Risk Evaluation and Mitigation Strategy (REMS) Document

[Drug/Class Name (Generic Name)] REMS Program

The REMS document template has five sections: I) Administrative Information II) REMS Goals III) REMS Requirements IV) REMS Assessment Timetable V) REMS Materials. Depending on the REMS requirements, the REMS document will include sections and text, as applicable.

Template Key
Red Text = Instructions
Black Text = Standardized text
Blue text with hyperlink = Name of REMS Material(s)
[Bracketed (blue or black) text] = Information that needs to be entered

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I. Administrative Information

Application Number(s): NDA/BLA [application number(s)] Use this only for single-applicant REMS.
Application Holder: [applicant name] Use this only for single-applicant REMS
Initial [Shared System] REMS Approval: [MM/YYYY]
Most Recent REMS Update: [MM/YYYY] Enter the date of the most recent REMS Revision or approved Modification. If there are no updates since the initial approval, delete the text.

II. REMS Goal(s)

This section describes the overall, safety-related health outcome that the REMS is designed to achieve (e.g., mitigate the risk of a particular serious adverse event) and the intermediate, measurable objectives. In many cases, it is not possible to measure a risk mitigation goal directly; therefore, it is important to include one or more intermediate, measurable objectives that, if achieved, indicate that the program is meeting its goal(s).

[Overall REMS goal]
1. [REMS objective]

2. [Other REMS objectives, as needed]

III. REMS Requirements

This section describes the REMS requirements for the applicant, including requirements that the applicant must undertake directly and requirements that the applicant must ensure that REMS participants undertake. REMS participants can include prescribers, dispensers, health care settings, patients (or their guardians), and wholesalers/distributors.

The REMS Requirements section is divided into two subsections. These subsections are labeled A and B in the template.

A. REMS Participant Requirements describes the requirements that REMS Participants must undertake.

B. REMS Applicant Requirements describes requirements for applicants to develop training, communications, systems and processes to support REMS operations and compliance.

Standardized text for the most commonly used REMS requirements is included in each subsection in black text. Retain the subsections that apply to your REMS, and delete the subsections that do not apply.

With-in each subsection, select the REMS requirements that apply to your REMS and delete the REMS requirements that do not apply.

Some REMS requirements have multiple versions to describe the different ways the requirement can be carried out (e.g., with or without using a REMS material). The different versions of the requirement appear in black text, separated by the word "OR" in red text. Select the appropriate version from among the choices provided and delete the version(s) that does not apply to your REMS.

Whenever possible, use the standardized text provided in the template. If you modify from the template text, you should provide a justification for doing so to facilitate FDA review.

---Start Subsection A---------------------------------

REMS Participant Requirements
This subsection describes the requirements that each REMS participant needs to undertake and that the applicant must ensure REMS participants comply with.

The information in this subsection is organized by REMS participant. There is a separate table for each participant that includes the following information:

[REMS Participant]	
[Timing Category]	1. [REMS Requirement] 2. [REMS Requirement] using [REMS Material]

[REMS Participant] = who (which participant) needs to complete the REMS Requirement(s)

[REMS Requirement] = what the REMS participant is required to do

[Timing Category] = when the participant must carry out the requirement

[REMS Material] = with what REMS material the participants need to carry out a requirement. Names of REMS materials are included as a hyperlink within the requirement text.

When listing the REMS materials, do not include the name of the REMS program in the name of the material. For example, use "Prescriber Enrollment Form" instead of "Drug X REMS Prescriber Enrollment Form."

[Applicant] must ensure that [List the participants who have requirements under this REMS e.g., **health care providers/pharmacies/health care settings/patients/wholesalers-distributors] comply with the following requirements:**

