

Risk Evaluation and Mitigation Strategy (REMS) Document

Part A. Aved¹ REMS Program

I. Administrative Information

Application Number: NDA 22219

Application Holder: Endo Pharmaceuticals, Inc.

Initial REMS Approval: 03/2014

Most Recent REMS Update: 12/2018

II. REMS Goals

The goals and objectives of the Aved REMS are to mitigate the negative outcomes associated with Aved-induced pulmonary oil microembolism (POME) and anaphylaxis by:

1. Ensuring that Aved is dispensed only in certified healthcare settings that have immediate access on-site to equipment and personnel trained to manage POME and anaphylaxis
2. Informing healthcare providers that Aved can cause POME and anaphylaxis, which have the potential to lead to serious medical consequences (e.g., respiratory distress and syncope);
3. Informing healthcare providers about the safe use of Aved, including proper administration technique and patient observation; and
4. Informing patients about the risks of POME and anaphylaxis associated with Aved and the importance of remaining at the healthcare setting for 30 minutes after each injection.

III. REMS Requirements

Endo Pharmaceuticals, Inc. must ensure that healthcare providers, patients, healthcare settings, and wholesalers-distributors comply with the following requirements:

1. Healthcare Providers who prescribe Aved must:

- | | |
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| To become certified to prescribe | <ol style="list-style-type: none">1. Review Aved's Prescribing Information.2. Review the following: Education Program for Healthcare Providers.3. Successfully complete the Knowledge Assessment and submit it to the REMS Program.4. Enroll in the REMS by completing the Healthcare Provider Enrollment Form and submitting it to the REMS Program. |
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¹ The AVEED-specific requirements contained in this document apply until the date of full approval of the first abbreviated new drug application (ANDA) referencing AVEED.

Before treatment initiation (first dose)	<ol style="list-style-type: none"> 5. Counsel the patient on the risks, including pulmonary oil embolism (POME) and anaphylaxis, and the need to remain at the healthcare setting for 30 minutes following each injection using the Patient Guide. 6. Provide the patient with a copy of Patient Guide.
During treatment, before each injection	<ol style="list-style-type: none"> 7. Counsel the patient on the risks, including pulmonary oil embolism (POME) and anaphylaxis, and the need to remain at the healthcare setting for 30 minutes following each injection using Patient Guide. Provide a copy of the Patient Guide to patient.

2. Patients who are prescribed Aveed:

Before treatment initiation	<ol style="list-style-type: none"> 1. Receive counseling from the prescriber on the risks, including pulmonary oil microembolism (POME) and anaphylaxis, and the need to remain at the healthcare setting for 30 minutes following each injection using Patient Guide.
Before administering	<ol style="list-style-type: none"> 2. Receive counseling on risks, including POME and anaphylaxis, and the need to remain at the healthcare setting for 30 minutes following each injection from the prescriber using Patient Guide.
After administration, for 30 minutes	<ol style="list-style-type: none"> 3. Be monitored for pulmonary oil embolism (POME) or anaphylaxis by remaining at the healthcare setting after the injection.

3. Healthcare settings that dispense Aveed must:

To become certified to dispense	<ol style="list-style-type: none"> 1. Have immediate access to the necessary equipment and personnel to manage POME and anaphylaxis on-site. 2. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the healthcare setting. 3. Have the authorized representative review the Education Program for Healthcare Settings. 4. Have the authorized representative enroll in the REMS Program by completing the Healthcare Settings Enrollment Form and submitting it to the REMS Program. 5. Train all relevant staff involved in dispensing Aveed using the Education Program for Healthcare Settings. 6. Establish processes and procedures to verify that all healthcare providers at the healthcare setting who prescribe Aveed are certified prior to prescribing Aveed, each patient is counseled before administration of the drug, and each patient is observed within the healthcare setting for 30 minutes following each injection.
Before dispensing	<ol style="list-style-type: none"> 7. Verify the prescriber is certified.

Before administering	8.	Counsel the patient on the risk of POME and anaphylaxis. Provide the patient with a copy of the Patient Guide .
After administering, for 30 minutes	9.	Assess the patient for POME and anaphylaxis.
To maintain certification to dispense	10.	Have a new authorized representative enroll in the REMS Program by completing the Healthcare Settings Enrollment Form if the authorized representative changes.
To maintain certification to dispense, every 2 years	11.	Have authorized representative review the Education Program for Healthcare Settings
	12.	Have the authorized representative re-enroll in the REMS Program by completing the Healthcare Settings Enrollment Form
At all times	13.	Not distribute, transfer, loan, or sell Aveed, except to certified dispensers with the same authorized representative.
	14.	Maintain records of staff training and certified prescribers.
	15.	Comply with audits carried out by Endo Pharmaceuticals, Inc. to ensure that all processes and procedures are in place and are being followed.

4. Wholesalers-distributors that distribute Aveed must:

To be able to distribute	1.	Establish processes and procedures to ensure that the drug is distributed only to certified healthcare settings that have one or more certified prescribers associated with that address.
At all times	2.	Distribute only to certified healthcare settings that have one or more certified prescribers associated with that address.
	3.	Maintain records of all shipments of Aveed.

Endo Pharmaceuticals, Inc. must provide training to healthcare providers who prescribe Aveed. The training includes the following educational materials: [Education Program for Healthcare Providers](#) and [Knowledge Assessment](#). The training is available online, or hardcopy through the Aveed REMS call center.

Endo Pharmaceuticals, Inc. must provide training to healthcare settings that dispense Aveed. The training includes the following educational materials: [Education Program for Healthcare Settings](#). The training is available online or hardcopy through the Aveed REMS call center.

To support REMS Program operations, Endo Pharmaceuticals, Inc. must:

1. Establish and maintain a REMS Program website, www.AveedREMS.com. The REMS Program website must include the capability to complete prescriber and healthcare setting certification or enrollment online, and the option to print the PI, Medication Guide, and REMS materials. All product websites for consumers and healthcare providers must include prominent REMS-specific links to the REMS Program website. The REMS Program website must not link back to the promotional product website(s).
2. Make the REMS Program website fully operational and all REMS materials available through www.AveedREMS.com or by calling the Aveed REMS Program Call Center (1-855-755-0494) within 30 calendar days of REMS modification (XX/XX/XXXX).
3. Establish and maintain a REMS Program call center for REMS participants at 1-855-755-0494.

4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the Aveed REMS Program.
5. Ensure healthcare providers are able to certify, and healthcare settings are able to certify and re-certify, by fax and online.
6. Ensure wholesalers-distributors are able to verify the healthcare setting is certified and has one or more certified prescribers associated with that address prior to distributing Aveed by providing access to the database of certified healthcare settings and prescribers.
7. Provide [REMS Program: An Introduction](#), and the Prescribing Information to REMS participants who (1) attempt to dispense or prescribe Aveed and are not yet certified or (2) inquire about how to become certified.
8. Confirm the healthcare setting has one or more certified prescribers associated with that address before certifying the healthcare setting.
9. Notify healthcare providers and healthcare settings within 2 business days after they become certified in the REMS Program.
10. Provide certified prescribers access to the database of certified healthcare settings.
11. Provide certified healthcare settings access to the database of certified prescribers.
12. Provide wholesalers-distributors access to the database of certified healthcare settings and certified prescribers.

To ensure REMS participants' compliance with the REMS Program, Endo Pharmaceuticals, Inc. must:

13. Verify annually that the authorized representative's name and contact information correspond to those of the current designated authorized representative for the healthcare setting. If different, the healthcare setting must be required to re-certify with a new authorized representative.
14. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: Aveed distribution and dispensing; certification of prescribers and healthcare settings to ensure that all healthcare settings have at least one certified prescriber associated with their address to be able to order and receive Aveed; and audits of REMS participants. These records must be readily available for FDA inspections.
15. Establish a plan for addressing noncompliance with REMS Program requirements.
16. Monitor prescribers, healthcare settings, and wholesalers-distributors on an ongoing basis to ensure the requirements of the REMS are being met. Take corrective action if non-compliance is identified, including de-certification.
17. Audit healthcare settings no later than 180 calendar days after they become certified, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements. Thereafter, healthcare settings are included in the annual audit plan.
18. Take reasonable steps to improve implementation of and compliance with the requirements in the Aveed REMS Program based on monitoring and evaluation of the Aveed REMS Program.

IV. REMS Assessment Timetable

Endo Pharmaceuticals, Inc. must submit REMS Assessments at 6 months, 12 months, and annually thereafter from the date of the initial approval of the REMS. To facilitate inclusion of as much information as possible while allowing reasonable time to prepare the submission, the reporting interval covered by each assessment should conclude no earlier than 60 calendar days before the submission date for that assessment. Endo Pharmaceuticals, Inc. must submit each assessment so that it will be received by the FDA on or before the due date.

V. REMS Materials

The following materials are part of the Aveed REMS:

Enrollment Forms:

Prescriber:

1. [Healthcare Provider Enrollment Form](#)

Healthcare Setting:

2. [Healthcare Setting Enrollment Form](#)

Training and Educational Materials:

Prescriber:

3. [Education Program for Healthcare Providers](#)
4. [Knowledge Assessment](#)
5. [REMS Program: An Introduction](#)

Patient:

6. [What You Need To Know About Aveed Treatment: A Patient Guide](#)

Healthcare Setting:

7. [Education Program for Healthcare Settings](#)
8. [REMS Program: An Introduction](#)

Other Materials:

9. [REMS Program website](#)

AVEED® REMS Healthcare Provider Enrollment Form

Instructions

AVEED is only available through the AVEED Risk Evaluation and Mitigation Strategy (REMS) Program. In order to prescribe AVEED, a healthcare provider must:

1. Ensure that your healthcare setting is enrolled. You cannot complete certification until your healthcare setting is enrolled.
2. Review the AVEED REMS Education Program for Healthcare Providers, including the Prescribing Information.
3. Successfully complete the AVEED REMS Knowledge Assessment.
4. Complete and submit this one-time AVEED REMS Healthcare Provider Enrollment Form.

For online enrollment processing, please go to **www.AveedREMS.com**.

For enrollment via fax, please complete all required fields on the next page and fax the page to **1-855-755-0495**. You will receive enrollment confirmation via your preferred method of communication (email or fax) within two business days.

For questions regarding the AVEED REMS Program, please either visit **www.AveedREMS.com** or call the AVEED REMS Program at **1-855-755-0494**.

Enrollment is not required for non-prescribing healthcare providers who will administer AVEED.

Healthcare Provider Responsibilities

By completing this form, I attest that:

- I understand that AVEED is only available through the AVEED REMS Program and that I must comply with the program requirements in order to prescribe and administer AVEED.
- I completed the AVEED REMS Education Program, including review of the AVEED Prescribing Information, and successfully completed the AVEED REMS Knowledge Assessment.
- I understand how to inject AVEED properly.
- I understand the risks of serious pulmonary oil microembolism (POME) reactions and anaphylaxis following the administration of AVEED, which have the potential to lead to serious medical consequences (e.g., respiratory distress and syncope), and how to manage these risks.
- Prior to initiating treatment and before each injection, I agree to provide a copy of “What You Need To Know About AVEED Treatment: A Patient Guide” to each patient and review it with them to inform them about the risk of serious POME reactions and anaphylaxis and the need to remain in my healthcare setting for **30 minutes** following each AVEED injection.
- I acknowledge that my healthcare setting must be a certified healthcare setting.
- I understand that each patient must be observed in the healthcare setting for **30 minutes** following each AVEED injection in order to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis following the administration of AVEED.
- I agree that personnel from the AVEED REMS Program may contact me to gather further information or resolve discrepancies or to provide other information related to the AVEED REMS Program.
- I understand that Endo Pharmaceuticals Solutions Inc. (Endo), its agents and contractors, such as the distributors, may contact me via phone, mail or email to survey me on the effectiveness of the program requirements for the AVEED REMS Program.
- I understand the importance of reporting serious events of POME and anaphylaxis following AVEED treatment.
- I attest that my healthcare setting has immediate access on-site to equipment and personnel trained to manage POME and anaphylaxis.

To report suspected adverse events, contact Endo at 1-800-462-3636, FDA at 1-800-FDA-1088 or **www.fda.gov/medwatch/report.htm**.

HEALTHCARE PROVIDER INFORMATION (*REQUIRED FIELDS):

M.D. D.O. Physician Assistant Nurse Practitioner Other _____

SPECIALTY:

Endocrinology Primary Care Urology Other _____

*First Name (please print) MI *Last Name (please print) *Email Address

*Phone Number Ext *DEA Number State License Number and State

*Prescriber NPI *Fax Number

*Healthcare Setting Name

*Address

*City *State *Zip

*Preferred Method of Communication (please select **one**)

Email Fax

I understand that this enrollment and certification only applies to me, and does not apply to any healthcare setting that employs me or in which I may have an interest.

*Healthcare Provider Signature * Date (MM/DD/YYYY)

HEALTHCARE PROVIDER INFORMATION (continued)

Please use the form below to list the names of additional affiliated healthcare settings, if necessary.

Name of associated HCS (please print)

Name of associated HCS (please print)

Name of associated HCS (please print)

If you plan on faxing this form to the Program, please provide your Prescriber NPI so we can associate these healthcare settings with your stakeholder record. You can provide this information below:

Prescriber NPI: _____

AVEED® REMS Healthcare Setting Enrollment Form

This form may be used to register a new healthcare setting, change the information for a certified healthcare setting (e.g., name of the Authorized Representative), or for reenrollment (required every two years).

Instructions

AVEED is only available through the AVEED Risk Evaluation and Mitigation Strategy (REMS) Program. In order to dispense and administer AVEED, each healthcare setting must:

1. Designate an Authorized Representative.
2. Review the AVEED REMS Education Program for Healthcare Settings, including the Prescribing Information.
3. Complete and sign the Healthcare Setting Enrollment Form. This Enrollment must be renewed every 2 years.
4. Associate certified Prescribing Healthcare Providers to your account. Your healthcare setting is not eligible to receive AVEED until you have associated at least one certified Prescribing Healthcare Provider.
5. Implement the necessary staff training and processes to comply with the AVEED REMS Program requirements.

For online enrollment, please go to **www.AveedREMS.com**.

For enrollment via fax, please complete all required fields on the next page and fax the page to **1-855-755-0495**. You will receive enrollment confirmation via your preferred method of communication (email or fax) within two business days.

For questions regarding the AVEED REMS Program, please either visit **www.AveedREMS.com** or call the AVEED REMS Program at **1-855-755-0494**.

