

Did IPMG Break Its Pledge to Improve iPLEDGE? Tips to Help You Navigate the New Website

By Dr. Susan Massick



Due to the FDA's concern regarding the high risk of teratogenicity associated with isotretinoin, the iPLEDGE program was introduced by the Isotretinoin Products Manufacturers Group (IPMG) and approved by the FDA in 2005 in an effort to prevent pregnancy and fetal exposure during isotretinoin treatment. Despite concerns raised by clinicians and the AAD regarding the program and its implementation, the FDA approved March 1, 2006, as the mandatory start date for iPLEDGE.ⁱ

In 2007, the FDA gained the authority to determine which medications would require Risk Evaluation and Management Strategy (REMS) programs to mitigate risks associated with certain drugs. In 2010, the iPLEDGE program was updated to the iPLEDGE REMS program with mandatory participation of all isotretinoin drug manufacturers and mandatory registration of all health care providers and pharmacies in order to prescribe and dispense isotretinoin to patients.ⁱⁱ

While the FDA determines which medications require a risk management program, the FDA does not develop nor direct the REMS programs—that is left to the drug manufacturers. According to the FDA, “the responsibility for implementing the iPLEDGE program and making sure that it works as intended rests with the [isotretinoin drug] manufacturers.”ⁱⁱⁱ

According to the FDA informational website, the FDA informed the IPMG in June 2018 of the need to change the REMS risk categories from gender-specific to gender-neutral categories. This change was approved on October 8, 2021, with the new categories designated as “patients who can get pregnant” and “patients who cannot get pregnant.”^{iv} This gender-neutral language was celebrated by clinicians and stakeholders as a welcome but long overdue update to pregnancy categories. The IPMG decided these changes were to be implemented at the same time of an anticipated website update on December 13, 2021.

While the website overhaul was deemed necessary due to phasing out of the old system platform, there were some concerns raised by clinicians and the AAD regarding the ease of this transition and the potential disruption of access to drug given time-sensitive approval windows for patients who can get pregnant. Disregarding these raised concerns, the IPMG moved forward with the website update on December 13, 2021. As we all experienced, unfortunately, the transfer to the new database and new system administrator did not go smoothly: clinicians and patients were unable to log into the system; iPLEDGE customer care agents were overwhelmed and unable to handle high call volumes resulting in absurdly long wait times (up to 5 hours or longer); pharmacies were unable to dispense medication; and patients were unable to access the system or receive their medications. It was a debacle.

It is debatable whether the iPLEDGE program has been effective in mitigating risk of pregnancy or fetal exposure to isotretinoin.^v What is clear is that despite the outcry from clinicians, pharmacists, and patients and advocacy by the AAD, there are no plans by the FDA to change the required REMS designation for isotretinoin nor plans by the IPMG to streamline the iPLEDGE process. Questions, such as why patients who cannot get pregnant need to be registered at all, remain. The AADA Council on Government Affairs and Health Policy, chaired by Dr. Bruce Brod, is actively seeking feedback with regard to your experiences using iPLEDGE in an effort to develop short-term and long-term solutions for IPMG to consider and hopefully implement. [Access the comment form here \(must be an AAD member\).](#)

For busy clinicians, however, the primary goal remains to be able to prescribe this medication when appropriate in an effort to provide safe, effective care for patients. *Below are a few tips and resources to help you navigate the system in its current form:*

CONTACT INFORMATION AND UPDATES

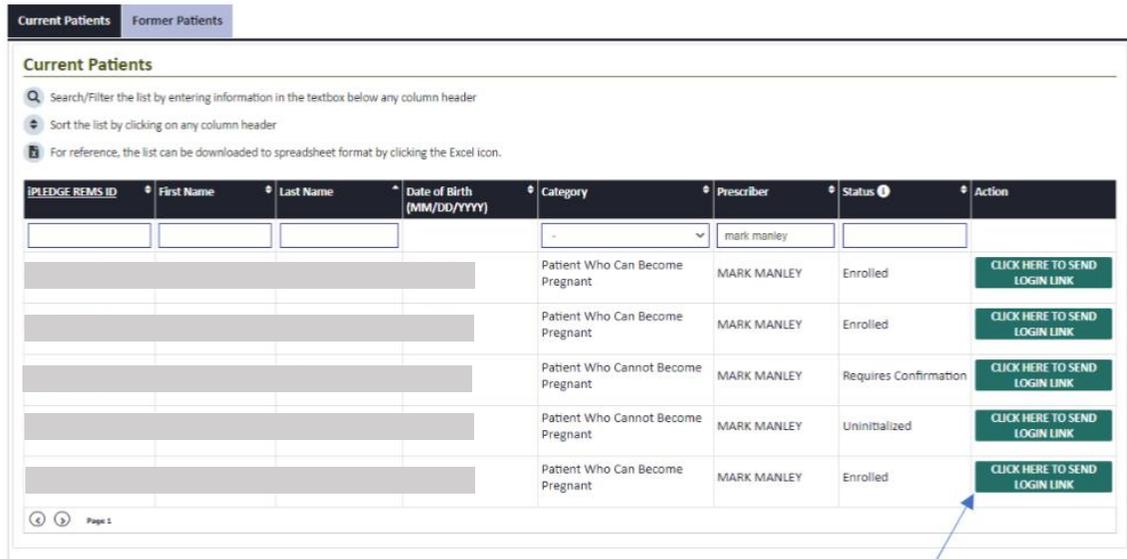
- Any updates to the FDA iPLEDGE REMS program are listed in chronological order at www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/pledge-risk-evaluation-and-mitigation-strategy-rems.
- iPLEDGE call center phone number: 1-866-495-0654 (best to call right at 9 AM EST)
- Email address: customersupport@iPledgeRemsSupport.com