1. Health Care Providers who prescribe [drug/class name] must:

To become certified to prescribe Include this timing category if there are requirements that the health care provider must complete to be able to prescribe	1. Be able to [clinical activity to be performed]. Include this requirement if the prescriber has to have the ability to carry out a particular activity, such as administer a particular treatment, diagnose a particular disease, or recognize a particular adverse event. 2. Review the drug's Prescribing Information. Note that the Prescribing Information is not appended to the REMS. 3. Review the following: [List the Prescriber Educational Material(s)]. Include this requirement if the health care provider is required to review certain educational materials that are provided as part of the REMS. 4. Take training provided by [entity providing the training, e.g. the REMS Program, a CE provider]. Include this requirement if instructor-led training is provided. 5. Successfully complete the [Knowledge Assessment] and submit it to the REMS Program. 6. Enroll in the REMS by completing the [Enrollment Form] and submitting it to the REMS Program.
Before treatment initiation (first dose) Include this timing category if there are requirements that the health care provider must complete with a patient, before the patient initiates treatment	7. Counsel the patient on [topic(s)]. Include this requirement if the health care provider is required to counsel the patient. The provider may be required to cover a particular topic, use a particular REMS material (e.g., counseling tool, Medication Guide), or both. **OR** Counsel the patient using [REMS Material]. **OR** Counsel the patient on [topic(s)] using [REMS Material]. **OR** Counsel the patient on [topic(s)] using [REMS Material]. Provide a copy of the material to the patient. 8. Provide the patient with the [REMS Material(s)]. Include this requirement if there are materials that must be provided to a patient (e.g., Patient Brochure, Medication Guide). Materials that are provided to the patient as part of another requirement (e.g. see requirements #7, #10, and

#11) do not need to be repeated here.

9. Assess the patient's [condition(s) or health status(es)]. Include this requirement if there is monitoring and/or a particular lab test that must take place (e.g., pregnancy test that needs to take place before each prescription). Repeat this requirement, as needed, to address multiple health conditions and/or lab tests.
OR
Assess the patient's [condition(s) or health status(es)]. Document and submit [the results] to the REMS Program using [REMS Material(s)].
OR
Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring].
OR
Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS Program using [REMS Material(s)].

10. Complete the [Patient Form]. Provide a completed copy of the form to the patient.
OR
Complete the [Patient Form]. Retain a completed copy in the patient's record.
OR
Complete the [Patient Form]. Provide a completed copy of the form to the patient and retain a copy in the patient's record. Include this requirement if there is an Patient Form that needs to be completed (e.g., a Patient-Provider Agreement Form), but that is <u>not required</u> to be submitted to the REMS Program (If the patient's information is required to be submitted to the REMS Program, use requirement #11).

11. Enroll the patient by completing and submitting the [applicable enrollment forms] [List all Enrollment Forms] to the REMS Program.
OR
Enroll the patient by completing and submitting the [applicable enrollment forms] [List all Enrollment Forms] to the REMS Program. Provide a completed copy of the form to the patient.
OR
Enroll the patient by completing and submitting the [applicable enrollment forms] [List all Enrollment Forms] to the REMS Program. Retain a completed copy in the patient's record.
Include this requirement if the Enrollment Form is required to be submitted to the REMS Program (If the patient's information is <u>not required</u> to be submitted to the REMS Program, use requirement #10). List the applicable Enrollment Forms if there are different Enrollment Forms for different patient populations (e.g., females of reproductive

1. Health Care Providers who prescribe [drug/class name] must:

	potential). 12. Prescribe no more than a [# of days] days' supply. 13. Not prescribe refills.
During treatment; before each [dose/infusion/prescription] Include this time category if there are requirements that the health care provider must complete with the patient, before each dose, infusion, or prescription	14. Counsel the patient on [topic(s)]. Include this requirement if the health care provider is required to counsel the patient. The provider may be required to cover a particular topic, use a particular REMS material (e.g. a counseling tool, a Medication Guide), or both. **OR** Counsel the patient using [REMS Material]. **OR** Counsel the patient on [topic(s)] using [REMS Material]. **OR** Counsel the patient on [topic(s)] using [REMS Material]. Provide a copy of the material to the patient. 15. Provide the patient with the [REMS Material]. Include this requirement if there are materials that must be provided to a patient (e.g. Patient Brochure, Medication Guide). Materials that are provided to the patient as part of another requirement (e.g. see requirements #7, #10, and #11) do not need to be repeated here. 16. Assess the patient's [condition(s) or health status(es)]. Include this requirement if there is monitoring and/or a particular lab test that must take place (e.g., pregnancy test that needs to take place before each prescription). Repeat this requirement, as needed, to address multiple health conditions and/or lab tests. **OR** Assess the patient's [condition(s) or health status(es)]. Document and submit [the results] to the REMS Program using [REMS Material(s)]. **OR** Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. **OR** Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS Program using [REMS Material(s)]. 17. Order the prescription using the [Prescription Order Form]. Include this requirement only when there is a separate Prescription Order Form that is not part of another REMS form, such as a Patient Enrollment Form, that the prescriber must use. 18. Prescribe no more than a [# of days] days' supply. 19. Not prescribe refills.