Authorized Representative Responsibilities

I am the Authorized Representative designated by my healthcare setting to coordinate the activities of the AVEED REMS Program. I agree to comply with the following program requirements:

- I understand that my healthcare setting must be certified with the AVEED REMS Program and have at least one certified prescriber associated with my facility to be able to order, receive or administer AVEED.
- I have completed the AVEED REMS Education Program for Healthcare Settings.
- I understand the risks of serious pulmonary oil microembolism (POME) reactions and anaphylaxis following the administration of AVEED.
- I understand this healthcare setting must verify the current Authorized Representative annually and renew its enrollment in the AVEED REMS Program every two years from the date of initial enrollment.
- This healthcare setting has immediate access on-site to equipment and personnel to manage POME or anaphylaxis.
- This healthcare setting will establish procedures and protocols that are subject to audit, to help ensure compliance with the safe use conditions required in the AVEED REMS Program, including the following:
 - All Healthcare Providers (HCPs) who prescribe AVEED in my healthcare setting are specially certified prior to prescribing AVEED and a record of such training must be maintained.
 - All non-prescribing HCPs who administer AVEED in my healthcare setting are trained and a record regarding such training must be maintained.
 - Prior to initiating treatment and before each injection, review with and provide a copy of “What You Need To Know About AVEED Treatment: A Patient Guide” to each patient to inform them about the risks of serious POME reactions and anaphylaxis.
 - To observe each patient administered AVEED for **30 minutes** at my healthcare setting following each injection in order to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis following the administration of AVEED.
- Not to loan, sell or transfer AVEED to another pharmacy, healthcare setting, prescriber, institution or distributor, except in the case where the transfer is to another certified healthcare setting (unique ship-to site address) where I am also the Authorized Representative.
- This healthcare setting must not dispense AVEED for home or patient self-administration.
- To make available to Endo Pharmaceuticals Solutions Inc. (Endo), and/or a designated third party or the FDA, documentation to verify understanding of, and adherence to, the requirements of the AVEED REMS Program.
- I understand that this certified healthcare setting must recertify in the AVEED REMS Program if the healthcare setting designates a new Authorized Representative.

THIS FORM IS BEING USED TO (CHECK ONE):

- Register a new healthcare setting
- Change the information for a certified healthcare setting
- Re-enrollment of a certified healthcare setting
- For change of information or reenrollment, provide HCS ID: FAC

AUTHORIZED REPRESENTATIVE INFORMATION (*REQUIRED FIELDS)

- M.D.
- D.O.
- Nurse
- Physician Assistant
- Practice Manager
- Other _____

*First Name (please print) _____ MI _____ *Last Name (please print) _____

Title _____ *Email Address _____ *Phone Number Ext _____ *Fax Number _____

*Preferred Method of Communication (please select one) Email Fax

Yes No **Does this healthcare setting have the necessary on-site equipment and personnel to manage POME or anaphylaxis?**

I understand that this enrollment only applies to me as the designated Authorized Representative of this healthcare setting. I will complete a separate enrollment form for each healthcare setting (unique ship-to site address) for which my designation and responsibilities extend. Failure to enroll a healthcare setting and have certified healthcare providers in the AVEED REMS program will result in the inability to receive shipments of AVEED.

Healthcare Setting Authorized Representative Signature* _____ Date* (MM/DD/YYYY) _____

HEALTHCARE SETTING INFORMATION (*REQUIRED FIELDS)

*Healthcare Setting Name _____

*DEA Number (On file with distributor account) _____

*Address _____

*City _____ *State _____ *ZIP _____

Setting Type:

- Group practice
- Independent practice
- Institution
- Central Ordering Pharmacy
- Infusion Center
- Other _____

*Phone Number _____ *Fax Number _____ *Email Address _____

Fax this page to **1-855-755-0495**.

CERTIFIED HEALTHCARE PROVIDERS (PLEASE LIST ALL CERTIFIED HEALTHCARE PROVIDERS ASSOCIATED WITH THIS FACILITY)

*First Name (please print)	MI	*Last Name (please print)	DEA/NPI Number
*First Name (please print)	MI	*Last Name (please print)	DEA/NPI Number
*First Name (please print)	MI	*Last Name (please print)	DEA/NPI Number
*First Name (please print)	MI	*Last Name (please print)	DEA/NPI Number

Fax this page to **1-855-755-0495**.



Rx Only

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August 2018 www.AveedREMS.com 1-800-462-ENDO (3636)

AVEED[®] REMS Education Program for Healthcare Providers

This Education Program Includes Information About:

- AVEED REMS Program requirements
- Serious POME reactions and anaphylaxis with AVEED injection
- Proper administration of AVEED
- Counseling your patient
- Required Knowledge Assessment

What is the AVEED REMS (Risk Evaluation and Mitigation Strategy) Program?

A REMS is a strategy to manage known or potential risks associated with a drug, and is required by the FDA to ensure that the benefits of the drug outweigh its risks. AVEED is available only under a restricted program called the AVEED REMS Program because of the risks of serious pulmonary oil microembolism (POME) reactions and anaphylaxis. The AVEED REMS Education Program is designed to train healthcare providers (HCPs) who prescribe and/or administer AVEED about these risks.

- **Prescribing Healthcare Providers** must be certified in the AVEED REMS Program to be able to prescribe AVEED. Prescribing Healthcare Providers cannot complete certification until their primary healthcare setting is enrolled.
- **Healthcare settings** must be certified in the AVEED REMS Program and have one or more associated certified prescribing healthcare providers to be able to order AVEED.
- **Non-Prescribing Healthcare Providers** who will administer AVEED to patients must review the AVEED REMS Education Program for Healthcare Providers before injecting AVEED.

Steps for Healthcare Provider Certification:

- 1 Ensure that your healthcare setting is enrolled. You will not be able to complete certification until your healthcare setting is enrolled.
- 2 Review the AVEED REMS Education Program, including the Prescribing Information
- 3 Successfully complete the 10 question Knowledge Assessment
- 4 Complete and sign the one-time Healthcare Provider Enrollment Form

The AVEED REMS Education Program, Knowledge Assessment, Healthcare Provider Enrollment Form, and other AVEED REMS Program tools are available online at www.AveedREMS.com or by contacting the AVEED REMS Program at 1-855-755-0494 to request materials.

You can review the educational materials, enroll, and complete the knowledge assessment online at www.AveedREMS.com or review the printed versions and fax your enrollment form and knowledge assessment.

You will not be able to prescribe AVEED without completing your certification in the AVEED REMS Program.

Healthcare Setting Certification

Each healthcare setting must also be certified in the AVEED REMS Program and have one or more associated certified prescribing healthcare providers to be able to order, dispense, and administer AVEED. Visit www.AveedREMS.com for more information on healthcare setting certification.

Indication

AVEED® (testosterone undecanoate) injection is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired)
- Hypogonadotropic hypogonadism (congenital or acquired)

AVEED should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of POME and anaphylaxis.

The safety and efficacy of AVEED in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established. The safety and efficacy of AVEED in males less than 18 years old have not been established.

Serious Risks of POME and Anaphylaxis

With each AVEED injection, there is a potential for serious POME reactions or anaphylaxis to occur. These reactions can occur after any injection of AVEED during the course of therapy, including after the first dose.

The signs and symptoms of serious POME reactions and anaphylaxis overlap. It is important to observe patients in your healthcare setting for 30 minutes after each AVEED injection to determine whether medical intervention is necessary.

Serious POME reactions

POME occurring after an AVEED injection is believed to be caused by tiny droplets of oil, in which the testosterone undecanoate has been dissolved, that have traveled to the lungs.

- POME is **not** a blood clot
- There is a risk of POME occurring with each injection of AVEED

Symptoms of POME

The following symptoms of POME have been reported with AVEED:

- | | | | | |
|-----------------|---|---------------------|---|-----------------|
| - cough | ⋮ | - throat tightening | ⋮ | - hyperhidrosis |
| - urge to cough | ⋮ | - chest pain | ⋮ | - dyspnea |
| - dizziness | ⋮ | - syncope | ⋮ | |

- The majority of these events lasted a few minutes and resolved with supportive measures, e.g., by patient reassurance and/or administration of supplemental oxygen
- Some of the events lasted up to several hours and in some cases, emergency care and/or hospitalization were required

Anaphylaxis

Episodes of anaphylaxis, including life-threatening reactions, have been reported to occur following AVEED injection.

Strategies That May Mitigate These Risks:

- Take proper precautions and avoid injecting AVEED intravascularly
- Inject AVEED slowly (over 60 to 90 seconds)
- AVEED should not be used or should be discontinued in men with any known hypersensitivity to AVEED or to any of its ingredients (testosterone undecanoate, refined castor oil, benzyl benzoate)

• 30 Minute Post-Injection Patient Observation

- Observe patients in your healthcare setting for a period of 30 minutes after each AVEED injection to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis
- The majority of cases reported occurred during or within 30 minutes of the injection

- Your healthcare setting must have immediate access on-site to equipment and personnel trained to manage serious POME reactions and anaphylaxis

Proper Administration

AVEED is for intramuscular use only. Intravascular injection may lead to POME.

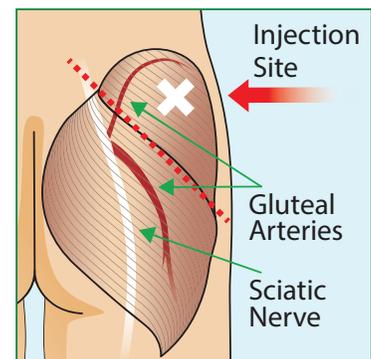
Only healthcare providers trained in the proper injection technique for AVEED should administer AVEED.

Proper Injection Technique for AVEED Intramuscular Injection

1. The site for injection for AVEED is the gluteus medius muscle site located in the upper outer quadrant of the buttock. Care must be taken to avoid the needle hitting the superior gluteal arteries and sciatic nerve.

2. Following antiseptic skin preparation, enter the muscle and maintain the syringe at a 90° angle with the needle in its deeply imbedded position. Grasp the barrel of the syringe firmly with one hand. With the other hand, pull back on the plunger to aspirate for blood. **IF BLOOD APPEARS IN THE SYRINGE DO NOT PROCEED WITH THE INJECTION**, as this is an indication that a blood vessel may have been punctured. Immediately withdraw the needle completely and replace it.

3. If no blood is aspirated, reinforce the current needle position to avoid any movement of the needle and slowly (**over 60 to 90 seconds**) depress the plunger carefully and at a constant rate, until all the medication has been delivered. Be sure to depress the plunger completely with sufficient controlled force. Withdraw the needle.



4. Observe the patient in the healthcare setting for 30 minutes after the injection in order to provide appropriate medical treatment in the event of a serious POME reaction or anaphylaxis.

Patient Counseling

With each injection of AVEED:

- Review the AVEED Patient Counseling Tool (“What You Need to Know about AVEED Treatment: A Patient Guide”) with patients and caregivers.
- Give the Patient Counseling Tool to the patient to read during their 30-minute wait in your healthcare setting.

Explain to patients:

- The importance of providing an accurate medical history about any previous allergic reactions to AVEED or its components (testosterone undecanoate, castor oil and benzyl benzoate)
- AVEED can only be administered by a trained HCP in a certified healthcare setting
- The risks of serious POME reactions and anaphylaxis associated with AVEED
- POME is not a blood clot
- How to recognize the symptoms of serious POME reactions and a severe allergic reaction (anaphylaxis)
- Report signs and symptoms to the healthcare setting staff immediately. These include:

<ul style="list-style-type: none"> - feeling dizzy or fainting - hoarseness or trouble speaking - trouble breathing - feeling flushed - itching, rash, or hives 	<ul style="list-style-type: none"> - coughing or feeling the need to cough - tightness in your throat - numbness and tingling in your arms - swelling of the face, throat or tongue 	<ul style="list-style-type: none"> - feeling very sweaty - chest pain - feeling unwell - stomach pain or vomiting
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The importance of waiting in the healthcare setting for 30 minutes post-injection to provide for appropriate medical treatment in the event of a serious POME reaction or anaphylaxis.

- The AVEED REMS Patient Counseling Tool contains an AVEED Injection Tracking Sheet. The purpose of this sheet is that the patient’s injection time and scheduled departure time – 30 minutes apart – can be recorded by the HCP and given to the patient. The patient will then know when they have waited 30 minutes and can leave the healthcare setting accordingly. Explain the importance of this tool to your patients and encourage them to use it every time.

<i>Healthcare Professional to Complete</i>		
Time I received the Injection	How long I need to wait in the office	Time I can leave the office
	30 minutes	

- Who to contact immediately if they experience any of the above signs or symptoms after leaving the healthcare setting
- Both serious POME reactions and anaphylaxis can occur after any injection of AVEED during the course of therapy, including after the first dose
- Who they should contact with any questions they may have regarding AVEED

Reporting of Adverse Events

Report suspected adverse events to Endo Pharmaceuticals at 1-800-462-3636. You also may report adverse event information to the FDA MedWatch Reporting System at 1-800-FDA-1088.

All AVEED REMS documents are available at www.AveedREMS.com, or call the AVEED REMS Program at 1-855-755-0494.

The completion of the AVEED REMS Education Program and enrollment process is NOT a substitute for reading the AVEED Prescribing Information and Medication Guide.

Other Resources for Healthcare Providers

The AVEED REMS Program does not include training on how to manage POME and anaphylaxis.

HCPs should also be familiar with current standards for the treatment of anaphylaxis. Treatment guidelines are provided by the following organizations:

- The American Academy of Allergy, Asthma and Immunology (AAAAI)
(<http://www.aaaai.org/home.aspx>)
- National Institute of Allergy and Infectious Diseases (NIAID)
(<http://www.niaid.nih.gov/Pages/default.aspx>)
- World Allergy Organization (WAO)
(<http://www.worldallergy.org/anaphylaxis/>)

Knowledge Assessment

Complete all 10 questions.

To become a certified healthcare provider in the AVEED REMS Program you will need to answer ALL questions correctly.

- Complete the Knowledge Assessment, populate and sign the one-time Healthcare Provider Enrollment Form online at **www.AveedREMS.com**

OR

- Fax your responses to all 10 Knowledge Assessment questions and a completed and signed one-time Healthcare Provider Enrollment Form to 1-855-755-0495

If you complete the Knowledge Assessment and Enrollment Form online, correspondence from the AVEED REMS Program confirming your enrollment and certification in the AVEED REMS Program will be sent via the preferred communication method (email or fax) selected on your enrollment.

If you return the Knowledge Assessment and Enrollment Form via fax, you will receive correspondence from the AVEED REMS Program via the preferred communication method (email or fax) selected on your enrollment form within two business days. Correspondence may include:

- How to retake the Knowledge Assessment, if necessary
- How to correct missing or invalid information provided on the Enrollment Form and resubmit to the AVEED REMS Program for re-processing, if necessary
- A confirmation of your enrollment and certification in the AVEED REMS Program (which requires no further action)

Questions 1-5 Multiple Choice. Select only **one** answer for each question.

QUESTION 1

Which of the following would be an appropriate patient for AVEED?

- A. 45-year-old female with a history of androgen insensitivity syndrome
- B. 16-year-old male with symptoms of delayed puberty and hypogonadism
- C. 40-year-old male with history of congenital hypogonadism complaining of fatigue and decreased libido
- D. 54-year-old male with a family history of prostate cancer and complaining of decreased urine output

QUESTION 2

Which of the following symptoms most accurately describes a patient experiencing an episode of post-injection pulmonary oil microembolism (POME)?

- A. Severe palpitations and diaphoresis one week post AVEED injection
- B. Headache, nausea, or vomiting prior to AVEED injection
- C. Rash, skin irritation, and erythema surrounding the injection site
- D. Cough, dyspnea, chest pain, and dizziness 5 minutes post-injection

QUESTION 3

Why should a patient wait in the healthcare setting for 30 minutes following each AVEED injection?

- A. To make sure their insurance information is accurate
- B. To provide them with follow-up appointment information
- C. To provide appropriate medical treatment in the event of a serious POME reaction or anaphylaxis
- D. To ensure that they do not eat for 30 minutes after an injection

QUESTION 4

What is the proper injection route and injection site for AVEED?

