

ADVISORY

FROM THE COMMITTEE ON WAYS AND MEANS

SUBCOMMITTEE ON HEALTH

FOR IMMEDIATE RELEASE CONTACT: (202) 225-3943

June 19, 2007

No. HL-15

Safe and Sensible:

Ensuring Kidney Patients Receive Safe and Appropriate Anemia Management Care

House Ways and Means Health Subcommittee Chairman Pete Stark (D-CA) announced today that the Subcommittee on Health will hold a public hearing on safety concerns regarding the dosing of erythropoiesis stimulating agents (ESAs), variations in utilization of ESAs across providers, and reimbursement issues. **The hearing will take place at 10 a.m. on Tuesday, June 26, 2007, in Room 1100, Longworth House Office Building.**

In view of the limited time available to hear witnesses, oral testimony at this hearing will be from the invited witness only. However, any individual or organization not scheduled for an oral appearance may submit a written statement for consideration by the Committee and for inclusion in the printed record of the hearing.

BACKGROUND:

The Medicare program began covering treatment for patients with End Stage Renal Disease (ESRD) beginning in 1972. According to the U.S. Renal Data System (USRDS), the dialysis population reached nearly 336,000 patients in 2004 at a cost of \$20.1 billion. This amounts to a 57 percent increase in Medicare ESRD spending since 1999. In 2004, the average annual cost per Medicare beneficiary was \$58,000.

When a patient's kidneys stop working, as is the case with ESRD patients, they often cannot produce enough of the hormone erythropoietin, which helps the body produce red blood cells. As a result, these patients suffer from anemia. Synthetic versions of erythropoietin are collectively referred to as erythropoiesis stimulating agents (ESAs), which are sold in the U.S. under the brand names of Epogen, Procrit, and Aranesp.

Dialysis care has made great strides in treating anemia, and this achievement is directly linked to significant increases in doses of ESAs. Dosing levels increased dramatically in recent years, with average weekly

dose of ESAs increasing nearly 4,000 units between 2000 and 2004. Medicare spending for ESAs increased by 17 percent from 2003 to 2004 alone, up to \$1.8 billion. Spending on ESAs per person per month is now nearly one-half of the monthly cost for dialysis.

While ESAs are critical to treatment of anemia for ESRD patients, higher doses that raise red blood cells above a certain threshold have been found to pose significant health risks to patients. The Food and Drug Administration (FDA) recently issued a black box label warning of risk of blood clots, strokes, heart failure and heart attacks in kidney patients in such circumstances. Furthermore, as both the Medicare Payment Advisory Commission and the Government Accountability Office point out, there are flaws in the current Medicare reimbursement system. The existing Medicare payment system incentivizes higher doses in certain circumstances, with resulting health risks and higher costs for beneficiaries and taxpayers.

"My priority for Medicare ESRD policy is to ensure patient safety while also protecting taxpayers from unnecessary expenditures," stated Chairman Stark in announcing the hearing. **"Health risks associated with higher doses and well-documented flaws in a payment system that encourages higher dosing highlights that this issue is ripe for reexamination. We must do better for our ESRD beneficiaries and for the taxpayers."**

FOCUS OF THE HEARING

The hearing will focus on the safety concerns regarding dosing of ESAs for ESRD, variations in utilization of ESAs across providers, and issues related to reimbursement.

DETAILS FOR SUBMISSION OF WRITTEN COMMENTS:

Please Note: Any person(s) and/or organization(s) wishing to submit for the hearing record must follow the appropriate link on the hearing page of the Committee website and complete the informational forms. From the Committee homepage, <http://waysandmeans.house.gov>, select "110th Congress" from the menu entitled, "Committee Hearings" (<http://waysandmeans.house.gov/Hearings.asp?congress=18>). Select the hearing for which you would like to submit, and click on the link entitled, "Click here to provide a submission for the record." Once you have followed the online instructions, completing all informational forms and clicking "submit" on the final page, an email will be sent to the address which you supply confirming your interest in providing a submission for the record. You MUST REPLY to the email and ATTACH your submission as a Word or WordPerfect document, in compliance with the formatting requirements listed below, by close of business **Tuesday, July 10, 2007**. Finally, please note that due to the change in House mail policy, the U.S. Capitol Police will refuse sealed-package deliveries to all House Office Buildings. For questions, or if you encounter technical problems, please call (202) 225-1721.

FORMATTING REQUIREMENTS:

The Committee relies on electronic submissions for printing the official hearing record. As always, submissions will be included in the record according to the discretion of the

Committee. The Committee will not alter the content of your submission, but we reserve the right to format it according to our guidelines. Any submission provided to the Committee by a witness, any supplementary materials submitted for the printed record, and any written comments in response to a request for written comments must conform to the guidelines listed below. Any submission or supplementary item not in compliance with these guidelines will not be printed, but will be maintained in the Committee files for review and use by the Committee.

1. All submissions and supplementary materials must be provided in Word or WordPerfect format and MUST NOT exceed a total of 10 pages, including attachments. Witnesses and submitters are advised that the Committee relies on electronic submissions for printing the official hearing record.

2. Copies of whole documents submitted as exhibit material will not be accepted for printing. Instead, exhibit material should be referenced and quoted or paraphrased. All exhibit material not meeting these specifications will be maintained in the Committee files for review and use by the Committee.

3. All submissions must include a list of all clients, persons, and/or organizations on whose behalf the witness appears. A supplemental sheet must accompany each submission listing the name, company, address, and telephone and fax numbers of each witness.

Note: All Committee advisories and news releases are available on the World Wide Web at <http://waysandmeans.house.gov>.

The Committee seeks to make its facilities accessible to persons with disabilities. If you are in need of special accommodations, please call 202-225-1721 or 202-226-3411 TTD/TTY in advance of the event (four business days notice is requested). Questions with regard to special accommodation needs in general (including availability of Committee materials in alternative formats) may be directed to the Committee as noted above.