1. Health Care Providers who prescribe [drug/class name] must:

During treatment; [at specified interval]

Include this time category if there are requirements that the health care provider must complete with the patient at specified intervals (i.e. not linked to the time/a visit that a prescription is written)

20. Counsel the patient on [topic(s)].
Include this requirement if the health care provider is required to counsel the patient. The provider may be required to cover a particular topic, use a particular REMS material (e.g. a counseling tool, a Medication Guide), or both.
OR
Counsel the patient using [REMS Material].
OR
Counsel the patient on [topic(s)] using [REMS Material].
OR
Counsel the patient on [topic(s)] using [REMS Material]. Provide a copy of the material to the patient.

21. Provide the patient with the [REMS Material].
Include this requirement if there are materials that must be provided to a patient (e.g. Patient REMS Program Brochure, Medication Guide). Materials that are provided to the patient as part of another requirement (e.g. see requirements #7, #10, and #11) do not need to be repeated here.

22. Assess the patient's [condition(s) or health status(es)].
Include this requirement if there is monitoring and/or a particular lab test that must take place (e.g., pregnancy test that needs to take place before each prescription). Repeat this requirement, as needed, to address multiple health conditions and/or lab tests.
OR
Assess the patient's [condition(s) or health status(es)]. Document and submit [the results] to the REMS Program using [REMS Material(s)].
OR
Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring].
OR
Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS Program using [REMS Material(s)].

1. Health Care Providers who prescribe [drug/class name] must:

After treatment discontinuation; [At specified interval] Include this time category if there are requirements that the health care provider must complete after the patient has discontinued treatment	23. Assess the patient's [condition(s) or health status(es)]. Include this requirement if there is monitoring and/or a particular lab test that must take place (e.g., pregnancy test that needs to take place). Repeat this requirement, as needed, to address multiple health conditions and/or lab tests. **OR** Assess the patient's [condition(s) or health status(es)]. Document and submit [the results] to the REMS Program using [REMS Material(s)]. **OR** Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. **OR** Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS Program using [REMS Material(s)]
To maintain certification to prescribe, [specified interval, e.g., every 2 years] Include this time category if there are requirements that the health care provider must complete to be able to continue prescribing	24. Review the drug's Prescribing Information. Note that the Prescribing Information is not appended to the REMS. 25. Review the following: [List the Educational Material(s)]. 26. Successfully complete the [Knowledge Assessment] and submit it to the REMS Program. 27. Re-Enroll in the REMS by completing the [Re-Enrollment Form] and submitting it to the REMS Program.
At all times Include this time category if there are requirements that the health care provider must complete on an ongoing basis, as part of complying with the REMS program	28. Report [adverse event(s) of interest] to [the Manufacturer/the REMS Program/MedWatch]. **OR** Report [adverse event(s) of interest] to the REMS Program using [REMS Form]. 29. Report [treatment discontinuation or transfer of care] to [the Manufacturer/the REMS Program]. Use this requirement if a patient is no longer under the prescriber's care or has discontinued treatment. 30. Maintain records of [REMS activity]. Include this requirement if there are records of certain REMS activities (e.g. records documenting staff's completion of REMS training) that must be maintained, but are not submitted to the REMS program. These records may be requested at any time by the applicant or as part of a REMS audit 31. Comply with audits carried out by [Entity to conduct audit, e.g., applicant, FDA, or third party acting on behalf of the applicant or FDA] to ensure that all processes and procedures are in place and are being followed. Include this requirement if the REMS participant has to agree to be audited.

2. Patients who are prescribed [drug/class name]:

If a particular REMS requirement applies only to a subset of patients (e.g. patients who can get pregnant), use the following format for the requirement:
    For [subset to which the requirement applies]: [Requirement]
    Example: For patients who can get pregnant: Counsel the patient on pregnancy prevention
If there are different requirements for different patient populations (e.g. pediatric), repeat this table for each population, and modify the header accordingly.