- A. Intramuscular injection in the gluteus muscle
- B. Intramuscular injection in the deltoid
- C. Intravascular injection in the gluteus muscle
- D. None of the above

If you plan on faxing this Knowledge Assessment to the Program please provide your Prescriber NPI so we can associate your progress with your stakeholder record. You can provide this information below.

Prescriber NPI: _____

QUESTION 5

Prior to administering an AVEED injection, you must counsel the patient using the Patient Counseling Tool “What You Need to Know about AVEED Treatment: A Patient Guide” and the AVEED Medication Guide on all of the following EXCEPT:

- A. The risks of serious POME and anaphylaxis associated with AVEED
- B. Techniques for aseptic self-injection of AVEED
- C. The importance of waiting 30 minutes post-injection in the healthcare setting in order to provide appropriate medical treatment in the event of a serious POME reaction or anaphylaxis
- D. Signs and symptoms of an adverse reaction and how to report them

Questions 6-10 (True or False)

QUESTION 6

In order to administer AVEED, my healthcare setting must also be certified.

T F

QUESTION 7

As a patient continues receiving AVEED injections, their risk of experiencing pulmonary oil microembolism (POME) or anaphylaxis decreases.

T F

QUESTION 8

If a patient experiences a hypersensitivity reaction (e.g., angioedema and/or hives) following an AVEED injection, it is appropriate to continue therapy with AVEED.

T F

QUESTION 9

Patients who feel comfortable with self-administering AVEED may do so after receiving their initial injection in the healthcare setting.

T F

QUESTION 10

It is a requirement of the AVEED REMS to review the Patient Counseling Tool “What you need to know about AVEED Treatment: A Patient Guide” with patients and provide them with a copy prior to each injection of AVEED.

T F

If you plan on faxing this Knowledge Assessment to the Program please provide your Prescriber NPI so we can associate your progress with your stakeholder record. You can provide this information below.

Prescriber NPI: _____

AVEED® REMS Program: An Introduction

What is the AVEED REMS (Risk Evaluation and Mitigation Strategy) Program?

A REMS is a strategy to manage known or potential risks associated with a drug, and is required by the FDA to ensure that the benefits of the drug outweigh its risks. AVEED is available only under a restricted program called the AVEED REMS Program because of the risks of serious pulmonary oil microembolism (POME) reactions and anaphylaxis.

AVEED REMS Program Requirements

Healthcare settings must be certified in the AVEED REMS Program to be able to order AVEED. One representative needs to enroll per healthcare setting (the “Authorized Representative”).

Prescribing Healthcare Providers must be certified in the AVEED REMS Program to be able to prescribe AVEED. Prescribing healthcare providers cannot complete certification until their healthcare setting is enrolled.

Non-Prescribing Healthcare Providers who will administer AVEED to patients must be trained on the *AVEED REMS Education for Healthcare Providers*.

Safe Use Actions You Must Implement for AVEED

- Ensure all healthcare providers who prescribe AVEED at your healthcare setting are certified in the AVEED REMS program
- Ensure all non-prescribing healthcare providers who administer AVEED are trained on:
 - Serious POME reactions and anaphylaxis
 - Proper administration of AVEED
 - Patient counseling
 - 30 minute post-injection patient observation
- Establish a process to ensure all patients are counseled about AVEED and receive *What You Need To Know About AVEED Treatment: A Patient Guide*

• **Establish a process to ensure each patient is observed for 30 minutes at the healthcare setting after each AVEED injection**

- Have the necessary equipment and personnel on-site to manage serious POME reactions or anaphylaxis
- Ensure a patient is NEVER provided AVEED for home or self-injection

Steps for Healthcare Setting Certification

1. Designate an Authorized Representative. This may be a prescribing or non-prescribing healthcare provider, practice manager or any responsible individual in the healthcare setting.
2. Review *AVEED REMS Education Program for Healthcare Settings*, including the Prescribing Information.
3. Complete and sign the Healthcare Setting Enrollment Form. This Enrollment must be renewed every 2 years.
4. Associate certified Prescribing Healthcare Providers to your account. Your healthcare setting is not eligible to receive AVEED until you have associated at least one certified Prescribing Healthcare Provider.
5. Implement the necessary staff training and processes to comply with the AVEED REMS Program requirements.
6. Recertify in the AVEED REMS Program if the healthcare setting designates a new Authorized Representative.

Steps for Healthcare Provider Certification

1. Ensure that your healthcare setting is enrolled. Prescribing healthcare providers will not be able to complete certification until their healthcare setting is enrolled.
Review *AVEED REMS Education Program for Healthcare Providers*, including the Prescribing Information.
2. Successfully complete the 10 question Knowledge Assessment.
3. Complete and sign the one-time Healthcare Provider Enrollment Form.

Where to Find REMS Program Information and Resources

The AVEED REMS Education Program, Healthcare Setting Enrollment Form, and other AVEED REMS Program tools are available online at www.AveedREMS.com or by contacting the AVEED REMS Program at 1-855-755-0494 to request materials.

What You Need to Know About AVEED® Treatment: A Patient Guide

Patients: Go over this Patient Guide with your healthcare provider.

- Ask any questions you have each time you get an AVEED injection.
- Keep this important safety information about the serious risks of AVEED.

Healthcare Providers: Review this Patient Guide with your patients before each injection

- Give them a copy to take home.
- On the back of this sheet, record the time the patient received AVEED and the time 30 minutes later when they can leave.

What is AVEED?

AVEED is a prescription medicine that contains testosterone. AVEED is used to treat adult men who don't make enough male hormone. You and your healthcare provider have determined that AVEED is an appropriate treatment for you. It is not known if AVEED is safe or effective to treat men who have low testosterone due to aging or for use in children younger than 18 years old.

AVEED contains testosterone in castor oil. Your healthcare provider will inject AVEED in the muscle of your buttocks. AVEED is then slowly released from your muscle into your body. You can only get AVEED in your doctor's office, clinic, or hospital because of the possible serious side effects.

What are the Most Serious Side Effects with AVEED Treatment?

- **Pulmonary oil microembolism (POME), a serious lung problem.** Tiny droplets of the castor oil in AVEED could travel from your muscle to your lungs after you get AVEED treatment. You can have symptoms such as coughing, trouble breathing, chest pain, or other symptoms. POME is not a blood clot that travels to your lungs.
- **Severe or life-threatening allergic reaction (anaphylaxis).** Signs and symptoms of a life-threatening allergic reaction are listed below.

These reactions can occur with any AVEED injection during your treatment, even if you have not had a reaction occur before.

Each time you get AVEED, stay in the doctor's office, clinic, or hospital for 30 minutes to be sure you do not have symptoms of POME or a severe allergic reaction.

What are the Signs and Symptoms of POME or Severe Allergic Reactions After Receiving AVEED?

POME and a severe allergic reaction can have the same symptoms, which may include one or more of the following:

- | | | |
|--|---|--|
| <ul style="list-style-type: none"> - trouble breathing - tightness in your throat - hoarseness or trouble speaking - chest pain - feeling very sweaty | <ul style="list-style-type: none"> - swelling of your face, tongue or throat - feeling unwell - feeling dizzy or fainting - coughing or feeling the need to cough | <ul style="list-style-type: none"> - itching, rash, or hives - numbness and tingling in your arms - stomach pain or vomiting - feeling flushed |
|--|---|--|

- **If you have any signs or symptoms of a serious reaction, get medical help right away:**
 - **During the 30-minute wait:** Tell your healthcare provider about your symptoms.
 - **After you leave the doctor's office, clinic, or hospital:** Follow your healthcare provider's instructions on getting emergency medical care.

These are **NOT** all the possible side effects of AVEED. See the AVEED Medication Guide that you were given or talk to your healthcare provider for medical advice about other side effects.

What Can I Do to Help Reduce the Risks of AVEED?

1. Tell your healthcare provider if you have ever had an allergic reaction to AVEED or any of its ingredients.

The ingredients in AVEED are:

- testosterone undecanoate
- castor oil
- benzyl benzoate

2. Know the signs and symptoms of POME and a severe allergic reaction.

3. **Each time you get AVEED treatment, stay in the doctor's office, clinic, or hospital for 30 minutes to be sure you do not have symptoms of POME or a severe allergic reaction. Check with your healthcare provider before leaving the office, clinic, or hospital.**

How Often Will I Receive an Injection of AVEED?

You will get 1 injection when you start, 1 injection 4 weeks later, and then 1 injection every 10 weeks thereafter.

Where Can I Get More Information on AVEED?

- Your healthcare provider will give you the AVEED Medication Guide to read each time you get an AVEED injection.
- You can also find additional information at www.AveedREMS.com or
- Contact the AVEED REMS Program at **1-855-755-0494**.

Injection Tracking Sheet

Use this tracking sheet so you know when 30 minutes have passed since your AVEED injection. If you have no symptoms of POME or a severe allergic reaction, check with your healthcare provider before you leave.

<i>Healthcare Professional to Complete</i>		
Time I received the Injection	How long I need to wait in the office	Time I can leave the office
	30 Minutes	

AVEED[®] REMS Education Program for Healthcare Settings

This Educational Piece Includes Information About:

- Serious POME reactions and anaphylaxis with AVEED Injection
- AVEED REMS Program requirements to implement in your healthcare setting
- Ordering AVEED

What is the AVEED REMS (Risk Evaluation and Mitigation Strategy) Program?

A REMS is a strategy to manage known or potential risks associated with a drug, and is required by the FDA to ensure that the benefits of the drug outweigh its risks. AVEED is available only under a restricted program called the AVEED REMS Program because of the risks of serious pulmonary oil microembolism (POME) reactions and anaphylaxis. The AVEED REMS Education Program for Healthcare Settings is designed to train healthcare setting Authorized Representatives on these serious risks, and AVEED REMS Program requirements to order AVEED for their healthcare setting.

- **Healthcare settings** must be certified in the AVEED REMS Program to be able to order AVEED and have at least one certified prescriber associated with the facility to be able to order, receive, or administer AVEED. Healthcare providers are associated to a healthcare setting by:
 - The healthcare provider selecting the healthcare setting during the healthcare provider enrollment process, or
 - Being associated to the healthcare setting by the Authorized Representative via the REMS Call Center
- **Prescribing Healthcare Providers** must be certified in the AVEED REMS Program to be able to prescribe AVEED.
- **Non-Prescribing Healthcare Providers** who will administer AVEED to patients must review the AVEED REMS Education for Healthcare Providers before injecting AVEED.

Steps for Healthcare Setting Certification

1	Designate an Authorized Representative
2	Review the AVEED REMS Education Program for Healthcare Settings, including the Prescribing Information
3	Verify annually the Authorized Representative on record
4	Complete and sign the Healthcare Setting Enrollment Form. This Enrollment must be renewed every 2 years
5	Associate certified Prescribing Healthcare Providers to your account. Your healthcare setting is not eligible to receive AVEED until you have associated at least one certified Prescribing Healthcare Provider.
6	Implement the necessary staff training and processes to comply with the AVEED REMS Program requirements

The AVEED REMS Education Program, Healthcare Setting Enrollment Form, and other AVEED REMS Program tools are available online at www.AveedREMS.com or by contacting the AVEED REMS Program at 1-855-755-0494 to request materials.

You can review the educational materials and enroll online at www.AveedREMS.com, or review the printed versions and fax your enrollment form to the AVEED REMS Program at 1-855-755-0495.

Your healthcare setting will not be able to order AVEED unless you meet these two requirements:

1. Your **healthcare setting** is certified
2. There is at least one **prescriber** certified in the Aveed REMS Program **associated with your healthcare setting**

Who Can Be An Authorized Representative?

An Authorized Representative at the healthcare setting can be:

- Prescribing healthcare providers
- Non-prescribing healthcare providers
- Practice manager, or
- Any responsible individual in the healthcare setting

Please check with your manager to ensure the appropriate person represents the healthcare setting and attests to the enrollment requirements as stated on the Healthcare Setting Enrollment Form.

- One representative needs to enroll per healthcare setting (the “Authorized Representative”). One Authorized Representative can manage more than one healthcare setting. The chosen Authorized Representative must be verified as current annually.
- Please note, there are no AVEED REMS requirements for staff at a healthcare setting that will not be involved with prescribing or administering AVEED.

Indication

AVEED® (testosterone undecanoate) injection is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired)
- Hypogonadotropic hypogonadism (congenital or acquired)

AVEED should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of POME and anaphylaxis.

The safety and efficacy of AVEED in men with “age-related hypogonadism” (also referred to as “late-onset hypogonadism”) have not been established. The safety and efficacy of AVEED in males less than 18 years old have not been established.

Serious Risks of POME and Anaphylaxis

With each AVEED injection, there is a potential for serious POME reactions or anaphylaxis to occur. These reactions can occur after any injection of AVEED during the course of therapy, including after the first dose.

The signs and symptoms of serious POME reactions and anaphylaxis overlap. It is important to observe patients in your healthcare setting for **30 minutes** after each AVEED injection to determine whether medical intervention is necessary.

Serious POME reactions

POME occurring after an AVEED injection is believed to be caused by tiny droplets of oil, in which the testosterone undecanoate has been dissolved, that have traveled to the lungs.

- POME is **not** a blood clot
- There is a risk of POME occurring with each injection of AVEED

Symptoms of POME

The following symptoms of POME have been reported with AVEED:

- | | | | | |
|-----------------|---|---------------------|---|-----------------|
| - cough | ⋮ | - throat tightening | ⋮ | - hyperhidrosis |
| - urge to cough | ⋮ | - chest pain | ⋮ | - dyspnea |
| - dizziness | ⋮ | - syncope | ⋮ | |

- The majority of these events lasted a few minutes and resolved with supportive measures e.g., by patient reassurance and/or administration of supplemental oxygen
- Some of the events lasted up to several hours and in some cases, emergency care and/or hospitalization were required

Anaphylaxis

Episodes of anaphylaxis, including life-threatening reactions, have been reported to occur following AVEED injection.

Strategies to implement in your healthcare setting to mitigate these risks:

- Ensure all healthcare providers who prescribe AVEED are certified in the AVEED REMS program
 - Maintain up-to-date records
 - Ensure all non-prescribing healthcare providers who administer AVEED are trained on:
 - Serious POME reactions and anaphylaxis
 - Patient counseling
 - 30-minute post-injection patient observation
 - Proper administration of AVEED
 - Maintain an up-to-date record of training
 - Establish a process to ensure all patients are counseled about AVEED and receive “What You Need To Know About AVEED Treatment: A Patient Guide”
- **Establish a process to ensure each patient is observed for 30 minutes at your healthcare setting after each AVEED injection**
- Have the immediate access on-site to equipment and personnel to manage serious POME reactions or anaphylaxis
 - Ensure a patient is NEVER provided AVEED for home or self-injection
 - Establish a process to ensure that your healthcare setting recertifies if the Authorized Representative changes

How Do I Order AVEED?

Contact the AVEED REMS Program at 1-855-755-0494.

The completion of the AVEED REMS Education Program and enrollment process is NOT a substitute for reading the AVEED Prescribing Information and Medication Guide.

All AVEED REMS documents are available at www.AveedREMS.com, or call the AVEED REMS Program at 1-855-755-0494.

Endo AVEED Website Screenshot Document

AVEED REMS Program

October 24, 2018

v 3.0

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AVEED[®] REMS (Risk Evaluation and Mitigation Strategy) Program

What is the AVEED REMS Program?

