WHAT'S NEW?

The iPLEDGE Program has implemented several enhancements to the iPLEDGE Program website and automated phone system. These do not represent changes to the program requirements for our patients, prescribers, designees, and pharmacies. The iPLEDGE Program sponsors are required to continually monitor and modify the program to meet the program goals and these changes are based on feedback from stakeholders and analysis of data collected.

This document will be removed from the website on August 10, 2012.

What’s New for All Stakeholders
- Publication of the iPLEDGE Non-Compliance Action Policy
- Roche Accutane® Withdrawal
- Versapharm Myorisan™ Integration

What’s New for Prescribers and Designees
- Additional prescriber attestation points for initial activation and annual re-activation
- Designees, like their affiliated prescribers, are now required to attest annually to the iPLEDGE program requirements
- Incorporation of a system-assisted risk categorization tool for registration of female patients
- Ability to re-register existing patients without obtaining call center override
- Ability to change female patient risk category without contacting the call center
- Ability to correct contraceptive choices during patient confirmation step
- Prescribers will receive an additional alert if abstinence is chosen as the method of contraception
- If the patient did not fill a prescription through the iPLEDGE system in the previous window, prescribers will be asked to verify isotretinoin use with the patient and enter the source of product
- An alert has been added to reinforce that the entire patient confirmation process, including a new pregnancy test, is required when the prescriber creates a new prescription window

Pregnancy Test Entry
- Qualitative Serum pregnancy test (positive/negative) results are now accepted
- Ability to enter post-therapy pregnancy test results for patients in the status of Inactive or Permanently Lost to Follow Up
- Pregnancy test Comment field has been removed
- Confirmation checkbox for the date of pregnancy test has been added as a signal to verify the accuracy of the entry before leaving the Pregnancy Test Entry page

Patient Discontinuation
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What’s New for Pharmacies

- Enhanced visibility of Risk Management Authorization (RMA) number and Do not dispense after date
- Ability to view Risk Management Authorization (RMA) numbers filled at the pharmacy location
- 12-digit RMA and check digit for optional use in pharmacy adjudication systems
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What’s New for All Stakeholders

Publication of the iPLEDGE Non-Compliance Action Policy
The Isotretinoin Risk Management Program (iPLEDGE) is a computer based restricted distribution program and pregnancy registry designed to support the public health goals that no woman who is already pregnant will initiate isotretinoin therapy and that no woman will become pregnant while on isotretinoin therapy for one month prior to, during, and for 30 days after the course of treatment. Compliance with the requirements of the iPLEDGE Program is necessary to achieve this public health goal, and potential fetal exposure is paramount when considering actions taken against a non-compliant stakeholder in iPLEDGE.

One of the components for the iPLEDGE Program is implementation of a plan to monitor, evaluate, and improve minimization of drug exposure during pregnancy and compliance with restrictions for safe use under the iPLEDGE program. This iPLEDGE Non-Compliance Action Policy sets forth the principles by which non-compliance by iPLEDGE stakeholders will be evaluated.

The iPLEDGE Non-Compliance Action Policy is permanently linked at the bottom of the Public Homepage found at www.iPLEDGEProgram.com.

Roche Accutane® Withdrawal
Roche Laboratories has withdrawn its New Drug Application (NDA) for Accutane®. The decision to withdraw the NDA is not being taken for reasons of safety or efficacy. As a result, Roche Laboratories no longer participates in the iPLEDGE Program.

However, isotretinoin has been and will continue to be available from Mylan Pharmaceuticals (Amnesteem®), Ranbaxy Laboratories (Sotret®), Teva Pharmaceuticals USA (Claravis™) and VersaPharm Incorporated (Myorisan™). To that end, the iPLEDGE Program will continue to operate and compliance with the program’s requirements is required to obtain, prescribe and dispense isotretinoin.

VersaPharm Myorisan™ Integration
VersaPharm Incorporated is now participating in the iPLEDGE Program with its isotretinoin product Myorisan™.
What’s New for Prescribers and Designees

Additional prescriber attestation points for initial activation and annual re-activation

During initial activation and annual re-activation for prescribers, there is a second page of Compliance Notice statements which prescribers must acknowledge. They include the following:

- iPLEDGE data will be analyzed for non-compliance
- Information entered into iPLEDGE is part of a patient’s medical record
- Prescribers are responsible for actions of designees
- The FDA can be notified of any non-compliance

Designees, like their affiliated prescribers, are now required to attest annually to the iPLEDGE program requirements

Designees working on behalf of a prescriber in iPLEDGE must acknowledge the following on an annual basis.

- iPLEDGE data will be analyzed for non-compliance
- Information entered into iPLEDGE is part of a patient’s medical record
- Prescribers are responsible for actions of designees
- The FDA can be notified of any non-compliance

All existing designees will be required to acknowledge these items when the new system version becomes available and annually thereafter. New designees will be required to attest to these items before they can act on behalf of an iPLEDGE prescriber.
Incorporation of a system-assisted risk categorization tool for registration of female patients

When registering a new patient, the iPLEDGE system will assist in assigning a patient to the proper risk category using a series of Yes/No questions as follows:

- Has patient had a hysterectomy?
- Has patient had a bi-lateral oophorectomy?
- Is this patient post-menopausal?