Before treatment initiation Include this time category if there are requirements that the patient must complete to be able to initiate treatment	1. Review the [List the Patient Material(s)]. 2. Complete [Patient Form] with the prescriber. Include this requirement if the patient form is not submitted to the REMS Program. If the form is submitted to the REMS Program, use requirement #3. 3. Enroll in the REMS Program by completing the [Enrollment Form] with the prescriber. Enrollment information will be provided to the REMS Program. Include this requirement if the form must be submitted to the REMS Program. Otherwise, use requirement #2. 4. Get [description of lab test]. **OR** Be monitored for [description of monitoring] Include this requirement if the patient is required to have a lab test completed or to be monitored. 5. Receive counseling from the prescriber on [topic(s)]. **OR** Receive counseling from the prescriber using [REMS Material]. **OR** Receive counseling from the prescriber on [topic(s)] using [REMS Material]. 6. Complete [Patient Questionnaire] Include this requirement if there are questions that patients need to answer (e.g. monthly questionnaire to assess a patient's understanding of the drug's risks and safe use conditions).
During treatment; before each [dose/infusion/prescription] Include this time category if there are requirements that the patient must complete prior to receiving subsequent prescriptions	7. Receive counseling from the prescriber on [topic(s)]. **OR** Receive counseling from the prescriber using [REMS Material]. **OR** Receive counseling from the prescriber on [topic(s)] using [REMS Material]. 8. Get [description of lab test]. **OR** Be monitored for [description of monitoring]. Include this requirement if the patient is required to have a lab test completed or to be monitored. 9. Complete [Patient Questionnaire]. Include this requirement if there are questions that patients need to answer (e.g. monthly questionnaire to assess a patient's understanding of the drug's risks and safe use conditions).

2. Patients who are prescribed [drug/class name]:

During treatment Include this time category if there are requirements that the patient must adhere to during treatment (i.e. not linked to the time a prescription is written)	10. Adhere to the safe use conditions, including [safe use condition(s), e.g. use of contraception]. **OR** Adhere to the safe use conditions described in the [Patient Educational Material]. **OR** Adhere to the safe use conditions, including [safe use condition(s), e.g. use of contraception] described in the [Patient Educational Material]. 11. Get [description of lab test]. **OR** Be monitored for [description of monitoring]. Include this requirement if the patient is required to have a lab test completed or to be monitored.
During treatment after administration Include this time category if there are requirements that the patient must complete at after administration during treatment (i.e. not linked to the time a prescription is written)	12. Get [description of lab test]. **OR** Be monitored for [description of monitoring]. Include this requirement if the patient is required to have a lab test completed or to be monitored
During treatment; [At specified interval] Include this time category if there are requirements that the patient must complete at specified intervals during treatment (i.e. not linked to the time a prescription is written)	13. Get [description of lab test]. **OR** Be monitored for [description of monitoring]. Include this requirement if the patient is required to have a lab test completed or to be monitored.
After treatment discontinuation; [At specified interval] Include this time category if there are requirements that the patient must complete after they have discontinued treatment	14. Get [description of lab test]. **OR** Be monitored for [description of monitoring]. Include this requirement if the patient is required to have a lab test completed or to be monitored.
At all times Include this time category if there are requirements that the patient must complete on an ongoing basis, while under the REMS program	15. Inform the prescriber if [conditions under which prescriber should be contacted]. 16. Have the [item] with you. Include this requirement if the patient is required to have on hand or carry with them a specific item or intervention (e.g., wallet card, bracelet, emergency treatment).

3.[Health care settings/prescribers/pharmacies] that dispense [drug/class name] must:

To become certified to dispense Include this time category if there are requirements that the dispenser must complete to be able to dispense	1. Be able to [clinical activity to be performed]. Include this requirement if the dispenser has to have the ability to carry out a particular activity, such as administer a particular treatment. 2. Have [personnel with specific training/experience and/or specific equipment] on-site. Include this requirement if the health care setting needs to have personnel with particular training or particular medical equipment on-site. 3. Designate an authorized representative to carry out the certification process and oversee implementation and compliance with the REMS Program on behalf of the [health care setting/pharmacy]. Include this requirement if the health care setting must designate an authorized representative to act on the healthcare setting's behalf. 4. Have the authorized representative review the [List the Educational Material(s)]. Include this requirement if the authorized representative is required to review certain educational materials that are provided as part of the REMS. 5. Have the authorized representative successfully complete the [Knowledge Assessment] and submit it to the REMS Program. 6. Have the authorized representative enroll in the REMS Program by completing the [Enrollment Form] and submitting it to the REMS Program. **OR** Have the authorized representative enroll in the REMS Program by completing and submitting the applicable enrollment form(s): [List all Enrollment Forms]. Use this version of the requirement if there are different enrollment forms for different types of settings (e.g. inpatient vs. outpatient pharmacy, chain vs. independent pharmacy). 7. Train all relevant staff involved in [activity] on [training topic(s)]. **OR** Train all relevant staff involved in [activity] using [REMS Material(s)]. **OR** Train all relevant staff involved in [activity] on [training topic(s)] using [REMS Material(s)]. 8. Take training provided by [entity providing the training, e.g. the applicant, a CE provider]. Include this requirement if instructor-led training is provided 9. Establish processes and procedures to verify [safe use conditions to be met].