A REMS is a strategy to manage known or potential serious risks associated with a drug product and is required by the FDA to ensure the benefits of the drug outweigh its risks. The purpose of the AVEED REMS Program is to inform Healthcare Providers, Healthcare Settings and patients about the risks of:

- Serious pulmonary oil microembolism (POME) reactions
- Anaphylaxis

AVEED REMS Program Requirements

- **Training** — for Healthcare Providers and authorized representatives of Healthcare Settings on serious POME reactions and anaphylaxis associated with AVEED, safe use strategies, and REMS Program requirements.
- **Certification** — for [Prescribing Healthcare Providers](#) by completing training, Knowledge Assessment and enrollment into the AVEED REMS Program.
- **Certification** — for [Healthcare Settings](#) by completing training and enrollment into the AVEED REMS Program. Each Healthcare Setting must be certified in the AVEED REMS Program and have at least one certified prescriber associated with the facility to be able to order, receive, or administer AVEED.
- **Patient counseling** — about the risks of serious POME reactions and anaphylaxis. Healthcare Providers must give patients the Patient Counseling Tool: *"What You Need to Know About AVEED Treatment: A Patient Guide."*
- **Patient observation** — patients must remain in Healthcare Setting for 30 minutes after each AVEED injection.

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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2. Home Page – Signed In

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AVEED[®] REMS (Risk Evaluation and Mitigation Strategy) Program

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3. Healthcare Provider Certification – Home Page

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AVEED® REMS Program

Healthcare Provider Certification

Prescribing Healthcare Providers must be certified in the AVEED REMS Program in order to prescribe AVEED.

Certification in the AVEED REMS Program includes the following four steps:

- 1** Ensure that your healthcare setting is enrolled. You will not be able to complete certification until your healthcare setting is enrolled.
- 2** Review the AVEED REMS Education Program, including the Prescribing Information
- 3** Successfully complete the 10 question Knowledge Assessment
- 4** Complete and sign the one-time Healthcare Provider Enrollment Form

- You can complete the training and enrollment online by clicking below, or by downloading the print version of the training and faxing your Knowledge Assessment and enrollment form into the AVEED REMS Program at 1-855-755-0495.

[Click here to complete the AVEED REMS Training and Enrollment online](#)

- Non-Prescribing Healthcare Providers must also be trained on the AVEED REMS Education Program for Healthcare Providers.

Enrollment is not required for Non-Prescribing Healthcare Providers. Click below to complete the training online.

[Click here to complete the AVEED REMS Training online](#)

- Your Healthcare Setting must also be certified in the AVEED REMS Program in order for you to prescribe AVEED.

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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Program Materials for Healthcare Provider

-  [AVEED REMS Program: An Introduction](#)
-  [AVEED REMS Education Program for Healthcare Providers](#)
-  [Healthcare Provider Enrollment Form](#)
-  [Patient Counseling Tool: What You Need to Know About AVEED Treatment: A Patient Guide](#)

Adobe® Reader® is required to view all of these PDFs. If you do not have it installed, download it [free here](#).



4. Healthcare Setting Certification - Home Page

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AVEED® REMS Program

Healthcare Setting Certification

Healthcare Settings must be certified in the AVEED REMS Program and have at least one certified prescriber associated with the facility to be able to order, receive, or administer AVEED.

To become certified in the AVEED REMS Program, an Authorized Representative of the Healthcare Setting must do the following:

- 1 Designate an Authorized Representative
- 2 Review the AVEED REMS Education Program for Healthcare Settings, including the Prescribing Information
- 3 Verify annually the Authorized Representative on record
- 4 Complete and sign the Healthcare Setting Enrollment Form. This Enrollment must be renewed every 2 years
- 5 Associate certified Prescribing Healthcare Providers to your account. Your healthcare setting is not eligible to receive AVEED until you have associated at least one certified Prescribing Healthcare Provider
- 6 Implement the necessary staff training and processes to comply with the AVEED REMS Program requirements

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- All healthcare providers at the the healthcare setting must be certified prior to prescribing AVEED.
- Non-Prescribing Healthcare Providers who will administer AVEED to patients must review the AVEED REMS Education for Healthcare Providers before injecting AVEED.

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Program Materials for Healthcare Setting

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What You Need to Know About AVEED® Treatment: A Patient Guide

Patients: Go over this Patient Guide with your healthcare provider.

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- Keep this important safety information about the serious risks of AVEED.

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AVEED contains testosterone in castor oil. Your healthcare provider will inject AVEED in the muscle of your buttocks. AVEED is then slowly released from your muscle into your body. You can only get AVEED in your doctor's office, clinic, or hospital because of the possible serious side effects.

What are the Most Serious Side Effects with AVEED Treatment?

- **Pulmonary oil microembolism (POME), a serious lung problem.** Tiny droplets of the castor oil in AVEED could travel from your muscle to your lungs after you get AVEED treatment. You can have symptoms such as coughing, trouble breathing, chest pain, or other symptoms. POME is not a blood clot that travels to your lungs.
- **Severe or life-threatening allergic reaction (anaphylaxis).** Signs and symptoms of a life-threatening allergic reaction are listed below.

These reactions can occur with any AVEED injection during your treatment, even if you have not had a reaction occur before.

Each time you get AVEED, stay in the doctor's office, clinic, or hospital for 30 minutes to be sure you do not have symptoms of POME or a severe allergic reaction.

What are the Signs and Symptoms of POME or Severe Allergic Reactions After Receiving AVEED?

POME and a severe allergic reaction can have the same symptoms, which may include one or more of the following:

- | | | |
|----------------------------------|---|--------------------------------------|
| - trouble breathing | - swelling of your face, tongue or throat | - itching, rash, or hives |
| - tightness in your throat | - feeling unwell | - numbness and tingling in your arms |
| - hoarseness or trouble speaking | - feeling dizzy or fainting | - stomach pain or vomiting |
| - chest pain | - coughing or feeling the need to cough | - feeling flushed |
| - feeling very sweaty | | |

- **If you have any signs or symptoms of a serious reaction, get medical help right away:**
 - **During the 30-minute wait:** Tell your healthcare provider about your symptoms.
 - **After you leave the doctor's office, clinic, or hospital:** Follow your healthcare provider's instructions on getting emergency medical care.

These are **NOT** all the possible side effects of AVEED. See the AVEED Medication Guide that you were given or talk to your healthcare provider for medical advice about other side effects.

What Can I Do to Help Reduce the Risks of AVEED?

1. Tell your healthcare provider if you have ever had an allergic reaction to AVEED or any of its ingredients. The ingredients in AVEED are:

- testosterone undecanoate
- castor oil
- benzyl benzoate

2. Know the signs and symptoms of POME and a severe allergic reaction.

3. **Each time you get AVEED treatment, stay in the doctor's office, clinic, or hospital for 30 minutes to be sure you do not have symptoms of POME or a severe allergic reaction. Check with your healthcare provider before leaving the office, clinic, or hospital.**

How Often Will I Receive an Injection of AVEED?

You will get 1 injection when you start, 1 injection 4 weeks later, and then 1 injection every 10 weeks thereafter.

Where Can I Get More Information on AVEED?

- Your healthcare provider will give you the AVEED Medication Guide to read each time you get an AVEED injection.
- You can also find additional information at www.AveedREMS.com or
- Contact the AVEED REMS Program at 1-855-755-0494.

Injection Tracking Sheet

Use this tracking sheet so you know when 30 minutes have passed since your AVEED injection. If you have no symptoms of POME or a severe allergic reaction, check with your healthcare provider before you leave.

<i>Healthcare Professional to Complete</i>		
Time I received the Injection	How long I need to wait in the office	Time I can leave the office
	30 Minutes	



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AVEED® REMS Forms & Resources



Adobe® Reader® is required to view all of these PDFs. If you do not have it installed, download it free [here](#).

Resources

-  [AVEED REMS Program: An Introduction](#) (Purpose: To provide an overview of the AVEED REMS Program requirements)
-  [What You Need Know About AVEED Treatment: A Patient Guide](#) (Purpose: To educate patients on the risks of AVEED)
-  [AVEED REMS Education Program for Healthcare Providers \(with Knowledge Assessment\)](#) (Purpose: To educate Healthcare Providers on the proper prescribing of AVEED and understand how to recognize and manage important post-injection reactions)
-  [AVEED REMS Education Program for Healthcare Settings](#) (Purpose: To educate Healthcare Setting Authorized Representatives on the AVEED REMS Program requirements to order, receive, and administer AVEED within their Healthcare Setting)
-  [Full Prescribing Information](#)
-  [Medication Guide](#)

Forms

-  [AVEED REMS Healthcare Provider Enrollment Form](#) (Purpose: Enroll Prescribing Healthcare Providers into the AVEED REMS Program)
-  [AVEED REMS Healthcare Setting Enrollment Form](#) (Purpose: Enroll Healthcare Settings into the AVEED REMS Program)

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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7. Program Enrollment Lookup for Prescribing Healthcare Providers

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

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AVEED® REMS Program Enrollment Lookup

To use the Program Enrollment Lookup, please start by choosing a tab; either Prescribing Healthcare Provider or Healthcare Setting. If searching for a Prescribing Healthcare Provider, please enter the Zip Code or Enrollment ID or DEA Number or last name and state and press the **Search** button. If searching for a Healthcare Setting, please enter the Enrollment ID or the zip code or city and state and press the **Search** button. Search results include contact information and certified participants/locations in the AVEED REMS Program.

Zip Code	Enrollment ID	DEA Number	Last Name	State
<input type="text"/>	-or- <input type="text"/>	-or- <input type="text"/>	-or- <input type="text"/>	-and- <input type="text"/>

The healthcare provider's (HCP's) REMS address does not need to match the healthcare setting (HCS) address. As long as both are enrolled, it is OK to ship.

Enrollment ID	Name	Address	City	State	Zip	Phone
0 item						

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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8. Program Enrollment Lookup for Healthcare Settings

Forgot Username? Forgot Password? Need an Account?

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AVEED® REMS Program Enrollment Lookup

To use the Program Enrollment Lookup, please start by choosing a tab; either Prescribing Healthcare Provider or Healthcare Setting. If searching for a Prescribing Healthcare Provider, please enter the Zip Code or Enrollment ID or DEA Number or last name and state and press the **Search** button. If searching for a Healthcare Setting, please enter the Enrollment ID or the zip code or city and state and press the **Search** button. Search results include contact information and certified participants/locations in the AVEED REMS Program.

Prescribing Healthcare ProviderHealthcare Setting

-or-

-or-

-and-

Show entries

Enrollment ID	Name	Address	City	State	Zip	Phone
FAC001100037635	CVS	4343N	SCOTTSDALE	Arizona	10019	242-343-2423
FAC001100021141	Location One	123 Test Location	SCOTTSDALE	Arizona	86286	480-345-3453
FAC001100044095	Russel Primary care	8901 Thomas st suite 290	Scottsdale	Arizona	13126	480-234-9239 - 480234
FAC001100045096	Second Healthcare setting	345 thomas rd suite 100	scottsdale	Arizona	10029	482-300-3493

1 - 4 of 4 items

9. Website Registration Page

Forgot Username? Forgot Password? Need an Account?



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AVEED™ REMS Program Account Registration

To begin your account setup process in the AVEED REMS Program please complete the fields below and click the **Create My Account** button. The identifier you specify for your Username is unique within the AVEED REMS Program website. Once you have successfully created your user account you'll be able to return to this website using this Username to manage your account within the program.

Account Information

First Name

Last Name

Email Address

Enrollment ID
Optional (If you enrolled via fax, please enter your enrollment ID)

Username

Use Email Address as Username

Password
(Your new password must be at least 8 characters in length and contain at least one letter and one number.)

Confirm Password

I'm not a robot 
reCAPTCHA
Privacy - Terms

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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AVEED® REMS Program Account Registration

Please select one of the following stakeholder types to ensure you are prompted with the AVEED REMS Education that is appropriate to your role:

- Healthcare Setting Authorized Representative** - An individual responsible for enrolling their Healthcare Setting in the AVEED REMS Program. This individual may be a prescribing or non-prescribing Healthcare Provider, a Practice Manager, or any responsible individual within the Healthcare Setting suitable to attest to the enrollment requirements. A Healthcare Setting must be certified in the AVEED REMS Program and have at least one certified prescriber associated with the facility to be able to order, receive, or administer AVEED.
- Prescribing Healthcare Provider** - A Prescribing Healthcare Provider is responsible for prescribing AVEED and/or administering AVEED in an enrolled Healthcare Setting. Prescribing Healthcare Providers must be certified in the AVEED REMS Program to be able to prescribe AVEED. Prescribing Healthcare Providers cannot complete certification until their healthcare setting is enrolled.
- Non-Prescribing Healthcare Provider** - A Healthcare Provider who does not prescribe AVEED but is responsible for administering AVEED in an enrolled Healthcare Setting. Non-Prescribing Healthcare Providers who will administer AVEED must review the AVEED REMS Education for Healthcare Providers before injecting AVEED.

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For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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11. Stakeholder Identification Confirmation for Prescribing Healthcare Provider

Prescribing Healthcare Provider

Based on the response selected, please confirm you are registering as a Prescribing Healthcare Provider.

A Prescribing Healthcare Provider is responsible for prescribing AVEED and/or administering AVEED in an enrolled Healthcare Setting. Prescribing Healthcare Providers must be certified in the AVEED REMS Program to be able to prescribe AVEED. Prescribing Healthcare Providers cannot complete certification until their healthcare setting is enrolled.

If the user you are registering does not meet the definition of a Prescribing Healthcare Provider, please select **Cancel** to change your response; otherwise, please select **Confirm** to continue.

12. Stakeholder Identification Confirmation for Healthcare Setting

Authorized Representative for Healthcare Setting

Based on the response selected, please confirm you are registering as an Authorized Representative for Healthcare Setting.

An Authorized Representative for Healthcare Setting is an individual responsible for enrolling their Healthcare Setting in the AVEED REMS Program. This individual may be a prescribing or non-prescribing Healthcare Provider, a Practice Manager, or any responsible individual within the Healthcare Setting suitable to attest to the enrollment requirements. A Healthcare Setting must be certified in the AVEED REMS Program and have at least one certified prescriber associated with the facility to be able to order, receive, or administer AVEED.

If the user you are registering does not meet the definition of an Authorized Representative for Healthcare Setting, please select **Cancel** to change your response; otherwise, please select **Confirm** to continue.

13. Stakeholder Identification Confirmation for Non-Prescribing Healthcare Provider

Non-Prescribing Healthcare Provider

Based on the response selected, please confirm you are registering as a Non-Prescribing Healthcare Provider.

A Non-Prescribing Healthcare Provider does not prescribe AVEED but is responsible for administering AVEED in an enrolled Healthcare Setting. Non-Prescribing Healthcare Providers who will administer AVEED must review the AVEED REMS Education for Healthcare Providers before injecting AVEED.

If the user you are registering as does not meet the definition of a Non-Prescribing Healthcare Provider, please select **Cancel** to change your response; otherwise, please select **Confirm** to continue.

