Hospitals and healthcare providers in private practice-based clinics that are certified in the ESA APPRISE Oncology Program may modify the ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form) and present the modified form to patients in either paper or electronic form, provided that the Acknowledgement Form conforms with the following criteria:

**Allowable formatting-related changes include:**
- Removal of title, instructions, and footnoted text
- Addition of patient identifier and/or clinic/hospital identifiers (eg, name and/or logo, barcodes)
- Changes to make the form compatible with existing systems, including electronic- and paper-based systems

**NO changes should be made to boxed content**

The hospital or private practice-based clinic must maintain evidence of compliance that the Acknowledgment Form was signed by both the patient or patient representative and the healthcare provider prior to the initiation of each new course of ESA therapy.

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**Guidelines for Acknowledgment Form Integration**

**Within Healthcare Systems and Clinics**

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**ESA APPRISE Oncology Program Patient and Healthcare Provider Acknowledgment Form (Acknowledgment Form)**

Aranesp® (darbepoetin alfa), Epogen® (epoetin alfa), and Procrit® (epoetin alfa) are Erythropoiesis Stimulating Agents (ESAs) used for patients with cancer.

**Instructions for Healthcare Providers**

1. Counsel the patient on the risks and benefits of Aranesp® or Epogen®/Procrit® before each new course of ESA therapy.
2. Complete each section of the form as required with the patient.
3. Provide a copy of the signed form to the patient.

**Patient Acknowledgment of ESA Benefits and Risks**

**Benefits:**
- People with anemia have a lower-than-normal number of red blood cells (RBCs). ESA works like the human protein called erythropoietin to help your body make more RBCs.
- ESAs are used to reduce or avoid the need for RBC transfusions.

**Risks:**
- ESA may make my tumor grow faster and I may die sooner.

**Written Permission to Share Information**

I permit my healthcare provider to share this form with Amgen and Janssen Products, LP (the Sponsors) and their contractors that manage certain aspects of the ESA APPRISE Oncology Program (the Contractors). The Program Sponsors and Contractors agree to keep my information secure. They will use it for the purposes.

**Healthcare Provider Acknowledgment**

I acknowledge that prior to the initiation of this new course of ESA therapy:  
- I reviewed the patient on the risks and benefits of ESAs by reviewing the Acknowledgment Form.
- I discussed all concerns and answered all questions the patient had about treatment with ESAs to the best of my ability.
- I provided a copy of the signed Acknowledgment Form to the patient.

**Allowable formatting-related changes include:**
- Removal of title, instructions, and footnoted text
- Addition of patient identifier and/or clinic/hospital identifiers (eg, name and/or logo, barcodes)
- Changes to make the form compatible with existing systems, including electronic- and paper-based systems

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Aranesp® and Epogen® are registered trademarks of Amgen Inc. Procrit® is a registered trademark of Janssen Products, LP.

This document has been required by the US Food and Drug Administration as part of a Risk Evaluation and Mitigation Strategy (REMS) for Aranesp®, Epogen®, and Procrit®.

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This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

ANN T FARRELL
12/31/2013