WEBSITE NAVIGATION

- Laptop/desktop computers work best over tablet/smartphone, especially for drop down boxes.
- Use Chrome or Firefox browsers rather than Internet Explorer.
- Disable pop-up blocker if still experiencing browser issues.

REGISTRATION AND PATIENT UPDATES

- SSN digits are no longer needed but each patient registration needs a unique email address (i.e., parent can't use same email for more than one child).
- New Login Links for clinicians to send login info directly to patients' emails to avoid the call center. Click on the green box under Action. (Photo from iPLEDGE Trouble shooting Tips)^{vi}



The screenshot shows the 'Current Patients' tab in the iPLEDGE REMS system. It features a search bar, sorting options, and a table with columns for iPLEDGE REMS ID, First Name, Last Name, Date of Birth (MM/DD/YYYY), Category, Prescriber, Status, and Action. The Action column contains a green button labeled 'CLICK HERE TO SEND LOGIN LINK' for each patient row. A blue arrow points from the text below to this button.

iPLEDGE REMS ID	First Name	Last Name	Date of Birth (MM/DD/YYYY)	Category	Prescriber	Status	Action
				-	mark manley		
				Patient Who Can Become Pregnant	MARK MANLEY	Enrolled	CLICK HERE TO SEND LOGIN LINK
				Patient Who Can Become Pregnant	MARK MANLEY	Enrolled	CLICK HERE TO SEND LOGIN LINK
				Patient Who Cannot Become Pregnant	MARK MANLEY	Requires Confirmation	CLICK HERE TO SEND LOGIN LINK
				Patient Who Cannot Become Pregnant	MARK MANLEY	Uninitialized	CLICK HERE TO SEND LOGIN LINK
				Patient Who Can Become Pregnant	MARK MANLEY	Enrolled	CLICK HERE TO SEND LOGIN LINK

- The new “CLICK HERE TO SEND LOGIN LINK” feature allows you to send a patient a link to login to the iPLEDGE REMS website. More information of this feature can be found on your Home/Manage Patients screen.

WHAT'S NEW?
Send Login Link has been introduced on "Manage Patients" and "Manage Designees" screens. Please click [here](#) to see the instructions on how to use it.

- Only one prescription per each confirmation. (Ex: choose alternating daily dosages to get the desired average daily dose for those needing 50 mg or 70 mg a day).
- Count your days: iPLEDGE has removed the helpful calendar, and you cannot update before 30 days in patients who can get pregnant—best to reschedule for a minimum of 31 days from update.
- Abstinence remains a choice for patients who can get pregnant. Be sure to alert patients to click on the link on their screen pledging that they will remain abstinent while on isotretinoin. This will keep you from getting email warnings.
- Consider having paper copies of consent form that patients can sign and be scanned in for a more efficient online registration system. You as the prescribing physician are responsible to review the entire consent form with each patient when registering.

Additional tips from iPLEDGE REMS program can be accessed here: [iPLEDGE Troubleshooting Tips](#)
Link for your patients to submit their experiences: <https://www.aad.org/public/pledge-story>

¹ "FDA Fails to Postpone March 1 Start Date of iPLEDGE program for Isotretinoin Patients." Published 02/26/2006. www.biospace.com/article/fda-fails-to-postpone-march-1-start-date-of-pledge-program-for-isotretinoin-patients/

² "iPLEDGE Risk Evaluation and Mitigation Strategy (REMS)." Updated 01/14/2022. www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-pledge-rems

³ FDA Statement: "FDA Urges Manufacturers to Develop Solutions for iPLEDGE REMS Website." Published 12/23/2021. www.fda.gov/drugs/drug-safety-and-availability/fda-urges-manufacturers-develop-solutions-pledge-rems-website.

⁴ "Questions and Answers on the iPLEDGE REMS." Published 10/12/2021. www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/questions-and-answers-pledge-rems

⁵ Shin, Janet; Cheetham, T. Craig; Wong, Linda; Niu, Fang; Kass, Elizabeth; Yoshinaga, Monica A.; Sorel, Mike; McCombs, Jeffrey S.; Sidney, Stephen (December 2011). "The impact of the iPLEDGE program on isotretinoin fetal exposure in an integrated health care system". *Journal of the American Academy of Dermatology*. 65 (6): 1117–1125

⁶ [iPLEDGE REMS – Troubleshooting Tips \(pledgeprogram.com\)](#)