

Impact of the Change in CMS Billing Rules for Erythropoietin on Hemoglobin Outcomes in Dialysis Patients

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Key Words

Anemia · Dialysis · Erythropoietin · Hemoglobin · Medicare

Abstract

On April 1, 2006, new Centers for Medicare and Medicaid Services (CMS) rules for billing erythropoietin (EPO) for dialysis patients went into effect. Two key provisions of the rules were to cap the dose for a single patient at 500,000 IU/month and to mandate a 25% reduction in dose for patients whose latest hemoglobin (HGB) or hematocrit (HCT) in the prior month exceeded 13 g/dl or 39%, respectively. The purpose of this article is to document the effect of the rules change on HGB outcomes in a single large dialysis provider whose computer system was modified to enforce the rules. HGB and EPO doses for 5 months following the implementation were analyzed retrospectively. The most noteworthy observation is that while the rule appears to have reduced the percentage of patients with an HGB of >13 g/dl slightly, it has also increased the percentage of patients with HGB in the medically undesirable range of <11 g/dl.

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Background

The Centers for Medicare and Medicaid Services (CMS) issued Change Request 4135, the 'National Monitoring Policy for EPO and Aranesp[®] for End Stage Renal

Disease (ESRD) Patients Treated in Renal Dialysis Facilities' in Transmittal 751 on November 10, 2005. This CMS EPO Monitoring Policy (EMP) took effect on April 1, 2006. Two key provisions of the rules were to cap the dose for a single patient at 500,000 IU/month and to mandate a 25% reduction in dose for patients whose latest hemoglobin (HGB) or hematocrit (HCT) in the prior month exceeded 13 g/dl or 39%, respectively.

This analysis of the effect of the EMP on hemoglobin outcomes is limited to the dialysis facilities which were owned by Fresenius Medical Care North America (FMCNA) prior to the acquisition of Renal Care Group (RCG) in March 2006. RCG facilities were not included because the EMP rules were implemented differently in the RCG information system. In the FMCNA system, the computer system was set up to prevent entry of physician orders or administration of doses which would exceed the 500,000 IU limit. The maximum allowable dose per administration depends on the frequency of the medication order, i.e., 35,000 U 3×/week dosing, 50,000 IU 2×/week dosing, and 100,000 IU 1×/week dosing.

While the EMP policy allows the use of HGB or HCT, for simplicity the remaining discussion will focus on HGB values. The FMCNA recommended anemia management algorithm continues to encourage physicians to modify dose to achieve a target HGB of 11–12 g/dl. However, if a patient's latest HGB in the prior month is >13 g/dl, then the FMCNA computer system requires that the dose in the EPO prescription be reduced by 25%

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on the first of the following month. Approximately 10 days before the end of the month, the system provides a report on which patients require dose changes. Immediately prior to the end of the month, any of those physician orders which have not been reduced by at least 25% are terminated by automatic entry of an end-of-the-month stop date in the order. For patients with an HGB of >13 g/dl, the computer system will not accept a new physician's order for EPO that does not meet the mandatory minimum dose reduction. A validation process run each day makes sure that the administered doses are equal to the ordered doses. After any data entry errors have been corrected, clinical variances must be documented for any remaining discrepancies. Thus, the computer system essentially has enforced the new CMS rules. While minimum and maximum dose limits had previously been used to catch data entry errors for doses which were substantially (typically 3 times) outside the expected range, never before has the FMCNA computer system been used to restrict physician orders.

It should be mentioned that the requirement to change doses effective on the first of the month was a change in clinical practice for the 1,100+ legacy FMCNA facilities. This requirement stemmed from the fact that the fiscal intermediaries who process bills to Medicare could only evaluate dose reductions on a month-to-month basis. Even ignoring the issue of differences in the number of days in consecutive calendar months, if a physician were to reduce the dose per treatment by 25%, from 4,000 to 3,000 U/Rx halfway through the month (on the 7th of 12 treatments in month 1), the apparent dose reduction on a month-to-month basis would be given by:

$$\frac{(\text{Total month 1 dose} - \text{total month 2 dose})/\text{total month 1 dose}}{(42,000 - 36,000)/42,000} = 14.2\%$$

Because this would appear to be less than the required 25% dose reduction, the fiscal intermediary would pay for only 75% of the 36,000 IU billed in month 2, which clearly would be a tremendous financial burden for the dialysis provider. By delaying the dose reduction until the first of the month, the total month 1 dose is 48,000 IU, and the month-to-month dose reduction is exactly 25%. On Friday, August 25, 2006, in Transmittal 1043, CMS released Change Request 5251 which changed the EMP rules effective on October 1, 2006. The change request eliminates the reference to a specific minimum dose reduction of 25%, and requires the provider to indicate whether the dose has been 'reduced and maintained in response to a hematocrit or hemoglobin level'. The same document states: 'Providers are reminded that CMS ex-

pects that as the hematocrit approaches 36.0% (hemoglobin 12.0 g/dl), a dosage reduction occurs. Providers are expected to maintain hematocrit levels between 30.0 to 36.0% (hemoglobin 10.0–13.0 g/dl).' As of September 1, 2006, FMCNA is awaiting further clarification and has not changed its implementation of the April version of the EMP rules.

