have one.
 - Where can pharmacy staff locate their enrollment ID?
 - i. Enrollment IDs are located under the "My Profile" section (see screenshot on page 3)
 - Pharmacy's Authorized Representative (AR) should educate all staff about upcoming changes.
 - On Sunday, June 26, 2022, users will receive an email with a link to reset their passwords.
- 3. What is changing as part of the transition?
 - For outpatient pharmacies that previously used the Contact Center or the Bosentan REMS Website to generate a Pre-Dispense Authorization (PDA), there is no change.
 - For outpatient/chain pharmacies that previously used the REMS Pharmacy Network
 "Switch" to obtain a PDA, the switch will no longer be available after 8:00pm ET Friday,
 June 24, 2022.
 - i. Pharmacies will need to obtain PDAs by either logging into the Bosentan REMS Website or calling the Contact Center.
 - For inpatient pharmacies, there is no change to the process for completing an Inpatient REMS Requirement Verification.

- Pharmacies will be able to enter Testing and Patient Counseling Information via the Bosentan REMS Website.
 - If the required liver testing, pregnancy testing, or patient counseling has not been confirmed, the pharmacy can confirm with the patient or prescriber that the testing or counseling has been completed and enter this confirmation on the Bosentan REMS Website.
- Pharmacies will no longer be able to enter Patient Testing and Counseling via the Interactive Voice Response (IVR) system.
- 4. How many days is a generated PDA valid for?
 - There will be no change with the transition. There is no expiration date for a PDA. If bosentan is not dispensed, the pharmacy should reverse the PDA on the Bosentan REMS Website.
- 5. Will an outpatient or chain pharmacy location be able to dispense bosentan during the system transition weekend, beginning 8:00pm ET Friday, June 24, 2022 until 8:00am ET Monday, June 27, 2022?
 - Bosentan cannot be dispensed during the time that the Bosentan REMS Website will
 unavailable due to the system transition. As inpatient pharmacies do not need to
 receive a PDA prior to the dispensing, bosentan can still be dispensed in an inpatient
 setting over the transition weekend.
- 6. As a pharmacy staff member, how do I update my email and locate my Enrollment ID?
 - Upon login to the application, you will choose "Edit Profile" from the dropdown next to "Username". You will be able to view and edit your email address. Your Enrollment ID will be in the bottom left. See below for screenshot.



All Prescribers:

- 1. What is changing as part of the transition?
 - Prescribers will be able to add Prescriber Designee(s) via the Bosentan REMS Website:
 - Prescriber Designees must complete their enrollment on the Bosentan REMS
 Website following being added by the prescriber.
 - Prescriber Designees will be able to update patient information after the patient has been enrolled.
 - Prescriber Designees will be able to confirm completion of liver testing and/or pregnancy testing and patient counseling.
- 2. As a prescriber, how do I update my email?
 - Upon login to the application, you will choose "Edit Profile" from the dropdown next to "Username". You will be able to view and edit your email address. See below for a screen shot.



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