November 15, 2021

Syneos Health
1030 Sync Street
Morrisville, NC 27560
Attention: iPLEDGE Sponsors

Submitted electronically via iPLEDGE2021PrescribersInfo@syneoshealth.com

Dear Syneos Health and iPLEDGE® sponsors,

On behalf of the nearly 16,500 U.S.-based members of the American Academy of Dermatology Association (AADA), I was pleased with the recent announcement by the U.S. Food and Drug Administration (FDA) to modify the iPLEDGE Risk Evaluation and Mitigation Strategy (REMS) program to change the classification of patients into 2 categories – those who can become pregnant and those who cannot. This is a real step forward in eliminating barriers to access for those patients who cannot become pregnant, while still maintaining patient safety.

While welcoming that change, for which we have directly advocated, we have grave concerns about other proposed changes, outlined in the informational video and announcement. To our knowledge, no stakeholders, prescribers, or patients were consulted in the technical changes being made. As outlined below, the changes and the timeline for them will cause major difficulties for patients and prescribers. **Thus, the AADA strongly urges a delay in implementation until the following issues are addressed:**

Concerns with workflow disruptions:

- Electronic consent must be done by prescriber and patient and be administered before patient leaves the visit. This may only be feasible if practices have tablets or scribes in exam room. However, physicians would need clarification on several points about this new enrollment system:

    - Can designated staff enroll patients on behalf of dermatologists using this approach? Currently the ability to designate this to staff exists. Has the role of designated office staff changed and if so, please elaborate on this? Will delegates or designees be able

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to help in the transitioning tasks as outlined?

- Paper-based practices and practices without scribes or digital point of care will have much difficulty incorporating this new workflow and it may delay or limit access to care for patients. Can a workflow be adapted for those practices where the patient signs electronically, but the prescriber has additional time to sign and submit? The patient could then sign upon check-in when a computer is accessible.

- Many offices do not have computers in the room. Is the expectation that the patient would enter the electronic physician workroom to sign forms? From our initial analysis we are concerned this many not be HIPAA compliant. If laptops or tablet devices are needed it will require more time and additional resources to acquire this and so implementation needs to be delayed beyond 12/10/21.

- We continue to believe that there are circumstances (though perhaps as an exception – e.g., different language with need for translator for patients who do not have access to Wi-Fi or computers) where paper consent is preformed and then inputted into the system by administrative staff. Will there be an allowance for this?

- Many times, patients do not have all the necessary information with them at visit (i.e., the last 4 digits of the social security number). We are concerned this will impact the workflow if the patient needs to supply this at a later time. It will also create inefficiencies for both patients and practices which are already reeling from the hardships of the pandemic.

Concerns with patient enrollment via telemedicine:

- Many patient visits are now being conducted via telemedicine rather than in person due to the pandemic. These patients will also need a way to enroll. Can further clarification be provided on how the new system will work for telemedicine visits?

Concerns with implementation of new system:

- As outlined, physicians will have to go into the new system on December 13, 2021 and check all their existing patients to make sure they are assigned to one of the two new pregnancy categories. For many practices, this will require a great deal of administrative work at a time when practices are dealing with severe labor shortages.

    - Physicians have to login to ipledgeprogram.com before December 10th to get their date of personal significance (DOPS) to use the new system. Many physicians may not realize that if they have a 4-digit password (which was standard for many years) this is no longer sufficient and they will be locked out of the system unless they go in and use their old 4-digit password to enter a date of personal significance in format Month/Day/Year.

- Physicians also need their NPI to access the new system. Their previous login will not work. Since some dermatologists working in larger practices may not have ready access to their NPI, this needs to be made explicit with a link for how they can find their NPI.
    - How will staff designees login since they are not physicians and do not have an NPI number? They will need clear instructions as well.
- We are concerned that abruptly changing to the new system on a single day increases the risk of a website crash or systemic failure while overburdening the iPLEDGE technical support. Historically, iPLEDGE often has very long telephone wait times. Are measures in place to ensure adequate technological support?
- Is it possible to have a period of overlap among the two systems during a transition time and delay the implementation to allow more time for physicians or administrative staff to make this change? It will be extremely onerous for both small and large practices who have isotretinoin patients, especially with the increased strain on staff and physicians due to the pandemic.
- Administrative staff will also need to make sure new patients after December 10th are enrolled in the electronic system, yet it seems like there will be a lag time of two days until they can be enrolled on 12/13/21. This will delay access to isotretinoin and delay treatment.
- Will educational materials only be available electronically? If that is the case it may be difficult for office settings without ready access to a computer and printer. If patients can only access materials electronically it may widen health disparities for individuals who do not have access to broadband of the technology to use it. In the video, it states that paper versions of the enrollment forms will be available to order or to print. Are physicians still able to use paper consents? If so, how will that integrate with the e-signature requirement?

Concerns with pregnancy test requirements:

- How will the new system integrate variable workflows for meeting pregnancy test requirements?
    - The requirement of having enrollment occur in office only after proof of a negative pregnancy is burdensome. Many offices do not have CLIA-certified in-office pregnancy testing so patients must be sent to an outside lab to get urine or serum pregnancy testing, sometimes in conjunction with their other pertinent baseline labs.
    - The new requirements will lead to an extra in person visit which can delay enrollment and end up increasing the cost of medical care such as increased copays, the cost of transportation, as well as time away from work and school.
    - We strongly urge having a way to input all information and then **Pend** the application until the pregnancy test is received.

Conclusion

We thank you again, for collaborating with us to have iPLEDGE become more gender inclusive. Until these implementation concerns are addressed, **we strongly urge the FDA and the iPLEDGE Sponsors to delay implementation**. We look forward to working more closely with representatives from the FDA, the iPLEDGE sponsors, and Syneos to advance needed iPLEDGE changes, and welcome the opportunity to have a discussion about these issues. AJ Custard, JD, Manger, Regulatory Policy, will be our primary point of contact on this issue. He can be reached at (202) 230-6650 or ajcustard@aad.org.

Sincerely,

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President, American Academy of Dermatology Association