Methods

Hemoglobin results for approximately 95,000 patients per quarter were included in this analysis. Patients were included regardless of modality (HD vs. PD), setting (in-center vs. home), admission status (permanent or transient), or medication use. No patients or laboratory results were excluded. For each time period, intra-patient 3-month averages were determined as the mean of all HGB values in the 3 months. For creation of histograms, the 3-month averages were rounded to the nearest 0.1 g/dl. Intra-patient 1-month HGB averages were also determined. The mean of the patient mean HGB was then calculated for trending.

EPO doses administered in-center are recorded for each dialysis treatment. Intra-patient 1-month averages were determined as the mean of all in-center doses in 1 month. The mean of the patient mean dose was then calculated for trending.

Results

Figure 1 shows the distribution of 3-month average HGB immediately before and after the implementation of the EMP on April 1, 2006. It is not surprising that there is a relatively small difference between the two distributions, given that the lifespan of the red blood cell in dialysis patients averages 64 days [1]. Overall, there was a 0.2% decrease in the percentage of patients with a 3-month average HGB of >13 g/dl. On the other hand, there was a 1.1% increase in the percentage of patients with a 3-month average HGB of <11 g/dl. An HGB of <11 g/dl has previously been shown to be associated with a greater risk of mortality and hospitalization [2, 3].

Figure 2 shows the distribution of the 3-month average HGB 3 months before and 2 months after the rules were changed. Due to the publishing schedule, only 5 months of follow-up could be included. With the longer follow-up time, the percentage of patients with a 3-month average HGB of <11 g/dl increased (2.0% in 5 months), but surprisingly the percentage of patients with a 3-month average HGB of >13 g/dl actually *increased* by 0.7%, rather than decreasing further. Closer inspection reveals that a rise of 1.0% occurred between Q2 2006 and June–August 2006,

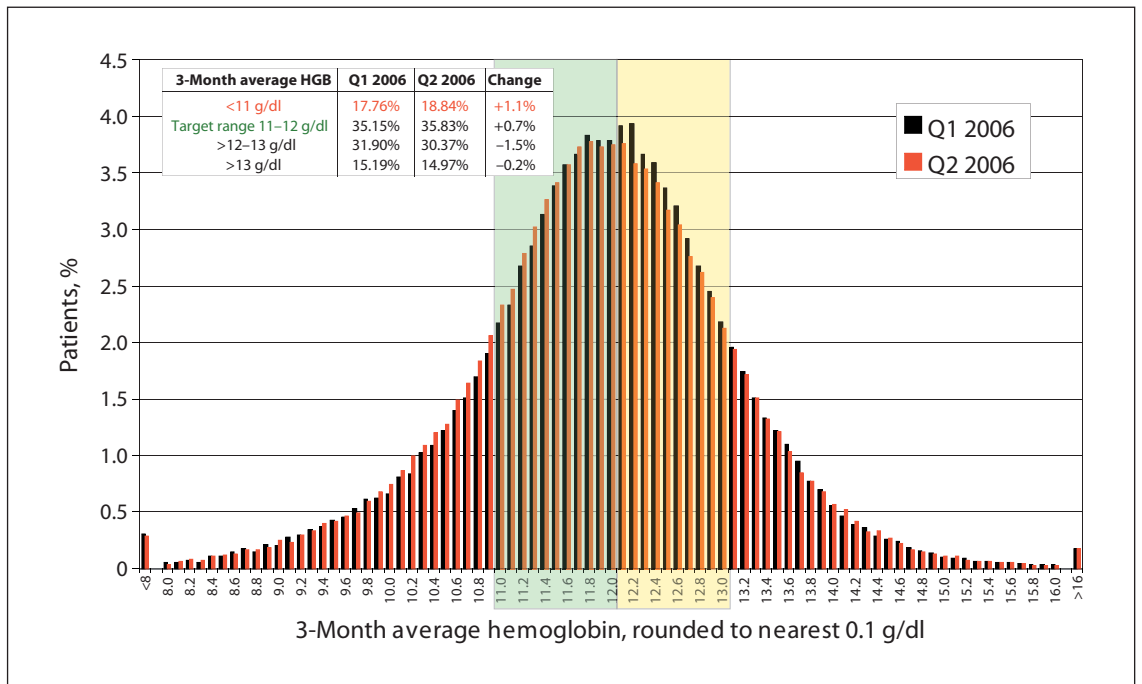


Fig. 1. Distribution of 3-month average hemoglobin immediately before and after implementation of the CMS EPO monitoring policy on April 1, 2006.

