

Dear iPLEDGE Program SAB Member,

We are contacting you on behalf of the Sponsors of the iPLEDGE® REMS Program. The Food and Drug Administration (FDA) and the iPLEDGE Program Sponsors have received inquiries from external stakeholders raising concerns about patient access to certain REMS drugs during the COVID-19 National Emergency.

As you are aware, the iPLEDGE Program REMS requires pregnancy testing of Females of Reproductive Potential and other patient monitoring so that they may receive isotretinoin. FDA recognizes that during the COVID-19 national emergency, completion of REMS-required testing or other patient monitoring may be difficult because patients may be self-isolating and/or subject to quarantine. During this time, FDA will not object to healthcare providers using their best medical judgement to ensure their patients continue to have access to drugs subject to these REMS.

To that end, we are requesting that the following information be forwarded to your members regarding the iPLEDGE Program.

Requirement	Changes Due to COVID-19
Telemedicine	<ul style="list-style-type: none">▪ Prescriber to use best medical judgement to manage their patients.<ul style="list-style-type: none">➢ Please refer to the March 17, 2020 notice from The Department of Health and Human Services Office for Civil Rights (“Notification of Enforcement Discretion for telehealth remote communications during the COVID-19 nationwide public health emergency”) for guidance.
Pregnancy Testing	<ul style="list-style-type: none">▪ Pregnancy test can be “at-home”. The tests can be obtained at drug store, grocery store, or online retailer.▪ The test results and date performed must be communicated to prescriber.▪ Prescriber or designee would enter the date performed (specimen collection date) and test results per usual iPLEDGE program process.
Prescription Window	<ul style="list-style-type: none">▪ This requirement will not change.
Two Forms of Birth Control or Abstinence	<ul style="list-style-type: none">▪ This requirement will not change.

Best,

Syneos PMO on behalf of the IPMG