The responses to these questions during patient registration will properly classify a patient according to the iPLEDGE requirements. If an unusual medical circumstance exists and you believe that this automatic classification is not correct, you will have the opportunity to request an exception, which may require further discussion with an iPLEDGE representative, and submission of supporting documentation.

This new system feature will reduce misinterpretation of program requirements and make it easier for prescribers to comply with iPLEDGE requirements regarding patient risk category.

Ability to re-register existing patients without obtaining call center override

If a patient is registered in iPLEDGE under your care, and needs to be re-registered for another course of treatment, you or your delegate prescriber can re-register the patient without obtaining an override code from the iPLEDGE Call Center. This function is available on the Manage Patients screen.

Note that if a patient was most recently under the care of another prescriber, then re-registration will still require an override code as it has in the past.

Ability to change female patient risk category without contacting the call center

If a female patient is incorrectly registered in a risk category (FCBP or FNCBP), the prescriber can change the patient’s risk category without intervention from the iPLEDGE Call Center.

When selecting this option from the Manage Patients page, the prescriber will be presented with the same Yes/No questions regarding program criteria that are presented during the new patient registration process. This will ensure that the program criteria are accurately applied during the change in patient type, and that this change in patient risk category is justified and compliant with iPLEDGE requirements.
**Ability to correct contraceptive choices during patient confirmation step**

If a Female Patient of Childbearing Potential (FCBP) is confirmed using contraception methods that are incorrect, you can change these choices via an option from the Manage Patients page. All program requirements, such as a 30-day waiting period when a patient switching from abstinence to another form of contraception, will be enforced when using this new feature.

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**Prescribers will receive an additional alert if abstinence is chosen as the method of contraception**

When Abstinence is chosen as a form of contraception, you will be reminded of the program guidelines for using abstinence as a contraception method, including the guideline that patients who are not likely to remain abstinent for their course of isotretinoin treatment should consider using two other forms of birth control.

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**If the patient did not fill a prescription through the iPLEDGE system in the previous window, prescribers will be asked to verify isotretinoin use with the patient and enter the source of product**

If a Female of Childbearing Potential (FCBP) patient had a previous prescription window that did not result in a Risk Management Authorization (RMA) number being issued by iPLEDGE, then the patient either did not fill her prescription, or filled and picked up their prescription at a pharmacy that did not obtain an RMA in iPLEDGE. Dispensing a prescription without obtaining an RMA from iPLEDGE is considered pharmacy non-compliance.

If this occurs, the next time the patient is confirmed, you may be asked a question regarding whether or not the patient received drug in their previous prescription window, and if so, you will be asked to provide information regarding the pharmacy that dispensed the drug.

Providing this input to the iPLEDGE system will help the program to contact pharmacies that may require assistance in following the iPLEDGE requirements. However, this information is not required, and not responding does not impact the patient’s ability to start their next prescription window or get their next prescription.

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**An alert has been added to reinforce that the entire patient confirmation process, including a new pregnancy test, is required when the prescriber creates a new prescription window**

Every new prescription window requires the prescriber to complete the entire patient confirmation process, including obtaining a new pregnancy test from a CLIA certified lab. If the timing of re-confirmation indicates that a new pregnancy test may have been omitted from the process, you may be reminded of this requirement.

Examples of when this might occur include re-confirmation of the patient immediately after the following:
- A prescription window was entered that was immediately expired (i.e. pregnancy test specimen collection date more than 7 days old).
- A prescription denial occurred at the pharmacy due to the patient’s prescription window having expired.

In such situations, the iPLEDGE message displayed will remind you to complete the entire confirmation and counseling process to start a new prescription window, including entry of a new CLIA certified pregnancy test result using the date of specimen collection.

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**Pregnancy Test Entry**

**Qualitative Serum pregnancy test (positive/negative) results are now accepted**
In addition to the Urine and Quantitative Serum Pregnancy tests that are acceptable in iPLEDGE, a CLIA-certified Qualitative Serum Pregnancy test that does not return a specific hCG level is now also acceptable in iPLEDGE.

Choosing Qualitative Serum as the test type when entering pregnancy test results will not require the entry of an hCG value.

**Ability to enter post-therapy pregnancy test results for patients in the status of Inactive or Permanently Lost to Follow Up**
In the past, the iPLEDGE system would not accept a Post-therapy Pregnancy test once the patient had reached a status of Inactive or Permanently Lost to Follow Up. The iPLEDGE system has been updated to allow for entry of post-therapy pregnancy tests regardless of patient status, so post-therapy pregnancy tests can be entered at any time.

The iPLEDGE system will determine if entry of such tests meets the post therapy requirement of either the date of last dose or 30 days after the last dose. It will also accept supplemental tests that do not meet either criteria, or are in addition to tests already entered that have met the program post-therapy requirements.