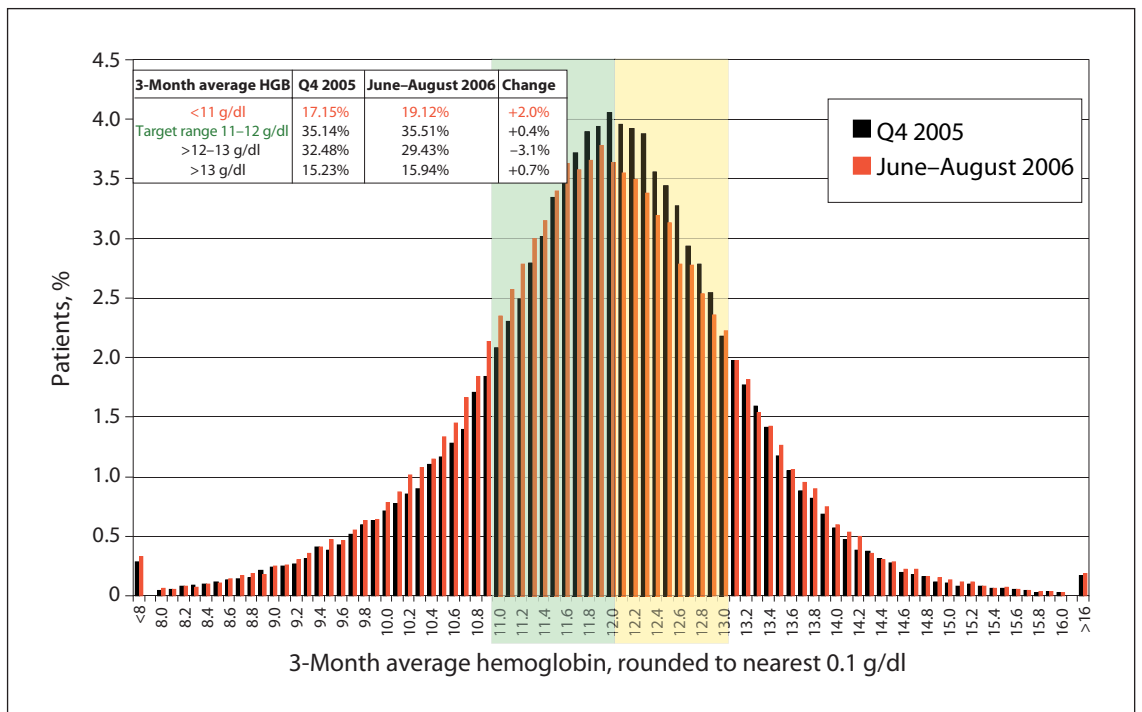


Fig. 2. Distribution of 3-month average hemoglobin 3 months before and 2 months after implementation of the CMS EPO monitoring policy on April 1, 2006.

Fig. 3. Trend in 3-month average hemoglobin before and after implementation of the CMS EPO monitoring policy on April 1, 2006. ▲ = Mean ± SD of 3-month average HGB; ● = SD of 3-month average HGB.