14. Healthcare Setting Lookup for Prescribing Healthcare Provider

Frank Adam ▾



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AVEED® REMS Program Account Registration

Please provide the zip code or city/state to find your Healthcare Setting Location

Zip Code -or- City -and- State Show entries

Name	Address	City	State	Zip
0 item				

I cannot find my Healthcare Setting

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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15. Prescribing Healthcare Provider Results

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AVEED® REMS Program Account Registration

Please provide the zip code or city/state to find your Healthcare Setting Location

Zip Code: -or- City: -and- State: Show entries

	Name	Address	City	State	Zip
<input type="radio"/>	543654654	43546436 54365	scottsdale	AZ	85251
<input type="radio"/>	DATAWARE HOUSE	4343 n scottsdale rd	SCOTTSDALE	AZ	85251
<input type="radio"/>	TEST	4343 N Scottsdale RD	SCOTTSDALE	AZ	85251
<input type="radio"/>	TEST SETTING	4343 N Scottsdale Rd	Scottsdale	AZ	85251
<input type="radio"/>	TEST SITE TWO	4343 N Scottsdale Rd	SCOTTSDALE	AZ	85251
<input type="radio"/>	TESTING TEST	55354 Test St	SCOTTSDALE	AZ	85251

1 - 6 of 6 items

I cannot find my Healthcare Setting

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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16. Healthcare Setting Lookup for Non-Prescribing Healthcare Provider

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AVEED® REMS Program Account Registration

Please provide the zip code or city/state to find your Healthcare Setting Location

Zip Code -or- City -and- State Show entries

Name	Address	City	State	Zip
0 item				

If the Healthcare Setting you are looking for does not exist in the list above, please contact the Authorized Representative of the setting.

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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17. Non-Prescribing Healthcare Provider Results

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AVEED® REMS Program Account Registration

Please provide the zip code or city/state to find your Healthcare Setting Location

Zip Code: -or- City: -and- State: Show entries

	Name	Address	City	State	Zip
<input type="radio"/>	543654654	43546436 54365	scottsdale	AZ	85251
<input type="radio"/>	DATAWARE HOUSE	4343 n scottsdale rd	SCOTTSDALE	AZ	85251
<input type="radio"/>	TEST	4343 N Scottsdale RD	SCOTTSDALE	AZ	85251
<input type="radio"/>	TEST SETTING	4343 N Scottsdale Rd	Scottsdale	AZ	85251
<input checked="" type="radio"/>	TEST SITE TWO	4343 N Scottsdale Rd	SCOTTSDALE	AZ	85251
<input type="radio"/>	TESTING TEST	55354 Test St	SCOTTSDALE	AZ	85251

1 - 6 of 6 items

If the Healthcare Setting you are looking for does not exist in the list above, please contact the Authorized Representative of the setting.

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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18. Prescribing Healthcare Provider Enrollment Form

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AVEED® REMS Healthcare Provider Enrollment

To enroll as a Prescribing Healthcare Provider in the AVEED REMS Program, please complete the form below and click **Next**. All fields below are required unless otherwise indicated.

Prescribing Healthcare Provider

First Name

Middle Initial (opt)

Last Name

Position/Credential (opt)

Specialty (opt)

Specialty Other

Email Address (opt)

Phone Ext (opt)

DEA Number

State License Number (opt)

State Issued (opt)

Prescriber NPI

Fax

Preferred Method of Communication Email Fax

Healthcare Setting Information

Healthcare Setting Name

Healthcare Setting Address

Healthcare Setting Address 2 (opt)

Healthcare Setting City

Healthcare Setting State

Healthcare Setting Zip

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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19. Prescribing Healthcare Provider Re-Enrollment Form

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AVEED® REMS Healthcare Provider Enrollment

To enroll as a Prescribing Healthcare Provider in the AVEED REMS Program, please complete the form below and click **Next**. All fields below are required unless otherwise indicated.

Prescribing Healthcare Provider

First Name	<input type="text" value="David"/>
Middle Initial	<input type="text"/> (opt)
Last Name	<input type="text" value="Smith"/>
Position/Credential	<input type="text" value="M.D."/> (opt)
Specialty	<input type="text" value="Endocrinology"/> (opt)
Specialty Other	<input type="text"/>
Email Address	<input type="text" value="testuserb@gmail.com"/> (opt)
Phone	<input type="text" value="602-123-4567"/> Ext <input type="text"/> (opt)
DEA Number	<input type="text" value="BS3107424"/>
State License Number	<input type="text" value="15924"/> (opt)
State Issued	<input type="text" value="Wyoming"/> (opt)
Prescriber NPI	<input type="text" value="1548290406"/>
Fax	<input type="text" value="602-123-4567"/>
Preferred Method of Communication	<input checked="" type="radio"/> Email <input type="radio"/> Fax

Healthcare Setting Information

Healthcare Setting Name	<input type="text" value="K MART CORP"/>
Healthcare Setting Address	<input type="text" value="2840 E MAIN ST"/>
Healthcare Setting Address 2	<input type="text"/> (opt)
Healthcare Setting City	<input type="text" value="MESA"/>
Healthcare Setting State	<input type="text" value="Arizona"/>
Healthcare Setting Zip	<input type="text" value="85213"/>

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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20. Healthcare Setting Enrollment Form

Frank am ▾

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AVEED® REMS Healthcare Setting Enrollment

To enroll as an Authorized Representative of a Healthcare Setting in the AVEED REMS Program, please complete the form below and click **Next**. All fields below are required unless otherwise indicated.

Authorized Healthcare Setting Representative

First Name

Middle Initial (opt)

Last Name

Position/Credential (opt)

Other Position/Credential

Title (opt)

Email Address (opt)

Phone Ext (opt)

Fax

Preferred Method of Communication Email Fax

Healthcare Setting Information

Healthcare Setting Name

Healthcare Setting Type (opt)

Other Healthcare Setting Type

Healthcare Setting Address

Healthcare Setting Address 2 (opt)

Healthcare Setting City

Healthcare Setting State

Healthcare Setting Zip

Healthcare Setting Email Address (opt)

Healthcare Setting Phone Ext (opt)

Healthcare Setting Fax

Healthcare Setting DEA Number (on file with distributor account)

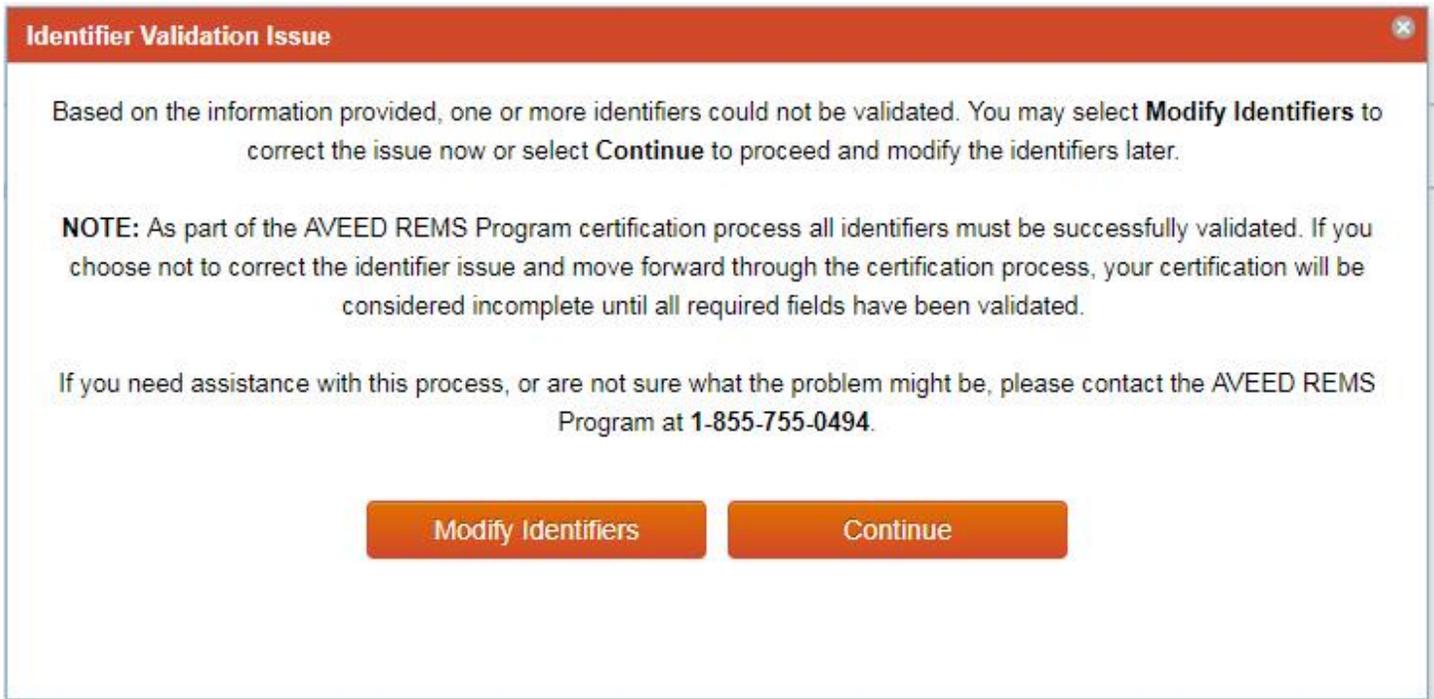
This Form Is Being Used To

Does this healthcare setting have the necessary on-site equipment and personnel to manage POME or anaphylaxis? Yes No

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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21. Enrollment Form with Invalid Identifier Message



Identifier Validation Issue

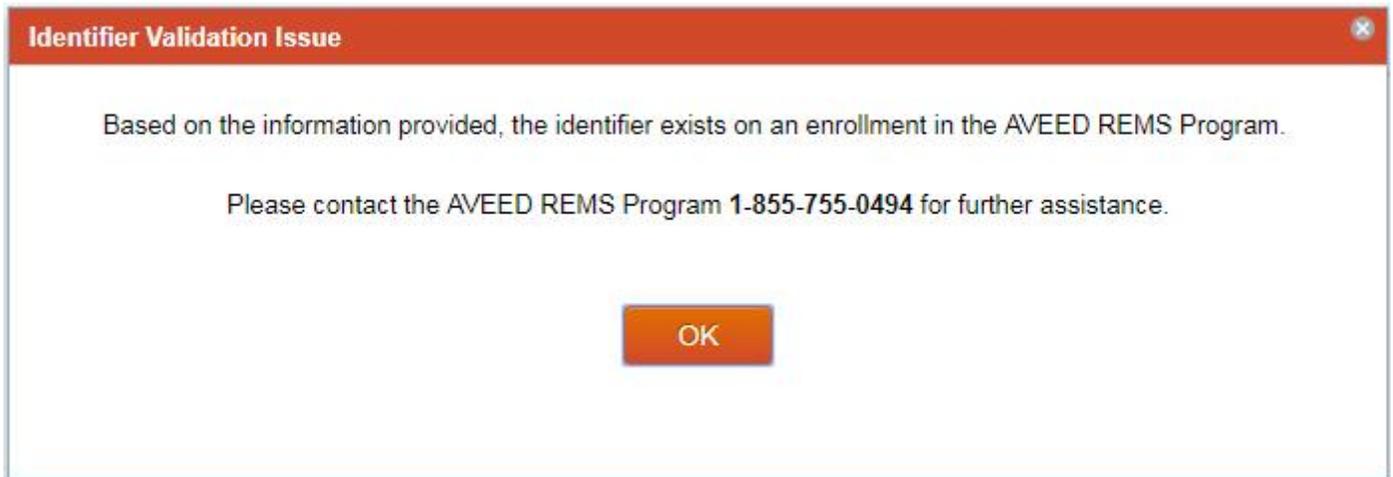
Based on the information provided, one or more identifiers could not be validated. You may select **Modify Identifiers** to correct the issue now or select **Continue** to proceed and modify the identifiers later.

NOTE: As part of the AVEED REMS Program certification process all identifiers 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 AVEED REMS Program at **1-855-755-0494**.

Modify Identifiers **Continue**

22. Enrollment Form with Duplicate Identifier Message



Identifier Validation Issue

Based on the information provided, the identifier exists on an enrollment in the AVEED REMS Program.

Please contact the AVEED REMS Program **1-855-755-0494** for further assistance.

OK

23. Healthcare Setting Identification Complete for Healthcare Providers

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AVEED® REMS Healthcare Setting Identification Complete

Thank you! You may proceed to the AVEED REMS Education Program by clicking the **Education Program** button below.

You must review the AVEED REMS Education Program to become trained on the risks and safe use of AVEED. Alternatively, you may proceed to your **My Account** page to view your progress.

My Account	Education Program
---	--

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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24. Enrollment Form Complete for Healthcare Settings

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AVEED® REMS Enrollment Form Complete

Thank you! You may proceed to the AVEED REMS Education Program by clicking the **Education Program** button below.

You must review the AVEED REMS Education Program to become trained on the risks and safe use of AVEED. Alternatively, you may proceed to your **My Account** page to view your enrollment progress.

[My Account](#) [Education Program](#)

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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25. Education Program Start Page for Healthcare Providers

Frank am ▾

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AVEED[®] REMS Education Program for Healthcare Providers

This Education Program Includes Information About:

- AVEED REMS Program requirements
- Serious POME reactions and anaphylaxis with AVEED injection
- Proper administration of AVEED
- Counseling your patient
- Required Knowledge Assessment

What is the AVEED REMS (Risk Evaluation and Mitigation Strategy) Program?

A REMS is a strategy to manage known or potential risks associated with a drug, and is required by the FDA to ensure that the benefits of the drug outweigh its risks. AVEED is available only under a restricted program called the AVEED REMS Program because of the risks of serious pulmonary oil microembolism (POME) reactions and anaphylaxis. The AVEED REMS Education Program is designed to train healthcare providers (HCPs) who prescribe and/or administer AVEED about these risks.

- **Prescribing Healthcare Providers** must be certified in the AVEED REMS Program to be able to prescribe AVEED. Prescribing Healthcare Providers cannot complete certification until their primary healthcare setting is enrolled.
- **Healthcare Settings** must be certified in the AVEED REMS Program and have one or more associated certified prescribing healthcare providers to be able to order AVEED.
- **Non-Prescribing Healthcare Providers** who will administer AVEED to patients must review the AVEED REMS Education Program for Healthcare Providers before injecting AVEED.

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For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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Steps for Healthcare Provider Certification:

The AVEED REMS Education Program, Knowledge Assessment, Healthcare Provider Enrollment Form, and other AVEED REMS Program tools are available online at www.AveedREMS.com or by contacting the AVEED REMS Program at 1-855-755-0494 to request materials.

You can review the educational materials, enroll, and complete the knowledge assessment online at www.AveedREMS.com or review the printed versions and fax your enrollment form and knowledge assessment.

You will not be able to prescribe AVEED without completing your certification in the AVEED REMS Program.

- 1 Ensure that your healthcare setting is enrolled. You will not be able to complete certification until your healthcare setting is enrolled.
- 2 Review the AVEED REMS Education Program, including the Prescribing Information
- 3 Successfully complete the 10 question Knowledge Assessment
- 4 Complete and sign the one-time Healthcare Provider Enrollment Form

Healthcare Setting Certification

Each healthcare setting must also be certified in the AVEED REMS Program and have one or more associated certified prescribing healthcare providers to be able to order, dispense, and administer AVEED. Visit www.AveedREMS.com for more information on healthcare setting certification.

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For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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Indication

AVEED® (testosterone undecanoate) injection is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired)
- Hypogonadotropic hypogonadism (congenital or acquired)

AVEED should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of POME and anaphylaxis.

The safety and efficacy of AVEED in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. The safety and efficacy of AVEED in males less than 18 years old have not been established.

