FAQ/Standard Response:

Question: The iPLEDGE website is not functioning and I can't get through to the call center. I have patients here that I cannot register or treat as a result. What is the Academy doing to address this?

The Academy is aware of the issues faced by dermatologists and patients attempting to use the new iPLEDGE platform today. We are in contact with the FDA and Syneos in an effort to share your experience and urgently communicate that the new platform rollout out has been a nightmare for dermatology practices and their patients and has created an unacceptable disruption in patient care.

Over the last several weeks we have repeatedly warned the FDA and Syneos that the proposed changes did not reflect clinical practice and would impede patient care. Our outreach has included submitting an emergency request for FDA to reconsider. The Academy met with more than 50 members of the FDA the first week of December and after presenting our significant concerns with both the old and the new systems, asked for a halt to the program until those concerns could be addressed. We were told no, with the explanation that suspending the iPLEDGE program would not, from FDA's perspective, provide the safeguards that are necessary to prevent embryofetal exposure. They also assured us that the iPLEDGE administrator was taking steps to address many of our concerns before today's launch. Clearly that has not been the case.

The Academy appreciates members sharing these issues and will utilize this information as we continue to urgently seek solutions to the immediate crisis as well as to longstanding issues with the program.

Question: I cannot get through to the call center OR Wait times on the phone can be hours-long, are the iPLEDGE sponsors prepared to address this?

This was a primary concern the Academy communicated with both FDA and the iPLEDGE administrator. The FDA strongly emphasized to the iPLEDGE Sponsors that they needed to anticipate high call volume during the transition of the iPLEDGE program to the new platform and the need to be appropriately staffed to handle the increased call volume. We were told that the call center had been directed to implement measures to mitigate hold times, including increased staffing, a callback

feature that allows the caller to remain in the queue but not on the phone, and a voicemail option for non-urgent requests. Did you receive that option?

The iPLEDGE sponsors have notified the FDA that the iPLEDGE REMS Contact Center will be administered by a different vendor than the current one.

Question: Why didn't the Academy do something sooner?

The Academy began communicating our concerns with these changes as soon as they were announced. As we have been urging delays and changes to the program with both FDA and the iPLEDGE administrator, we have shared available updates with members through our e-newsletters and through member alerts.

Question: When enrolling a new patient can I use a paper consent form instead of requiring electronic consent?

Effective with the Monday December 13, 2021 launch of the updated iPLEDGE REMS website, the iPLEDGE sponsors indicated they would be providing paper consent forms on the iPLEDGE REMS website to download and complete to accommodate your request to allow the use of paper consent forms when enrolling a new patient in the iPLEDGE REMS. The enrollment process on the website will also reportedly include an option for the prescriber to select a checkbox, indicating a paper copy of the consent form has been signed and is on file.

Question: Are Prescribers allowed to separate the entry of patient informed consent and the prescriber counseling attestation from the administrative task of entering patient demographic information into the system (e.g., name, DOB, pregnancy test results); allowing designees to enter enrollment data?

FDA has stated that the iPLEDGE Sponsors are working to implement technical updates to address this request. FDA stated that they understand that some issues require more complex solutions, and they are working with the iPLEDGE Sponsors to address this concern; however, this was not addressed prior to December 13, 2021.

Question: Will the transition Allow for patient informed consent to be obtained via telemedicine?

The modification will allow for patient informed consent to be obtained via telemedicine. Page 7 of the Prescriber Information Q&A document disseminated by

the iPLEDGE Sponsors on November 30, 2021 indicates how a remote patient can be enrolled by a prescriber electronically:

“The enrollment process must be done on-line. However, during the patient enrollment and informed consent process, the patient can choose the "Type It" option so a request for their electronic signature is sent to their preferred method of communication (email or text message).”

This capability will be available at launch on December 13, 2021.

Question: Am I allowed to continue to accept the use of at-home pregnancy tests

The flexibility to allow home pregnancy tests is due to the COVID-19 pandemic-related Public Health Emergency (PHE) currently in effect. Once the PHE is lifted, patients will be required to have their monthly pregnancy tests performed in a CLIA-certified lab. Please note, the initial pregnancy test required for patient enrollment does not have to be performed in a CLIA-certified lab.

Question: Due to the system change for patient categories, do I have to change the patient risk category for each of my patients?

The new iPLEDGE website will prompt the prescriber to update the patient risk category for all active patients. The iPLEDGE Sponsors clarified in their December 6, 2021 update to the Prescriber Information Session Q&A that this process does not need to be completed for all patients at once at the time of the prescriber’s initial login to the iPLEDGE system. Rather, prior to acting upon an individual patient, that patient’s risk category must be confirmed. The prescriber may return to the iPLEDGE website and perform other patients’ confirmations at a later time.

Question: What happens if I do not know my National Provider Identification (NPI)?

With regard to prescribers who do not recall their National Provider Identification (NPI) number, it can be found online via the National Plan and Provider Enumeration System: https://npiregistry.cms.hhs.gov/

A designee does not need an NPI number to be activated or to log in to the system.

Question: Are Pharmacists prepared for the transition?

Prescribers and Pharmacists currently enrolled in the iPLEDGE REMS were notified of the changes to the iPLEDGE REMS in accordance with the communication activities outlined in the iPLEDGE REMS document, as found at the REMS @ FDA website: https://www.accessdata.fda.gov/scripts/cder/rems/index.cfm?event=RemsDetails.page&REMS=24

Additionally, a Pharmacist Information Session was held by the iPLEDGE Sponsors in July 2021 to preview the updated website. The new iPLEDGE REMS platform removes the “switch” pharmacy management system as a method to verify authorization to dispense isotretinoin and pharmacists can no longer use the switch system to obtain a pre-dispense authorization, known as a risk management authorization (RMA). As of December 13, 2021, pharmacists must obtain an RMA online by the two other methods currently available; by accessing the iPLEDGE REMS website or by telephone via the PLEDGE REMS Contact Center (866-495-0654) prior to dispensing each isotretinoin prescription.