3. [Health care settings/prescribers/pharmacies] that dispense [drug/class name] must:

	Include this requirement if the dispenser is responsible for setting up their own system to verify that safe use conditions have been met. If requirement #9 is included, also include requirement #12 to verify that safe use conditions have been met before dispensing.
Before dispensing Include this time category if there are requirements that the dispenser must complete before dispensing	10. Counsel the patient on [topic(s)]. Include this requirement if the health care provider is required to counsel the patient. The provider may be required to cover a particular topic, use a particular REMS material (e.g. a counseling tool, a Medication Guide), or both. **OR** Counsel the patient using [REMS Material]. **OR** Counsel the patient on [topic(s)] using [REMS Material]. **OR** Counsel the patient on [topic(s)] using [REMS Material]. Provide a copy of the material to the patient. 11. Provide the patient with the [REMS Material]. Include this requirement if there are materials that must be provided to a patient (e.g. Patient REMS Program Brochure, Medication Guide). 12. Verify that [safe use conditions to be met] through the processes and procedures established as a requirement of the REMS Program. Include this requirement if the dispenser must verify that safe use conditions have been met before dispensing, and must use systems established through requirement #9. 13. Obtain authorization to dispense each prescription by contacting the REMS Program to verify [safe use condition to be met]. Include this requirement if the dispenser must obtain authorization from the REMS Program to dispense the drug. 14. Dispense no more than a [# of days] days' supply. 15. Not dispense refills.

3.[Health care settings/prescribers/pharmacies] that dispense [drug/class name] must:

After dispensing Include this time category if there are requirements that the dispenser must complete after dispensing	16. Assess the patient's [condition(s) or health status(es)]. Include this requirement if there is monitoring and/or a particular lab test that must take place (e.g., pregnancy test that needs to take place before each prescription). Repeat this requirement, as needed, to address multiple health conditions and/or lab tests. **OR** Assess the patient's [condition(s) or health status(es)]. Document and submit [the results] to the REMS Program using [REMS Material(s)]. **OR** Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. **OR** Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS Program using [REMS Material(s)].
Before administering *If the drug is administered by a health care provider*: Include this time category if there are requirements that the healthcare provider must complete before the drug is administered	17. Counsel the patient on [topic(s)]. Include this requirement if the health care provider is required to counsel the patient. The provider may be required to cover a particular topic, use a particular REMS material (e.g. a counseling tool, a Medication Guide), or both. **OR** Counsel the patient using [REMS Material]. **OR** Counsel the patient on [topic(s)] using [REMS Material]. **OR** Counsel the patient on [topic(s)] using [REMS Material]. Provide a copy of the material to the patient. 18. Provide the patient with the [REMS Material]. Include this requirement if there are materials that must be provided to a patient (e.g. Patient Brochure, Medication Guide). 19. Assess the patient's [condition(s) or health status(es)]. Include this requirement if there is monitoring and/or a particular lab test that must take place (e.g., pregnancy test that needs to take place before each prescription). Repeat this requirement, as needed, to address multiple health conditions and/or lab tests. **OR** Assess the patient's [condition(s) or health status(es)]. Document and submit [the results] to the REMS Program using [REMS Material(s)]. **OR** Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. **OR** Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS Program using [REMS Material(s)].