Serious Risks of POME and Anaphylaxis

With each AVEED injection, there is a potential for serious POME reactions or anaphylaxis to occur. These reactions can occur after any injection of AVEED during the course of therapy, including after the first dose.

The signs and symptoms of serious POME reactions and anaphylaxis overlap. It is important to observe patients in your healthcare setting for 30 minutes after each AVEED injection to determine whether medical intervention is necessary.

Serious POME reactions

POME occurring after an AVEED injection is believed to be caused by tiny droplets of oil, in which the testosterone undecanoate has been dissolved, that have traveled to the lungs.

- POME is **not** a blood clot
- There is a risk of POME occurring with each injection of AVEED

Symptoms of POME

The following symptoms of POME have been reported with AVEED:

- | | |
|-----------------|---------------------|
| - cough | - throat tightening |
| - urge to cough | - chest pain |
| - dyspnea | - dizziness |
| - hyperhidrosis | - syncope |

- The majority of these events lasted a few minutes and resolved with supportive measures, e.g., by patient reassurance and/or administration of supplemental oxygen
- Some of the events lasted up to several hours and in some cases, emergency care and/or hospitalization were required

Anaphylaxis

Episodes of anaphylaxis, including life-threatening reactions, have been reported to occur following AVEED injection.

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For additional information about the AVEED REMS Program, please call 1-855-755-0494.



Strategies That May Mitigate These Risks:

- Take proper precautions and avoid injecting AVEED® intravascularly
- Inject AVEED slowly (over 60 to 90 seconds)
- AVEED should not be used or should be discontinued in men with any known hypersensitivity to AVEED or to any of its ingredients (testosterone undecanoate, refined castor oil, benzyl benzoate)
- **30 Minute Post-Injection Patient Observation**
 - Observe patients in your healthcare setting for a period of 30 minutes after each AVEED injection to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis
 - The majority of cases reported occurred during or within 30 minutes of the injection
- Your healthcare setting must have immediate access on-site to equipment and personnel trained to manage serious POME reactions and anaphylaxis

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For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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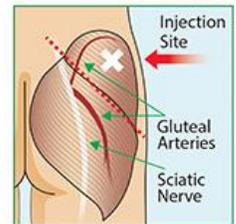
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Proper Administration

AVEED® is for intramuscular use only. Intravascular injection may lead to POME. Only healthcare providers trained in the proper injection technique for AVEED should administer AVEED.

Proper Injection Technique for AVEED Intramuscular Injection

1. The site for injection for AVEED is the gluteus medius muscle site located in the upper outer quadrant of the buttock. Care must be taken to avoid the needle hitting the superior gluteal arteries and sciatic nerve.
2. Following antiseptic skin preparation, enter the muscle and maintain the syringe at a 90° angle with the needle in its deeply imbedded position. Grasp the barrel of the syringe firmly with one hand. With the other hand, pull back on the plunger to aspirate for blood. **IF BLOOD APPEARS IN THE SYRINGE DO NOT PROCEED WITH THE INJECTION**, as this is an indication that a blood vessel may have been punctured. Immediately withdraw the needle completely and replace it.
3. If no blood is aspirated, reinforce the current needle position to avoid any movement of the needle and slowly (**over 60 to 90 seconds**) depress the plunger carefully and at a constant rate, until all the medication has been delivered. Be sure to depress the plunger completely with sufficient controlled force. Withdraw the needle.



4. Observe the patient in the healthcare setting for 30 minutes after the injection in order to provide appropriate medical treatment in the event of a serious POME reaction or anaphylaxis.

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Patient Counseling

With each injection of AVEED®:

- Review the AVEED Patient Counseling Tool ("What You Need to Know about AVEED Treatment: A Patient Guide") with patients and caregivers.
- Give the Patient Counseling Tool to the patient to read during their 30 minute wait in your healthcare setting.

Explain to patients:

- The importance of providing an accurate medical history about any previous allergic reactions to AVEED or its components (testosterone undecanoate, castor oil and benzyl benzoate)
- AVEED can only be administered by a trained HCP in a certified healthcare setting
- The risks of serious POME reactions and anaphylaxis associated with AVEED
- POME is not a blood clot
- How to recognize the symptoms of serious POME reactions and a severe allergic reaction (anaphylaxis)
- Report signs and symptoms to the healthcare setting staff immediately. These include:

<ul style="list-style-type: none"> - trouble breathing - tightness in your throat - hoarseness or trouble speaking - chest pain - feeling very sweaty 	<ul style="list-style-type: none"> - swelling of your face, tongue or throat - feeling unwell - feeling dizzy or fainting - coughing or feeling the need to cough 	<ul style="list-style-type: none"> - itching, rash or hives - numbness and tingling in your arms - stomach pain or vomiting - feeling flushed
--	---	---

The importance of waiting in the healthcare setting for 30 minutes post-injection to provide for appropriate medical treatment in the event of a serious POME reaction or anaphylaxis.

- The AVEED REMS Patient Counseling Tool contains an AVEED Injection Tracking Sheet. The purpose of this sheet is that the patient's injection time and scheduled departure time - 30 minutes apart - can be recorded by the HCP and given to the patient. The patient will then know when they have waited 30 minutes and can leave the healthcare setting accordingly. Explain the importance of this tool to your patients and encourage them to use it every time.

Healthcare Professional to Complete		
Time I received the Injection	How long I need to wait in the office	Time I can leave the office
	30 Minutes	

- Who to contact immediately if they experience any of the above signs or symptoms after leaving the healthcare setting
- Both serious POME reactions and anaphylaxis can occur after any injection of AVEED during the course of therapy, including after the first dose
- Who they should contact with any questions they may have regarding AVEED

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Reporting of Adverse Events

Report suspected adverse events to Endo Pharmaceuticals at 1-800-462-3636. You also may report adverse event information to the FDA MedWatch Reporting System at 1-800-FDA-1088.

All AVEED® REMS documents are available at www.AveedREMS.com, or call the AVEED REMS Program at 1-855-755-0494.

The completion of the AVEED REMS Education Program and enrollment process is NOT a substitute for reading the AVEED Prescribing Information and Medication Guide.

Other Resources for Healthcare Providers

The AVEED REMS Program does not include training on how to manage POME and anaphylaxis.

Healthcare Providers should also be familiar with current standards for the treatment of anaphylaxis. Treatment guidelines are provided by the following organizations:

- The American Academy of Allergy, Asthma and Immunology (AAAAI) (<http://www.aaaai.org/home.aspx>)
- National Institute of Allergy and Infectious Diseases (NIAID) (<http://www.niaid.nih.gov/Pages/default.aspx>)
- World Allergy Organization (WAO) (<http://www.worldallergy.org/anaphylaxis/>)

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32. Education Program Start Page for Healthcare Settings

Frank Adam ▾



AVEED
(testosterone undecanoate) injection 750mg/3mL, C

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AVEED[®] REMS Education Program for Healthcare Settings

This Educational Piece Includes Information About:

- Serious POME reactions and anaphylaxis with AVEED Injection
- AVEED REMS Program requirements to implement in your healthcare setting
- Ordering AVEED

What is the AVEED REMS (Risk Evaluation and Mitigation Strategy) Program?

A REMS is a strategy to manage known or potential risks associated with a drug, and is required by the FDA to ensure that the benefits of the drug outweigh its risks. AVEED is available only under a restricted program called the AVEED REMS Program because of the risks of serious pulmonary oil microembolism (POME) reactions and anaphylaxis. The AVEED REMS Education Program for Healthcare Settings is designed to train healthcare setting Authorized Representatives on these serious risks, and AVEED REMS Program requirements to order AVEED for their healthcare setting.

- **Healthcare Settings** must be certified in the AVEED REMS Program to be able to order AVEED and have at least one certified prescriber associated with the facility to be able to order, receive, or administer AVEED. Healthcare providers are associated to a healthcare setting by:
 - The healthcare provider selecting the healthcare setting during the healthcare provider enrollment process, or
 - Being associated to the healthcare setting by the Authorized Representative via the REMS Call Center
- **Prescribing Healthcare Providers** must be certified in the AVEED REMS Program to be able to prescribe AVEED
- **Non-Prescribing Healthcare Providers** who will administer AVEED to patients must review the AVEED REMS Education for Healthcare Providers before injecting AVEED

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For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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Steps for Healthcare Setting Certification:

- 1 Designate an Authorized Representative
- 2 Review the AVEED REMS Education Program for Healthcare Settings, including the Prescribing Information
- 3 Verify annually the Authorized Representative on record
- 4 Complete and sign the Healthcare Setting Enrollment Form. This Enrollment must be renewed every 2 years
- 5 Associate certified Prescribing Healthcare Providers to your account. Your healthcare setting is not eligible to receive AVEED until you have associated at least one certified Prescribing Healthcare Provider.
- 6 Implement the necessary staff training and processes to comply with the AVEED REMS Program requirements

The AVEED REMS Education Program, Healthcare Setting Enrollment Form, and other AVEED REMS Program tools are available online at www.AveedREMS.com or by contacting the AVEED REMS Program at 1-855-755-0494 to request materials.

You can review the educational materials and enroll online at www.AveedREMS.com, or review the printed versions and fax your enrollment form to the AVEED REMS Program at 1-855-755-0495.

Your healthcare setting will not be able to order AVEED unless you meet these two requirements:

1. Your healthcare setting is certified
2. There is at least one **prescriber** certified in the Aveed REMS Program **associated with your healthcare setting**

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For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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Who Can Be An Authorized Representative?

An Authorized Representative at the healthcare setting can be:

- Prescribing healthcare providers
- Non-prescribing healthcare providers
- A practice manager, or
- Any responsible individual in the healthcare setting

Please check with your manager to ensure the appropriate person represents the healthcare setting and attests to the enrollment requirements as stated on the Healthcare Setting Enrollment Form.

- One representative needs to enroll per healthcare setting (the "Authorized Representative"). One Authorized Representative can manage more than one healthcare setting. The chosen Authorized Representative must be verified as current annually.
- Please note, there are no AVEED® REMS requirements for staff at a healthcare setting that will not be involved with prescribing or administering AVEED.

Indication

AVEED (testosterone undecanoate) injection is an androgen indicated for testosterone replacement therapy in adult males for conditions associated with a deficiency or absence of endogenous testosterone:

- Primary hypogonadism (congenital or acquired)
- Hypogonadotropic hypogonadism (congenital or acquired)

AVEED should only be used in patients who require testosterone replacement therapy and in whom the benefits of the product outweigh the serious risks of POME and anaphylaxis.

The safety and efficacy of AVEED in men with "age-related hypogonadism" (also referred to as "late-onset hypogonadism") have not been established. The safety and efficacy of AVEED in males less than 18 years old have not been established.

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Serious Risks of POME and Anaphylaxis

With each AVEED® injection, there is a potential for serious POME reactions or anaphylaxis to occur. These reactions can occur after any injection of AVEED during the course of therapy, including after the first dose.

The signs and symptoms of serious POME reactions and anaphylaxis overlap. It is important to observe patients in your healthcare setting for **30 minutes** after each AVEED injection to determine whether medical intervention is necessary.

Serious POME reactions

POME occurring after an AVEED injection is believed to be caused by tiny droplets of oil, in which the testosterone undecanoate has been dissolved, that have traveled to the lungs.

- POME is **not** a blood clot
- There is a risk of POME occurring with each injection of AVEED

Symptoms of POME

The following symptoms of POME have been reported with AVEED:

- | | | | | |
|-----------------|--|---------------------|--|-----------------|
| - cough | | - throat tightening | | - hyperhidrosis |
| - urge to cough | | - chest pain | | - dyspnea |
| - dizziness | | - syncope | | |

- The majority of these events lasted a few minutes and resolved with supportive measures, e.g., by patient reassurance and/or administration of supplemental oxygen
- Some of the events lasted up to several hours and in some cases, emergency care and/or hospitalization were required

Anaphylaxis

Episodes of anaphylaxis, including life-threatening reactions, have been reported to occur following AVEED injection.

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Strategies to implement in your healthcare setting to mitigate these risks:

- Ensure all prescribing healthcare providers who prescribe AVEED® are certified in the AVEED REMS program
 - Maintain up-to-date records
- Ensure all non-prescribing healthcare providers who administer AVEED are trained on:
 - Serious POME reactions and anaphylaxis
 - Patient counseling
 - 30 minute post-injection patient observation
 - Proper administration of AVEED
- Maintain an up-to-date record of training
- Establish a process to ensure all patients are counseled about AVEED and receive "What You Need To Know About AVEED Treatment: A Patient Guide"

• Establish a process to ensure each patient is observed for 30 minutes at your healthcare setting after each AVEED injection

- Have immediate access on-site to equipment and personnel to manage serious POME reactions or anaphylaxis
- Ensure a patient is NEVER provided AVEED for home or self-injection
- Establish a process to ensure that your healthcare setting recertifies if the Authorized Representative changes

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For additional information about the AVEED REMS Program, please call 1-855-755-0494.



How Do I Order AVEED®?

Contact the AVEED REMS Program at **1-855-755-0494**.

All AVEED REMS documents are available at www.AveedREMS.com, or call the AVEED REMS Program at **1-855-755-0494**.

The completion of the AVEED REMS Education Program and enrollment process is NOT a substitute for reading the AVEED Prescribing Information and Medication Guide.

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38. Education Program Confirmation for Prescribing Healthcare Providers

Frank Adam ▾

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AVEED[®] REMS Education Program Confirmation

Knowledge Assessment is required before you can complete enrollment in the AVEED REMS Program.

You may proceed to the **Knowledge Assessment** in the following pages to complete your enrollment in the AVEED REMS Program. Alternatively, you may proceed to your **My Account** page to view your enrollment progress.

My Account	Knowledge Assessment
---	---

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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39. Education Program Confirmation for Healthcare Settings

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**AVEED**
(testosterone undecanoate) injection 750mg/3mL, C

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AVEED[®] REMS Education Program Confirmation

You have now completed the Education Program.

You may proceed to **Attestation** on the following page in order to complete your enrollment in the AVEED REMS Program. Alternatively, you may proceed to your **My Account** page to view your enrollment progress.

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For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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40. Education Program Confirmation for Non-Prescribing Healthcare Providers

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AVEED® REMS Education Program Confirmation

You have now completed the Education Program.

Your AVEED REMS Education Program confirmation code is:

Education Program Confirmation Code: EDU-1616-53C6-26FE

You may proceed to your **My Account** page by clicking the My Account button to view your progress and account information.

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For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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41. Knowledge Assessment Question 1

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AVEED® REMS Knowledge Assessment Questions

You are now going to review 10 questions that will test your knowledge of appropriate use and administration of AVEED. To be an enrolled prescribing healthcare provider in the AVEED REMS Program you will need to answer ALL questions correctly.

Question 1

Which of the following would be an appropriate patient for AVEED?

Select one option:

- A 45-year-old female with a history of androgen insensitivity syndrome
- B 16-year-old male with symptoms of delayed puberty and hypogonadism
- C 40-year-old male with history of congenital hypogonadism complaining of fatigue and decreased libido
- D 54-year-old male with a family history of prostate cancer and complaining of decreased urine output

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42. Knowledge Assessment Question 2

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AVEED[®] REMS Knowledge Assessment Questions

[Question 2](#)

Which of the following symptoms most accurately describes a patient experiencing an episode of post-injection pulmonary oil microembolism (POME)?