**Pregnancy test Comment field has been removed**
Previously, there was a “Comments” field available on all iPLEDGE website pages where pregnancy tests results were reported. This field has been removed to ensure that the prescribers are using the “Test Results” and “Diagnosis” fields to report pregnancy test results, and not using the free form comments to provide contradictory or non-related information.

**Confirmation checkbox for the date of pregnancy test has been added as a signal to verify the accuracy of the entry before leaving the Pregnancy Test Entry page**
Since accurate entry of pregnancy test specimen collection date is critical for record of a patient’s post therapy follow up, iPLEDGE will ask you to confirm that the date is correct before allowing Post Therapy Pregnancy Test Entry. This is intended to ensure accuracy of pregnancy test specimen collection date, and assist you in remaining compliant with the post therapy program requirements.

iPLEDGE will also ask you to confirm specimen collection date entry when reporting a patient pregnant.
**Patient Discontinuation**

**Additional discontinue reason codes**
In addition to the existing discontinuation reasons of Completed Therapy, Pregnant and Other, the following reasons have been added.

- Patient Never Started Therapy
- Patient Has Insurance Considerations
- Patent is Lost to Follow Up

These new discontinue selections reflect additional reasons why patients typically discontinue therapy, and are provided so that these reasons are no longer classified as “Other”.

Definitions of all discontinue reasons are provided on the Web.

*Comment box for patient discontinuation only available for reason = Other*
When discontinuing a patient, the free-form comments entry field will only be displayed when the discontinue reason is “Other”. For all other discontinue reasons, there will be no entry field available for input of free-form comments.
Other

Spanish Patient Introductory Brochure in bundles of 3
When ordering iPLEDGE Educational Materials, Patient Introductory Brochures in Spanish will be packaged in bundles of 3 instead of 5. This will allow you more flexibility to order the desired number of this item.

Patient Program Status Page
The displayed prescription authorizations for a patient’s most recent course of treatment are now sorted in descending order in the Prescriptions Filled box located in the Patient Program Status Page.

New Prescriber/Designee Home Page Design
The Safety Notice text will now be displayed in its entirety on the home page.

Action Required List – “Need More Time” option can now only be used once per course of treatment
Previously, the system allowed selection of the “Need More Time” action any number of times in the Action Required List. The “Need More Time” option is now selectable only once during a patient’s course of treatment.
What’s New for Patients

**Request information on previous prescription window if no fill was recorded**
If you are a Female Patient of Childbearing Potential (FCBP), and your most recent prescription window did not result in a prescription being recorded in iPLEDGE, either you did not fill your prescription, or you filled your prescription at a pharmacy that did not comply with the iPLEDGE requirements for pharmacies.

If this occurs, the next time that you demonstrate comprehension by answering the program questions, the iPLEDGE system may ask you whether or not you received isotretinoin in your previous prescription window. If you did, you will be asked to provide information regarding the pharmacy where you got the prescription.

Providing this input to the iPLEDGE system will help the program to contact pharmacies that may require assistance in following the iPLEDGE requirements. However, this information is not required, and not responding will not impact your ability to start your next prescription window or get your next prescription filled.

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**Reminder regarding abstinence as birth control method**
If you enter Abstinence into the iPLEDGE system as your primary form of birth control, you will be reminded of the iPLEDGE requirements for abstinent patients. You will also be reminded that if you do not think you can remain abstinent during your isotretinoin therapy, that you should consider using two other forms of birth control.

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**“Patient Registration Information” button on Public homepage**
On the public homepage, a new button has been added for use by patients seeking information on how to become registered in iPLEDGE. The resulting information informs patients that they must be registered by a Health Care Professional, such as a doctor.

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**New Patient Home Page Design**
The Safety Notice text will now be displayed in its entirety on the home page.

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What's New for Pharmacies

**Enhanced visibility of Risk Management Authorization (RMA) number and Do not dispense after date**
When a pharmacy authorizes a prescription in the iPLEDGE system, the Risk Management Authorization (RMA) Number will be displayed in larger, bold print, with highlighted directions to write the RMA and the date by which the prescription must be picked up on the prescription bag sticker.

**Ability to view Risk Management Authorization (RMA) numbers filled at the pharmacy location**
Pharmacists can now look up the Risk Management Authorization (RMA) numbers issued at their pharmacy. This function is available by selecting “Reverse Prescriptions” on the Pharmacy Homepage, and then clicking on the link for “Forgot the RMA Number?  Look it up here”.

**12-digit RMA and check digit for optional use in pharmacy adjudication systems**
The Risk Management Authorization (RMA) number will now be 12 digits, and include check-digit logic that can optionally be incorporated into pharmacy adjudication systems to ensure that a valid iPLEDGE RMA number has been obtained for each prescription.

Any pharmacy that wants to incorporate this logic into its adjudication system should contact the iPLEDGE program for additional information.

**New Pharmacy Home Page Design**
The Safety Notice text will now be displayed in its entirety on the home page.

**RMA Denial Message**
The prescription fill denial message has been modified to include the following text:

“You are **NOT** authorized to fill this prescription. The iPLEDGE program safety requirements are not currently met. Failure to adhere to this denial may result in this pharmacy being deactivated from the iPLEDGE Program.”