The Pennsylvania Society of Oncology and Hematology (PSOH) represents over 400 practitioners in the field of medical oncology and hematology in Pennsylvania. We are opposed to the current proposed CMS restrictions on coverage of erythropoiesis stimulating agents (ESA's). Our comments are as follows:

1. We oppose the concept of restricting the delivery of these agents to patients with "anemia of myelodysplasia" and myeloma. Several placebo-controlled trials have demonstrated efficacy without adverse effects. There can be little rationale for the replacement of efficacious therapy with the well-recognized risk related to blood transfusion.

2. CMS has incorporated coverage limits relative to patients with tumors having "erythropoieis receptors". There are no data to support this in any way. This has never been shown to be a factor and has never risen above the hypothetical level of reasoning. Incorporating this kind of rationale into a national coverage policy is not only impractical but also irresponsible.

3. Placing thresholds on beginning ESA's only when hemoglobin's are less than 9 gm/dl cannot be justified clinically. Invariably transfusions are not far away or ongoing by that level. Most every clinical experience with ESA's have predictably begun ESA at a higher hemoglobin concentration to avoid exactly that.

4. Limiting the duration of therapy to 12 week has little practical basis. Many regimens of therapy carry far beyond that time. There should never be a time constraint placed on a necessary biologic. Events in biology have never followed a calendar.

These are just a few of the issues that demonstrate flaws in the CMS proposal. What seems to be lost in the mission to limit ESA's is the realization that blood transfusions (which will then replace ESA's) have a well-recognized and frequently far-reaching adverse reaction potential. Bacterial transmission (1 in 1,000 units), hepatitis B (1 in 137,000 units), hepatitis C and HIV (1 in 1,000,000 units), graft vs. host (particularly in our patient population) .15%, and potentially fatal anaphylactoid reactions (1 in 20,000 units) only begin to define the risk associated with a blood transfusion.

In summary, we would request that CMS reconsider it's stance on their proposed ESA restrictions.

Ed Balaban, D.O.
President-Elect
Pennsylvania Society of Oncology and Hematology