Select one option:

- A Severe palpitations and diaphoresis one week post AVEED injection
- B Headache, nausea, or vomiting prior to AVEED injection
- C Rash, skin irritation, and erythema surrounding the injection site
- D Cough, dyspnea, chest pain, and dizziness 5 minutes post-injection

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43. Knowledge Assessment Question 3

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AVEED® REMS Knowledge Assessment Questions

Question 3

Why should a patient wait in the healthcare setting for 30 minutes following each AVEED injection?

Select one option:

- A To make sure their insurance information is accurate
- B To provide them with follow-up appointment information
- C To provide appropriate medical treatment in the event of a serious POME reaction or anaphylaxis
- D To ensure that they do not eat 30 minutes after an injection

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44. Knowledge Assessment Question 4

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AVEED® REMS Knowledge Assessment Questions

[Question 4](#)

What is the proper injection route and injection site for AVEED?

Select one option:

- A Intramuscular injection in the gluteus muscle
- B Intramuscular injection in the deltoid
- C Intravascular injection in the gluteus muscle
- D None of the above

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45. Knowledge Assessment Question 5

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AVEED[®] REMS Knowledge Assessment Questions

Question 5

Prior to administering an AVEED injection, you must counsel the patient using the Patient Counseling Tool "What You Need to Know about AVEED Treatment: A Patient Guide", and the AVEED Medication Guide on all of the following EXCEPT:

Select one option:

- A The risks of serious POME and anaphylaxis associated with AVEED
- B Techniques for aseptic self-injection of AVEED
- C The importance of waiting 30 minutes post-injection in the healthcare setting in order to provide appropriate medical treatment in the event of a serious POME reaction or anaphylaxis
- D Signs and symptoms of an adverse reaction and how to report them

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46. Knowledge Assessment Question 6

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AVEED[®] REMS Knowledge Assessment Questions

Question 6

In order to administer AVEED, my healthcare setting must also be certified.

Select one option:

- A True
- B False

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47. Knowledge Assessment Question 7

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AVEED® REMS Knowledge Assessment Questions

Question 7

As a patient continues receiving AVEED injections, their risk of experiencing pulmonary oil microembolism (POME) or anaphylaxis decreases.

Select one option:

- A True
- B False

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48. Knowledge Assessment Question 8

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AVEED® REMS Knowledge Assessment Questions

Question 8

If a patient experiences a hypersensitivity reaction (e.g., angioedema and/or hives) following an AVEED injection, it is appropriate to continue therapy with AVEED.

Select one option:

- A True
- B False

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49. Knowledge Assessment Question 9

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AVEED[®] REMS Knowledge Assessment Questions

Question 9

Patients who feel comfortable with self-administering AVEED may do so after receiving their initial injection in the healthcare setting.

Select one option:

- A True
- B False

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50. Knowledge Assessment Question 10

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AVEED® REMS Knowledge Assessment Questions

Question 10

It is a requirement of the AVEED REMS to review the Patient Counseling Tool "What you need to know about AVEED Treatment: A Patient Guide" with patients and provide them with a copy prior to each injection of AVEED.

Select one option:

- A True
- B False

[Submit Assessment](#)

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AVEED® REMS Knowledge Assessment Results

You have now completed the assessment.

Congratulations!

You answered all the questions correctly and have passed the assessment.

Please click the **Complete Attestation** button to complete the last enrollment step.

Knowledge Assessment Final Results

Question #	Your Answer
1	C
2	D
3	C
4	A
5	B
6	A
7	B
8	B
9	B
10	A

Knowledge Assessment Confirmation Code: **1613-53E1-1379**

[Complete Attestation](#)

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AVEED® REMS Knowledge Assessment Results

You have now completed the assessment.

Unfortunately, you did not answer all the questions correctly and have not passed the assessment. You will have a maximum of six attempts to pass the assessment. Please click on the **Retake Assessment** button below to change your incorrect answers and resubmit.

After three attempts, the AVEED REMS Education Program must be reviewed again before retaking the Knowledge Assessment.

Alternatively, you may revisit the AVEED REMS Education Program, then take the assessment again

Knowledge Assessment Final Results

Question #	Your Answer
1	A
2	A
3	D
4	B
5	A
6	B
7	A
8	A
9	A
10	B

[Education Program](#)

[Retake Assessment](#)

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53. Prescribing Healthcare Provider Attestation

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AVEED® REMS Healthcare Provider Attestation

To complete your online enrollment into the AVEED REMS Program, review the acknowledgement below, attest to the terms and provide your signature along with signature date before clicking on the **Submit** button.

Healthcare Provider

Name: Frank Adam

Healthcare Provider Responsibilities

By completing this form, I attest that:

- I understand that AVEED is only available through the AVEED REMS Program and that I must comply with the program requirements in order to prescribe and administer AVEED.
- I completed the AVEED REMS Education Program, including review of the AVEED Prescribing Information, and successfully completed the AVEED REMS Knowledge Assessment.
- I understand how to inject AVEED properly.
- I understand the risks of serious pulmonary oil microembolism (POME) reactions and anaphylaxis following the administration of AVEED, which have the potential to lead to serious medical consequences (e.g., respiratory distress and syncope), and how to manage these risks.
- Prior to initiating treatment and before each injection, I agree to provide a copy of "What You Need To Know About AVEED Treatment: A Patient Guide" to each patient and review it with them to inform them about the risk of serious POME reactions and anaphylaxis and the need to remain in my healthcare setting for **30 minutes** following each AVEED injection.
- I acknowledge that my healthcare setting must be a certified healthcare setting.
- I understand that each patient must be observed in the healthcare setting for **30 minutes** following each AVEED injection in order to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis following the administration of AVEED.
- I agree that personnel from the AVEED REMS Program may contact me to gather further information or resolve discrepancies or to provide other information related to the AVEED REMS Program.
- I understand that Endo Pharmaceuticals Solutions Inc. (Endo), its agents, and contractors, such as the distributors, may contact me via phone, mail or email to survey me on the effectiveness of the program requirements for the AVEED REMS Program.
- I understand the importance of reporting serious events of POME and anaphylaxis following AVEED treatment.
- I attest that my healthcare setting has immediate access on-site to equipment and personnel trained to manage POME and anaphylaxis.

To report suspected adverse events contact Endo at 1-800-462-3636, FDA at 1-800-FDA-1088 or www.fda.gov/medwatch/report.htm.

I understand that this enrollment and certification only applies to me, and does not apply to any healthcare setting that employs me or in which I may have an interest.

Your signature and today's date are required to complete your enrollment. Please type your name and date in the space provided below. This will serve as an electronic signature and will certify that you have read and agree with the terms provided.

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

Prescribing Healthcare Provider Signature Date

(First and Last Name)

[Print Form](#) [Submit](#)

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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54. Prescribing Healthcare Provider Attestation Incomplete for Invalid Identifiers

Frank Adam ▾

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AVEED® REMS Healthcare Provider Attestation

To complete your online enrollment into the AVEED REMS Program, review the acknowledgement below, attest to the terms and provide your signature along with signature date before clicking on the **Submit** button.

Healthcare Provider

Name: Frank Adam

Healthcare Provider Responsibilities

By completing this form, I attest that:

- I understand that AVEED is only available through the AVEED REMS Program and that I must comply with the program requirements in order to prescribe and administer AVEED.
- I completed the AVEED REMS Education Program, including review of the AVEED Prescribing Information, and successfully completed the AVEED REMS Knowledge Assessment.
- I understand how to inject AVEED properly.
- I understand the risks of serious pulmonary oil microembolism (POME) reactions and anaphylaxis following the administration of AVEED, which have the potential to lead to serious medical consequences (e.g., respiratory distress and syncope), and how to manage these risks.
- Prior to initiating treatment and before each injection, I agree to provide a copy of "What You Need To Know About AVEED Treatment: A Patient Guide" to each patient and review it with them to inform them about the risk of serious POME reactions and anaphylaxis and the need to remain in my healthcare setting for **30 minutes** following each AVEED injection.
- I acknowledge that my healthcare setting must be a certified healthcare setting.
- I understand that each patient must be observed in the healthcare setting for **30 minutes** following each AVEED injection in order to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis following the administration of AVEED.
- I agree that personnel from the AVEED REMS Program may contact me to gather further information or resolve discrepancies or to provide other information related to the AVEED REMS Program.
- I understand that Endo Pharmaceuticals Solutions Inc. (Endo), its agents, and contractors, such as the distributors, may contact me via phone, mail or email to survey me on the effectiveness of the program requirements for the AVEED REMS Program.
- I understand the importance of reporting serious events of POME and anaphylaxis following AVEED treatment.
- I attest that my healthcare setting has immediate access on-site to equipment and personnel trained to manage POME and anaphylaxis.

To report suspected:

Incomplete Certification

You are about to complete your attestation with one or more invalid identifiers. You may select *Modify Identifiers* to correct the issue now or select *Continue* to complete attestation.

As part of the AVEED REMS Program enrollment process all identifiers must be successfully validated for your certification in the program to be complete.

While your enrollment is incomplete, you will not be a valid prescriber in the AVEED REMS Program and you cannot prescribe AVEED to your patients.

Modify IdentifiersContinue

I understand that this have an interest.

Your signature and to as an electronic sign

By checking this accurate.

Prescribing Healthc

Print FormSubmit

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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55. Prescribing Healthcare Provider Attestation Incomplete for Unspecified HCS Message

The screenshot shows the AVEED website interface. At the top right, the user is logged in as 'Frank Adam'. The navigation menu includes 'Home', 'Patient Information', 'Education', 'Enroll', 'Forms & Resources', and 'My Account'. The main heading is 'AVEED® REMS Healthcare Provider Attestation'. Below this, there is a section for 'Healthcare Provider' with the name 'Frank Adam' entered. The 'Healthcare Provider Responsibilities' section contains a list of 10 bullet points regarding the provider's obligations. A red error message box titled 'Incomplete Certification' is overlaid on the form, stating: 'Thank you for completing the steps necessary to be certified in the AVEED REMS Program. Please be aware that you are not yet certified and will not be certified until you select a Healthcare Setting to affiliate with. You will need to contact the authorized representative of the Healthcare Setting you want to affiliate with and ask them to become certified in the AVEED REMS Program. Your Healthcare Setting must be certified in the program in order for you to prescribe AVEED.' The error message has an 'OK' button. At the bottom of the form, there are 'Print Form' and 'Submit' buttons. A footer note says 'For additional information about the AVEED REMS Program, please call 1-855-755-0494.' and there are links for 'Privacy Policy | Terms of Use | Contact Us'.

56. Prescribing Healthcare Provider Attestation Incomplete for Invalid DEA and Unspecified HCS Message

Frank Adam ▾

Important Safety Information | Prescribing Information | Medication Guide



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AVEED® REMS Healthcare Provider Attestation

To complete your online enrollment into the AVEED REMS Program, review the acknowledgement below, attest to the terms and provide your signature along with signature date before clicking on the **Submit** button.

Healthcare Provider

Name: Frank Adam

Healthcare Provider Responsibilities

By completing this form, I attest that:

- I understand that AVEED is only available through the AVEED REMS Program and that I must comply with the program requirements in order to prescribe and administer AVEED.
- I completed the AVEED REMS Education Program, including review of the AVEED Prescribing Information, and successfully completed the AVEED REMS Knowledge Assessment.
- I understand how to inject AVEED properly.
- I understand the risks of serious pulmonary oil microembolism (POME) reactions and anaphylaxis following the administration of AVEED, which have the potential to lead to serious medical consequences (e.g., respiratory distress and syncope), and how to manage these risks.
- Prior to initiating treatment and before each injection, I agree to provide a copy of "What You Need To Know About AVEED Treatment: A Patient Guide" to each patient and review it with them to inform them about the risk of serious POME reactions and anaphylaxis and the need to remain in my healthcare setting for **30 minutes** following each AVEED injection.
- I acknowledge that my healthcare setting must be a certified healthcare setting.
- I understand that each patient must be observed in the healthcare setting for **30 minutes** following each AVEED injection in order to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis following the administration of AVEED.
- I agree that personnel from the AVEED REMS Program may contact me to gather further information or resolve discrepancies or to provide other information related to the AVEED REMS Program.
- I understand that Endo Pharmaceuticals Solutions Inc. (Endo), its agents, and contractors, such as the distributors, may contact me via phone, mail or email to survey me on the effectiveness of the program requirements for the AVEED REMS Program.
- I understand the importance of reporting serious events of POME and anaphylaxis following AVEED treatment.
- I attest that my healthcare setting has immediate access on-site to equipment and personnel trained to manage POME and anaphylaxis.

To report suspected a...
I understand that this...
have an interest.
Your signature and too...
as an electronic signa...
 By checking this b...
accurate.
Prescribing Healthca...

Incomplete Certification

You are about to complete your attestation with one or more invalid identifiers and without affiliating with a Healthcare Setting. As part of the AVEED REMS Program certification process all identifiers must be successfully validated and you must be affiliated with a Healthcare Setting for your enrollment in the program to be complete. You will need to contact the authorized representative of the Healthcare Setting you want to affiliate with and ask them to enroll in the AVEED REMS Program. Your Healthcare Setting must be certified in the program in order for you to prescribe AVEED.

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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57. Healthcare Setting Attestation

Frank Adam ▾

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AVEED® REMS Healthcare Setting Attestation

To complete your online enrollment into the AVEED REMS Program, review the acknowledgement below, attest to the terms and provide your signature along with signature date before clicking on the **Submit** button.

Authorized Healthcare Setting Representative

Name: Frank Adam

Authorized Representative Responsibilities

I am the Authorized Representative designated by my healthcare setting to coordinate the activities of the AVEED REMS Program. I agree to comply with the following program requirements:

- I understand that my healthcare setting must be certified with the AVEED REMS Program and have at least one certified prescriber associated with my facility to be able to order, receive, or administer AVEED.
- I have completed the AVEED REMS Education Program for Healthcare Settings.
- I understand the risks of serious pulmonary oil microembolism (POME) reactions and anaphylaxis following the administration of AVEED.
- I understand this healthcare setting must verify the current Authorized Representative annually and renew its enrollment in the AVEED REMS Program every two years from the date of initial enrollment.
- **This healthcare setting has immediate access on-site to equipment and personnel to manage POME or anaphylaxis.**
- This healthcare setting will establish procedures and protocols that are subject to audit, to help ensure compliance with the safe use conditions required in the AVEED REMS Program, including the following:
 - All Healthcare Providers (HCPs) who prescribe AVEED in my healthcare setting are specially certified prior to prescribing AVEED and a record of such training must be maintained.
 - All non-prescribing HCPs who administer AVEED in my healthcare setting are trained and a record regarding such training must be maintained.
 - Prior to initiating treatment and before each injection, review with and provide a copy of "What You Need To Know About AVEED Treatment: A Patient Guide" to each patient to inform them about the risks of serious POME reactions and anaphylaxis.
 - To observe each patient administered AVEED for **30 minutes** at my healthcare setting following each injection in order to provide appropriate medical treatment in the event of serious POME reactions or anaphylaxis following the administration of AVEED.
- Not to loan, sell or transfer AVEED to another pharmacy, healthcare setting, prescriber, institution or distributor, except in the case where the transfer is to another certified healthcare setting (unique ship-to site address) where I am also the Authorized Representative.
- This healthcare setting must not dispense AVEED for home or patient self-administration.
- To make available to Endo Pharmaceuticals Solutions Inc. (Endo), and/or a designated third party or the FDA, documentation to verify understanding of, and adherence to, the requirements of the AVEED REMS Program.
- I understand that this certified healthcare setting must recertify in the AVEED REMS Program if the healthcare setting designates a new authorized representative.

