



TEGSEDI™ REMS Pharmacy Enrollment Form

Instructions:

TEGSEDI (inotersen) is available only through the TEGSEDI REMS, a restricted distribution program. Only prescribers, pharmacies, and patients enrolled in the program can prescribe, dispense, and receive TEGSEDI.

If you have questions, please contact the TEGSEDI REMS at 844-4TEG-REMS (844-483-4736).

Please fax this completed form to the TEGSEDI REMS at 1-855-4TEGREMS (855-483-4736).

AUTHORIZED PHARMACY REPRESENTATIVE RESPONSIBILITIES

I am the authorized representative designated by my pharmacy to coordinate the activities of the TEGSEDI REMS. By signing this form, I agree, on behalf of myself and my pharmacy, to comply with the following REMS requirements:

- I will oversee implementation of and ensure my pharmacy's compliance with the TEGSEDI REMS requirements
- I have reviewed the *Program Overview* and will ensure that all relevant staff involved in the dispensing of TEGSEDI are trained on the TEGSEDI REMS requirements using the *Program Overview*, and that a record of training is maintained
- I will enroll in the TEGSEDI REMS by completing the *Pharmacy Enrollment Form* and submitting it to the TEGSEDI REMS
- This pharmacy will establish processes and procedures to dispense no more than a 30-day supply of TEGSEDI
- I will ensure that, prior to dispensing TEGSEDI, this pharmacy will verify that the prescriber is certified and the patient is enrolled and is authorized to receive TEGSEDI by contacting the TEGSEDI REMS
- This pharmacy will dispense no more than a 30-day supply of TEGSEDI
- This pharmacy will have a new authorized representative enroll in the REMS by completing the *Pharmacy Enrollment Form* and submitting it to the REMS if the authorized representative changes
- This pharmacy will establish processes and procedures to ensure that adverse events of severe thrombocytopenia, serious bleeding with severe thrombocytopenia and glomerulonephritis are reported to the REMS
- This pharmacy will report severe thrombocytopenia, serious bleeding with severe thrombocytopenia and glomerulonephritis to the REMS
- I will ensure that this pharmacy will not distribute, transfer, loan, or sell TEGSEDI
- This pharmacy will maintain and make available appropriate documentation reflecting the staff's completion of REMS training and all processes and procedures are in place and being followed
- I understand that non-compliance with the requirements of the TEGSEDI REMS will result in decertification of my pharmacy and termination of authorization to dispense TEGSEDI
- This pharmacy will comply with audits by Akcea Therapeutics, the US Food and Drug Administration (FDA), or a designated third party acting on behalf of Akcea Therapeutics or FDA to ensure compliance with the TEGSEDI REMS

PHARMACY INFORMATION (*required)

Pharmacy Name*:

Pharmacy Address*:

City*:

State*:

Zip Code*:

Type of Pharmacy*: Specialty Long-term care Hospital pharmacy Other (please specify):

Pharmacy Identifier*
(at least one required)

NPI:

NCPDP:

DEA:

PHARMACY Ship to Address, if different than above

Pharmacy Address Line #1:

Pharmacy Address Line #2:

City:

State:

Zip Code:

AUTHORIZED PHARMACY REPRESENTATIVE INFORMATION (*required)		
First Name*:	Last Name*:	MI:
Telephone Number*:	Alternate Telephone Number:	Office Fax*:
Email*:	Preferred method of communication: <input type="checkbox"/> Email <input type="checkbox"/> Fax <input type="checkbox"/> Phone	
Authorized Pharmacy Representative Signature*: X	Date*:	

By completing and submitting this form and receiving enrollment confirmation, your pharmacy will be certified in the TEGSEDI REMS. You will receive confirmation of your enrollment via your preferred method of communication.

Phone: 1-844-483-4736 | www.TEGSEDIrems.com | Fax: 1-855-483-4736