

## Talking points on iPLEDGE Program Updates – as of 12/14/2021

*Introduce yourself; include your leadership role at the Academy*

- Isotretinoin has been used as a course of treatment for severe cystic acne for more than 25 years. It is FDA approved and considered to be the most effective treatment for severe acne by dermatologists, particularly for patients at risk of permanent acne scarring.
  - As severe acne is associated with depression and suicide, this medication can be a life-saving therapy for those who need it the most.
  - It has been used for other serious skin conditions such as ichthyosis and the prevention of skin cancer.
  - Treatment often results in prolonged clearance of acne, which can be permanent for some patients.
- iPLEDGE is a Risk Evaluation and Mitigation Strategy (REMS) program at the Food and Drug Administration (FDA) since 2005. The goals of the program are to:
  - Prevent fetal exposure to isotretinoin, which can cause severe birth defects, even after short exposure
  - Inform prescribers, pharmacists, and patients about isotretinoin's serious risks and safe-use conditions
- For years, the American Academy of Dermatology Association (AADA) and its members have been engaging with the FDA to make the iPLEDGE program less burdensome for patients and recommended improvements to the system.
- Most recently, we have engaged this group on the recently announced changes to the program that took effect on Dec. 13, 2021. We warned the FDA, the iPLEDGE administrator, Syneos Health, and the program sponsors of the enormous workflow challenges placed on physicians and practices, as well as the immediate threat of ensuring safe access to isotretinoin.
- The rollout of this new system has been tumultuous and patient access to this medication has been substantially disrupted.
- Leading up to this transition, the AADA and its members requested a delay in implementing this new platform to ensure proper workflows, training, and equipment were in place to deliver the highest quality of care to patients.
- The FDA and iPLEDGE did not listen to us. Now, physicians are facing an uphill battle to ensure the best outcomes for our patients.
- A few examples of how the system has been failing physicians and their patients:
  - The iPLEDGE website has been completely inaccessible or dysfunctional for prescribers, pharmacists, and patients.
  - Existing patients are missing from website for those who can login
  - Despite emphasis for increased staffing and improved call center protocols, the hold times are still averaging over several hours and the call center has been completely down for the majority of the time since 12/13 (We have received the message: "the number you have dialed is not in service")
  - The link to the paper consent form is broken on the website.
  - There is no longer the capability to accept patients who were previously enrolled by a different prescriber, which is important as young adults with acne may need to change prescriber if they move for school or work.
- The AADA is committed to the safe and responsible use of isotretinoin and supports continuing education for physicians and counseling and pregnancy testing for patients to prevent fetal exposure and other potential hazards connected to the use of this medication.
- Physicians have always been empowered and capable in their efforts to prevent fetal exposure to isotretinoin. Prescribers and pharmacists should continue to educate patients on the medication and provide counseling on contraception that helps accomplish that goal.