3.[Health care settings/prescribers/pharmacies] that dispense [drug/class name] must:

After administering *If the drug is administered by a healthcare provider*: Include this time category if there are requirements that the health care provider must complete after the drug is administered	20. Assess the patient's [condition(s) or health status(es)]. Include this requirement if there is monitoring and/or a particular lab test that must take place (e.g., pregnancy test that needs to take place before each prescription). Repeat this requirement, as needed, to address multiple health conditions and/or lab tests. **OR** Assess the patient's [condition(s) or health status(es)]. Document and submit [the results] to the REMS Program using [REMS Material(s)]. **OR** Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. **OR** Assess the patient's [condition(s) or health status(es)] by [list lab test(s) or monitoring]. Document and submit [the results] to the REMS Program using [REMS Material(s)].
To maintain certification to dispense, [specified interval, e.g. every 2 years] Include this time category if there are requirements that the dispenser must complete to be able to continue dispensing	21. Have the authorized representative review the [List the Educational Material(s)]. Include this requirement if the authorized representative is required to review certain educational materials that are provided as part of the REMS Program. 22. Have the authorized representative successfully complete the [Knowledge Assessment] and submit it to the REMS Program. **OR** 23. Have the authorized representative re-enroll in the REMS Program by completing the [Re-Enrollment Form]. **OR** Have the authorized representative re-enroll in the REMS Program by completing the applicable form(s): [List all Re-Enrollment Forms]. Use this version of the requirement if there are different enrollment forms for different types of settings (e.g. inpatient vs. outpatient pharmacy, chain vs. independent pharmacy). 24. Have the new authorized representative enroll in the REMS Program by completing the applicable form [Enrollment Form]. Include this requirement if the pharmacy designates a new authorized representative.

3.[Health care settings/prescribers/pharmacies] that dispense [drug/class name] must:

At all times

Include this time category if there are requirements that the dispenser must complete on an ongoing basis, while under the REMS program

25. Report [adverse event(s) of interest] to [the Manufacturer/the REMS Program/MedWatch].
    OR
    Report [adverse event(s) of interest] to the REMS Program using [REMS Form].
26. Return unused product to [the manufacturer].
27. Not distribute, transfer, loan, or sell [drug/class name].
    OR
    Not distribute, transfer, loan, or sell [drug/class name], except to certified dispensers.
28. Maintain records of [activity].
    Include this requirement if there are records of certain REMS activities (e.g. records documenting staff's completion of REMS training) that must be maintained, but are not submitted to the REMS program. These records may be requested by the applicant or as part of a REMS audit.
29. Comply with audits carried out by [Entity to conduct audit, e.g., applicant or third party acting on behalf of the applicant] to ensure that all processes and procedures are in place and are being followed.
    Include this requirement if the REMS participant has to agree to be audited.

4. Wholesalers that distribute [drug/class name] must:

To be able to distribute

Include this time category if there are requirements that the wholesaler must complete to be able to distribute

1. Establish processes and procedures to ensure that the drug is distributed only to certified [setting(s)].
2. Train all relevant staff involved in [activity] on [topic(s)].

4. Wholesalers that distribute [drug/class name] must:

At all times

3. Distribute only to certified [setting(s)].
4. Maintain records of [activity].
5. Comply with audits carried out by [Entity to conduct audit, e.g., applicant or third party acting on behalf of the applicant] to ensure that all processes and procedures are in place and are being followed.

--End Subsection A--

--**Start Subsection B**--
REMS Applicant Requirements
This subsection describes requirements for applicants to develop and make available REMS *training*; develop and disseminate REMS *communications materials*; develop systems and processes to support REMS *operations*; and ensure participants' *compliance* with the REMS.

REMS Training
The requirements under this heading relate to the requirement for the applicant to develop REMS training and provide to health care providers. REMS training requirements might also include the requirement for the applicant to develop a knowledge assessment for health care providers.
The REMS training requirements include information about how the training is being provided (e.g., website, mailing, in-person) and whether the training is being provided by a third party (such as a Continuing Education (CE) provider). The REMS training section may also include whether the applicant is required to provide funding for training.
If there are no requirements for the applicant to develop and make available REMS training, delete the requirements under this heading.

[Applicant] must provide training to health care providers who prescribe [drug/drug class].
The training includes the following educational material(s): [Educational Material(s)]. The training must be [describe how training will be provided, e.g. available on a website, delivered by the applicant or accredited CE providers, etc.].

[Applicant] must provide training to health care settings/prescribers/pharmacies who dispense [drug/drug class].

The training includes the following educational material(s): [Educational Material(s)]. The training must be [describe how training will be provided, e.g. available on a website, delivered by the applicant or accredited CE providers, etc.].