I understand that this enrollment only applies to me as the designated Authorized Representative of this healthcare setting. I will complete a separate enrollment form for each healthcare setting (unique ship-to site address) for which my designation and responsibilities extend. Failure to enroll a healthcare setting and have certified healthcare providers in the AVEED REMS program will result in the inability to receive shipments of AVEED.

Your signature and today's date are required to complete your enrollment. Please type your name and date in the space provided below. This will serve as an electronic signature and will certify that you have read and agree with the terms provided.

By checking this box, I agree that my HCS has the necessary on-site equipment and personnel to manage POME or anaphylaxis.

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

Authorized Healthcare Setting Representative Signature Date

(First and Last Name)

[Print Form](#) [Submit](#)

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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58. Prescribing Healthcare Provider Enrollment Confirmation

Frank Adam ▾

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AVEED® REMS Prescriber Enrollment Confirmation

Thank you! You have successfully enrolled into the AVEED REMS program.

You may now:

- [Download program resources](#)
- [Request program materials](#)
- [View your program profile](#)

Below is your AVEED REMS program Enrollment ID. Please note that you will also receive confirmation via your preferred method of communication that contains the information below that you will use for accessing specific areas of the AVEED REMS program website. Please retain this information in a secure place to which only you have access.

Enrollment ID: PRS012345789

[Print Confirmation](#) [My Account](#)

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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59. Healthcare Setting Enrollment Confirmation

Frank Adam ▾

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AVEED[®] REMS Program Healthcare Setting Enrollment Confirmation

Thank you! You have successfully enrolled your healthcare setting into the AVEED REMS Program.

You may now:

- [Add Healthcare Setting](#)
- [Download program resources](#)
- [Request program materials](#)
- [View your program profile](#)

Below is your AVEED REMS Program Enrollment ID. Please note that you will also receive confirmation via your preferred method of communication that contains the information below that you will use for accessing specific areas of the AVEED REMS program website. Please retain this information in a secure place to which only you have access.

Enrollment ID: FAC012345789

Print Confirmation

My Account

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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60. My Account for Prescribing Healthcare Providers

Frank Adam ▾

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My Account – Prescribing Healthcare Provider

Summer Hogan - Good Samaritan Hospital

Welcome to the AVEED REMS Program. Here you can:

- Manage and/or track your process through the Education Program and enrollment
- Download training materials to support implementation of the AVEED REMS Program

AVEED REMS Program Activity

Steps	Activity	Progress	Access
1.	Account Registration	Completed	✓
2.	Enrollment Data Collection	Completed	✓
3.	Education	Completed	✓ Download Training Materials
4.	Knowledge Assessment	Completed	✓ View Confirmation
5.	Enrollment Attestation	Enrolled	Print Confirmation
6.	Request Materials	Available	Order Now
7.	My Profile	Available	View

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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61. My Account for Prescribing Healthcare Providers – Enrollment Deactivated with Re-enrollment

Dilasha Hudson ▾



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My Account - Prescribing Healthcare Provider

Dilasha Hudson - Banner HCS

Welcome to the AVEED REMS Program. Here you can:

- Manage and/or track your process through the Education Program and enrollment
- Download training materials to support implementation of the AVEED REMS Program

AVEED REMS Program Activity

Steps	Activity	Progress	Access
1.	Account Registration	Completed	✓
2.	Enrollment Data Collection	Completed	✓
3.	Healthcare Setting Affiliation	Completed	✓
4.	Education	Completed	✓ Download Education Materials
5.	Knowledge Assessment	Completed	✓
6.	Enrollment Attestation	Deactivated	Reason: Opt Out
7.	Request Materials	Available	Order Now
8.	My Profile	Available	View
9.	Re-Enrollment	Incomplete	Resume Re-enrollment

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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62. My Account for Authorized Healthcare Setting Representative with Re-enrollment

Frank Adam ▾

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My Account - Healthcare Setting Authorized Representative

Test Testing - MAYERS MEMORIAL HOSPITAL DISTRICT INC

Welcome to the AVEED REMS Program. Here you can:

- Manage and/or track your process through the Education Program and enrollment
- Download training materials to support implementation of the AVEED REMS Program

AVEED REMS Program Activity

Steps	Activity	Progress	Access
1.	Enrollment Data Collection	Completed ✓	
2.	Education	Completed ✓	Download Education Materials
3.	Enrollment Attestation	Enrolled ✓	Print Confirmation
4.	Request Materials	Available	Order Now
5.	Manage Healthcare Settings/Providers	Available	Add/View
6.	My Profile	Available	View
7.	Re-Enrollment	Not Started	Not eligible until 10/30/2016

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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63. My Account for Non- Prescribing Healthcare Providers

Frank Adam ▾

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My Account – Non-Prescribing Healthcare Provider

Summer Hogan - Good Samaritan Hospital

Welcome to the AVEED REMS Program. Here you can:

- Manage and/or track your process through the Education Program
- Download training materials to support implementation of the AVEED REMS Program

AVEED REMS Program Activity

Steps	Activity	Progress	Access
1.	Account Registration	Completed	✓
2.	Education	Completed	✓ Download Training Materials

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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64. Knowledge Assessment View Confirmation from My Account

Frank Adam ▾

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Knowledge Assessment Results Completion Date: 03/28/2014

Congratulations **Frank Adam!** You have now completed the Knowledge Assessment.

Please click **Print Confirmation** to print a copy of your knowledge assessment confirmation code.

Knowledge Assessment Confirmation Code: 1451-099E-5565

The knowledge assessment confirmation code will be sent to your preferred method of communication.

[Print Confirmation](#)

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For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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65. Manage Healthcare Setting for View/Add Healthcare Settings

Frank Adam ▾

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AVEED® REMS Manage Healthcare Setting

View Healthcare Settings

View Healthcare Providers

Below are your current healthcare setting locations. Please click the **Add Healthcare Setting** button to add more healthcare setting locations.

Show 10 entries

Enrollment ID	Healthcare Setting	Address	Enrollment Status	Actions
FAC0118160291	js	12 main,Georgia, Georgia, 31830	Complete	View
FAC0118160320	JOHNSON	JOHNSON st,Illinois, Illinois, 62220	Complete	View
FAC0118164504	uyz	77 Illinois ave,Illinois, Illinois, 62906	Complete	View
FAC0118166527	qrz	11 Illinois,Illinois, Illinois, 62274	Complete	View
FAC0118161550	qwa	12 Illinois Suite 505A,Illinois, Illinois, 60461	Complete	View
FAC0118162640	aces	3344 Illinois,Illinois, Illinois, 62681	Incomplete - Invalid DEA	Edit
FAC0118160711	ioioio	55 Illinois,Illinois, Illinois, 62681	Complete	View
FAC0118162734	xyzabcd	44 Iowa,Iowa, Iowa, 52402	Complete	View
FAC0118165072	ajs	123 abc st,MIAMI, Florida, 33155	Complete	View
FAC0118162103	zhz	147 main,Miami, Florida, 33155	Complete	View

1 - 10 of 10 items

Print

Add Healthcare Setting

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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66. Manage Healthcare Setting for View/Add Healthcare Providers

Frank Adam ▾

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AVEED® REMS Manage Healthcare Setting

View Healthcare Settings View Healthcare Providers

Below are the Prescribing and Non-Prescribing Healthcare Providers associated with your Healthcare Setting along with their Education, Knowledge Assessment, and Enrollment status information.

Show entries

REMS#	Name	Stakeholder Type	Address	Status	Certified
PRS874125487	John Doe	Prescribing HCP	4343 N SCOTTSDALE RD, SCOTTSDALE, AZ, 85251	Pending Education	No
PRS845712547	Joe Smith	Prescribing HCP	4343 N SCOTTSDALE RD, SCOTTSDALE, AZ, 85251	Knowledge Assessment Complete	Yes
PRS745128478	Mary Brown	Prescribing HCP	4343 N SCOTTSDALE RD, SCOTTSDALE, AZ, 85251	Pending Knowledge Assessment	No
PRS845712647	Tom White	Prescribing HCP	4343 N SCOTTSDALE RD, SCOTTSDALE, AZ, 85251	Pending Education	No
PRS051427845	Sam Thomas	Prescribing HCP	4343 N SCOTTSDALE RD, SCOTTSDALE, AZ, 85251	Pending Education	No
EDU2-FEAF-BE87	Bob Johnson	Non-Prescribing HCP	4343 N SCOTTSDALE RD, SCOTTSDALE, AZ, 85251	Education Complete	No

1 - 6 of 6 items

Print

Add Healthcare Provider

To affiliate a Prescribing Healthcare Provider and/or a Non-Prescribing Healthcare Provider to your Healthcare Setting, please enter either their Enrollment ID (REMS #) for Prescribing Healthcare Providers or the Education Confirmation Code (REMS #) for Non-Prescribing Healthcare Providers and click **Search**. If your search results contain the Healthcare Provider you were looking for, please click **Add** to affiliate them to your Healthcare Setting. If you need to remove a record from your search results, please select the radio button next to the record and click **Remove**.

Enrollment ID

-or-

Education Confirmation Code

Search

	REMS#	Name	Stakeholder Type	Address	Status	Certified
<input type="radio"/>	PRS454517517	Peter Jackson	Prescribing HCP	4343 N SCOTTSDALE RD, SCOTTSDALE, AZ, 85251	Pending Education	No
<input type="radio"/>	PRS414178741	Mike Jones	Prescribing HCP	4343 N SCOTTSDALE RD, SCOTTSDALE, AZ, 85251	Pending Education	No

Remove Add

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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67. Manage Healthcare Setting for Add Healthcare Provider Message

Frank Adam ▾



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AVEED® REMS Manage Healthcare Setting

View Healthcare Settings
View Healthcare Providers

Below are the Prescribing and Non-Prescribing Healthcare Providers associated with your Healthcare Setting along with their Education, Knowledge Assessment, and Enrollment status information.

Show 10 entries

REMS#	Name	Stakeholder Type	Address	Status	Certified
PRS874125487	John Doe	Prescribing HCP	4343 N SCOTTSDALE RD,SCOTTSDALE, AZ, 85251	Pending Education	No
PRS845712547	Joe Smith	Prescribing HCP	4343 N SCOTTSDALE RD,SCOTTSDALE, AZ, 85251	Knowledge Assessment Complete	Yes
PRS745128478	Mary Brown	Prescribing HCP	4343 N SCOTTSDALE RD,SCOTTSDALE, AZ, 85251	Pending Knowledge Assessment	No
PRS845712647	Tom White	Prescribing HCP	4343 N SCOTTSDALE RD,SCOTTSDALE, AZ, 85251	Pending Education	No
PRS051427845	Sam Thomas	Prescribing HCP	4343 N SCOTTSDALE RD,SCOTTSDALE, AZ, 85251	Pending Education	No
EDU2-FEAF-BE87	Bob Johnson	Non-Prescribing HCP	4343 N SCOTTSDALE RD,SCOTTSDALE, AZ, 85251	Education Complete	No

1 - 6 of 6 items
⏪ 1 ⏩

Print

Add Healthcare Provider

Add Healthcare Provider
✕

To affiliate a Prescribing Healthcare Provider to your Healthcare Setting, please enter their Enrollment ID (REMS#) in the field below, click **Search**, and click **Confirm** to add the Healthcare Provider to your Healthcare Setting. If you need to remove a Healthcare Provider from your Healthcare Setting please contact the AVEED REMS Program at **1-855-755-0494**.

Cancel
Confirm

REMS#	Name	Stakeholder Type	Address	Status	Certified
<input type="radio"/> PRS454517517	Peter Walkson	Prescribing HCP	4343 N SCOTTSDALE RD,SCOTTSDALE, AZ, 85251	Pending Education	No
<input type="radio"/> PRS414178741	Mike Jones	Prescribing HCP	4343 N SCOTTSDALE RD,SCOTTSDALE, AZ, 85251	Pending Education	No

Remove
Add

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68. Healthcare Setting Profile

[Frank Adam](#) ▾

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AVEED® REMS Healthcare Setting Profile

Your healthcare setting profile information is displayed below. Please contact the AVEED REMS Program at 1-855-755-0494 to make any changes to your profile.

Authorized Healthcare Setting Representative Details

Name	Joe Smith
Position/Credential	Position/Credential
Title	Nurse
Phone	555-555-5555
Fax	555-555-1111
Email	Email@email.com
Preferred Method of Communication	Email

Healthcare Setting Information

Healthcare Setting Name	Healthcare Seting Name
Healthcare Setting Type	Institution
Healthcare Setting Address	123 street suite1 New York, New York 10001
Healthcare Setting Email Address	abc@xyz.com
Healthcare Setting Phone	555-555-5555
Healthcare Setting Fax	555-555-0000

Authorized Healthcare Setting Representative Enrollment Details

Enrollment ID	FAC12345789
Enrollment Status	Complete
Start Date	12/15/2013
Expiration Date	1/1/2016
DEA	AB1234578

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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69. Prescribing Healthcare Provider Profile

[Frank Adam](#) ▾

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AVEED® REMS Prescriber Profile

Your prescriber profile information is displayed below. Please contact the AVEED REMS Program at 1-855-755-0494 to make any changes to your profile.

Prescribing Healthcare Provider Details

Name	Joe Smith
Position/Credential	Position/Credential
Specialty	Urology
Phone	555-555-5555
Ext	123
Fax	555-555-1111
Email	Email@email.com
Preferred Method of Communication	Email

Healthcare Setting Information

Healthcare Setting Name	Healthcare Setting Name
Healthcare Setting Address	123 street suite1 New York, New York 10001

Prescribing Healthcare Provider Enrollment Details

Enrollment ID	FAC12345789
Enrollment Status	Complete
Start Date	12/15/2013
DEA	AB1234578
NPI	12345789
State License Number	2478471
State Issued	New York

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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AVEED® REMS Program Materials

To request materials, please complete and submit the form below.

Shipping Information

Please select your Shipping Address

(If your shipping address is different from what is listed in the drop down, please select "Other")

Street Address 1

Street Address 2 (opt)

City

State

Zip Code

Materials

Please select the desired quantity for each item requested.

▾ AVEED REMS Program: An Introduction

▾ What You Need to Know About AVEED Treatment: A Patient Guide

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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71. Contact Us

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

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Contact Us

If you have any questions, or require additional information, please call the AVEED REMS Program at 1-855-755-0494.

AVEED REMS Fax Number
1-855-755-0495

AVEED REMS Mailing Address
AVEED REMS Program
PO BOX 29237
PHOENIX AZ 85038-9237

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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72. Request Username

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)



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[Home](#) [Patient Information](#) [Education](#) [Enroll](#) [Forms & Resources](#) [My Account](#)

Request Username

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

First Name

Last Name

Email Address

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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73. Request Password

[Forgot Username?](#) [Forgot Password?](#) [Need an Account?](#)

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Request Password

Please enter your username in the space provided. Your username is the ID you established when creating your account and this ID was also sent to you upon completion of enrollment in the AVEED REMS Program.

Username

Email Address

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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74. Change Password

Frank Adam ▾



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[My Account](#)

Change Password

To change your password please enter your current password, your new password, and confirm your new password. 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.

Old Password

New Password

Confirm New Password

Submit

For additional information about the AVEED REMS Program, please call 1-855-755-0494.

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