REMS Communications
The requirements under this header support the development and dissemination of REMS communication materials to health care providers and professional organizations or societies. If there are no requirements for the applicant to disseminate REMS communications, delete the requirements under this heading.
The table below describes who should receive the REMS communication materials, what materials they should receive, as well as how, when and how often they should receive the materials. The table includes the following information:

Target Audience: The target audience is the particular group of health care providers that are the intended recipients of a REMS communication. For each target audience, include a description of the audience. Include an additional row for each distinct audience.
Communication Materials: The communication materials are intended to disseminate information about the REMS (e.g., REMS Letter for Health Care Providers and for Professional Societies, REMS Fact Sheets, Journal information piece, and REMS Slides).
Dissemination Plan: The dissemination plan describes how the communication materials will be distributed (e.g., via e-mail), the timing (e.g., start, end, how frequency), and whether there is any follow-up required. Include additional distribution plans if a given material is distributed in multiple ways.

To inform health care providers about the REMS Program and the risks and safe use of [drug/class name], [Applicant] must disseminate REMS communication materials according to the table below:

Target Audience	Communication Materials-& Dissemination Plans
[Target Audience]	[Communication Material(s)] • [Dissemination Plan 1] • [Dissemination Plan 2]

Target Audience	Communication Materials-& Dissemination Plans

Health care providers who are likely to prescribe [drug/class name]	Include Communication Materials that apply to this REMS and delete those that do not apply. Under each REMS communication, include dissemination methods that apply to this REMS and delete those that do not apply:
	REMS Letter(s): [Health Care Provider REMS Letter], [Professional Society REMS Letter*] with attachment(s) [REMS material(s)]
	  1. Mail within [X] calendar days of the [date [Drug] is first commercially distributed/approval of the REMS modification] ([mm/dd/yyyy]) and again[X] months later.
	  2. eMail within [X] calendar days of the [date [Drug] is first commercially distributed/approval of the REMS modification] ([mm/dd/yyyy]) and again[X] months later.
	  3. Make available via a link from the [Drug] REMS Program Website.
	  4. Disseminate through [field-based sales and medical representatives].
	  5. Disseminate through professional societies and request the letter or content be provided to their members.
	  6. Disseminate at Professional Meetings for [duration] from [the [date [Drug] is first commercially distributed/approval of the REMS modification] [(mm/dd/yyyy)].
	[Journal Information Piece]
	  1. Publish every [frequency, e.g. quarterly] for [duration] after the [date [Drug] is first commercially distributed/approval of the REMS modification] [(mm/dd/yyyy)] in the following journals:
	[Fact Sheet]
	  1. Disseminate and prominently display at Professional Meetings where [Applicant] has a presence for [duration] from the [date [Drug] is first commercially distributed/ approval of the REMS modification] [(mm/dd/yyyy)].
	  2. Disseminate through [field-based sales and medical representatives] during [the initial and/or follow-up] discussion with healthcare providers for [duration] after [[Drug] is first commercially distributed/approval of this REMS modification] [(mm/dd/yyyy)]. [Field-based sales and/or medical representatives] to orally review the risk messages contained in the REMS Factsheet during the visit with the health care provider.
	[Website]
	  1. Include all of the currently approved [REMS materials/Prescribing Information/Medication Guide].
	  2. Include a prominent REMS-specific link to the [Drug] REMS Program website. The [Drug] REMS Program website must not link back to the promotional product website(s).
	  3. Continue for [duration] from the [date [Drug] is first commercially distributed/approval of the REMS modification] ([mm/dd/yyyy]).

* Provide a list of the professional societies in your REMS Supporting Document

To support REMS Program operations, [applicant] must:

1. Establish and maintain a REMS Program website, [REMS Website]. The REMS Program website must include the capability to complete [prescriber/pharmacy/HCS setting] certification or enrollment online, [the capabilitly to enroll and manage patients 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 [medium e.g. website or call center] [by the date [Drug] is first commercially distributed /within [30/60/90] calendar days of REMS modification] [(mm/dd/yyyy)]. Include implementation dates only if applicable for a REMS modification.

3. Establish and maintain a REMS Program call center for REMS participants at [phone number].

4. Establish and maintain a validated, secure database of all REMS participants who are enrolled and/or certified in the [drug/class name] REMS Program.

5. Ensure [List REMS participants] are able to [REMS activity(ies), e.g. enrollment, dispensing authorization] by [method(s) through which activity may be completed]. Use this requirement to specify the multiple ways that an applicant must provide for a REMS participant to comply with a particular REMS requirement(s); for example, REMS participants must be able to enroll in the REMS by phone, fax, and online. Repeat this requirement as needed (e.g., to address multiple REMS participants, requirements, or activities).

6. Provide [List REMS Material(s)], and the Prescribing Information to REMS participants who (1) attempt to prescribe/dispense/distribute [Drug] and are not yet certified or (2) inquire about how to become certified.

7. Notify [List REMS participants] within [specific, reasonable amount of time] after they become certified in the REMS Program. Use this requirement if the REMS requires certification to prescribe and/or dispense the drug.

8. Provide certified prescribers access to the database of [certified pharmacies and enrolled patients].

9. Provide certified pharmacies access to the database of [certified prescribers and enrolled patients].

To ensure REMS participants' compliance with the REMS Program, [applicant] must:

10. Maintain adequate records to demonstrate that REMS requirements have been met, including, but not limited to records of: [drug] distribution and dispensing; certification of prescribers, pharmacies, and health care settings; enrolled patients; and audits of REMS participants. These records must be readily available for FDA inspections.

11. Establish a plan for addressing noncompliance with REMS Program requirements.

12. Monitor [List REMS participant(s) to be monitored] 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.

13. Audit [REMS participant(s) to be audited] no later than [number of days, e.g. 180 days] after they become certified, to ensure that all REMS processes and procedures are in place, functioning, and support the REMS Program requirements.
    OR
    Audit [REMS participant(s) to be audited] at [timing/interval/frequency of audit] to [goal of audit].Include this version of the requirement if the audit targets a specified percentage of the group (e.g., 10% of certified pharmacies). The [timing/interval/frequency] may specify that audits take place at a specified frequency or within a certain number of days after the REMS participant has enrolled in or become certified in the REMS. Repeat this requirement if the audit approach differs among different groups of REMS participants.

14. Take reasonable steps to improve implementation of and compliance with the requirements in the [drug/class name] REMS Program based on monitoring and evaluation of the [drug/class name] REMS Program. Include this requirement for all REMS with a subsection A.

---End Subsection B------------------------------------

IV.   REMS Assessment Timetable

This section describes the timetable for the applicant to submit its REMS Assessments. [NDA/BLA Holder(s)] must submit REMS Assessments at [time intervals/frequency, e.g. 18 months, 3 years, and 7 years from the date of the initial REMS approval **OR** 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. [NDA/BLA Holder(s)] must submit each assessment so that it will be received by the FDA on or before the due date.
This section does not apply to ANDAs, and should not be included in ANDA REMS document.

V. REMS Materials

The following materials are part of the [drug/class name] REMS and are appended:

Enrollment Forms:
    Prescriber:
        1.   [Prescriber Enrollment Form]

    Patient:
        2.   [Patient Enrollment Form]

        3.   If the REMS includes different enrollment forms for different patient populations, include them as follows:
            [Patient Enrollment Form for [type of patient]]

    Pharmacy:
        4.   [Pharmacy Enrollment Form]

        5.   If the REMS includes specific enrollment forms for different types of pharmacies, include them as follows:
            [[Type of pharmacy] Pharmacy Enrollment Form]
            For example:
            [Independent Pharmacy Enrollment Form]
            [Inpatient Pharmacy Enrollment Form]

    Health Care Setting:
        6.   [Healthcare Setting Enrollment Form]

        7.   [Other setting-specific Enrollment Forms, as needed]

    Other Enrollment Form(s): Include the names of other enrollment forms here

Training and Educational Materials
    Prescriber:
        8.   [Prescriber Education]

        9.   [REMS Program Overview]

        10.   [Knowledge Assessment]

    Pharmacy:
        11.   [Pharmacy Education]

        12.   [REMS Program Overview]

        13.   [Knowledge Assessment]

Patient Care Form(s)

14. [Patient Care Form] Include the names of forms used in patient care (other than enrollment forms), such as forms used to support patient monitoring or to document safe use conditions

Communication Materials

15. [Dear Health Care Provider letter]

16. [Professional Society REMS letter]

17. [Journal Information Piece]

18. [Fact Sheet]

Other Materials

19. [REMS Program website]

[Administrative forms and materials] Include any administrative forms or materials here, as well as materials that don't fit into the above categories