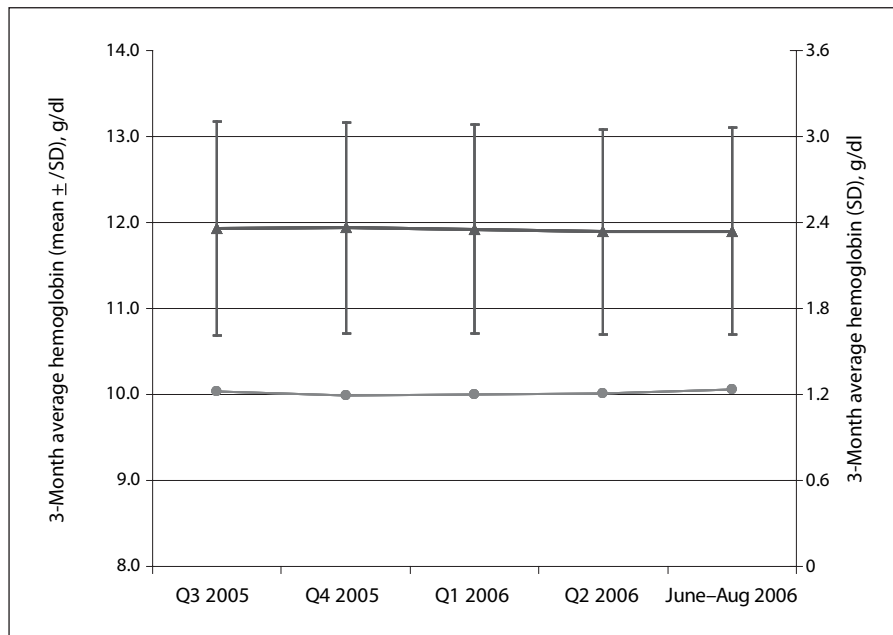
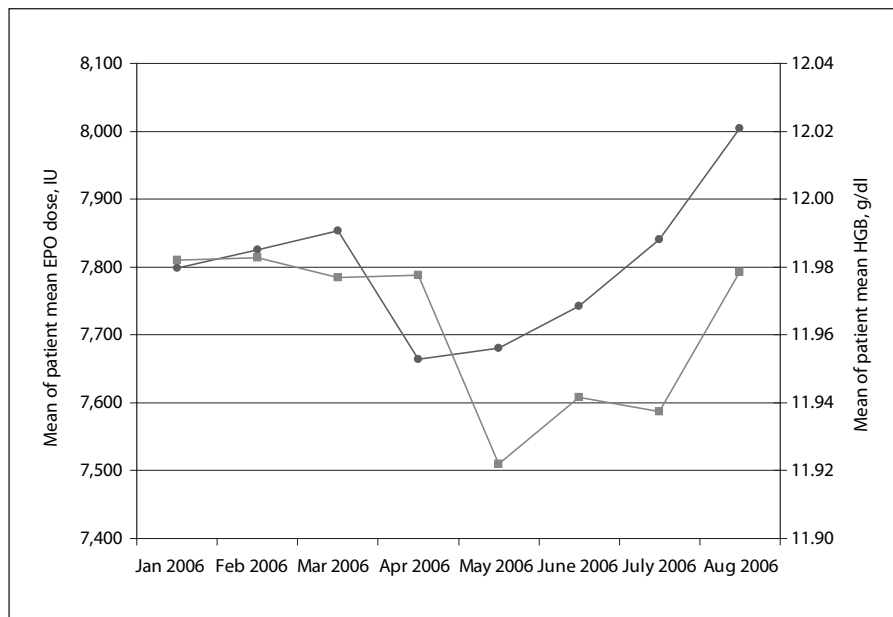


Fig. 4. A transient drop in the monthly mean hemoglobin followed a transient drop in the mean in-center EPO dose after implementation of the CMS EPO monitoring policy on April 1, 2006. ● = Mean in-center EPO dose; ■ = mean HGB.



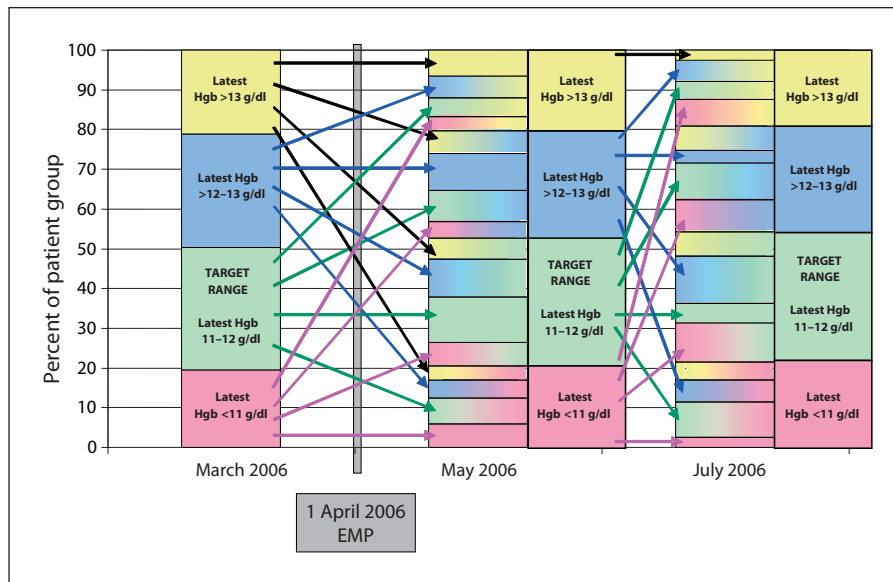
suggesting that physicians' attempts to counteract falling HGB values resulted in overshooting the target, and reduced the percentage of patients in the two central regions of the bell curve (i.e. 11–13 g/dl) by 2.7% over 5 months.

Figure 3 shows the trend in the 3-month average HGB over a 14-month period. A relatively small drop in mean HGB is noted after April 1, 2006. The standard deviation of the population is shown to be quite stable at 1.2 g/dl, consistent with previous data [4]. If anything, there ap-

pears to be a small rise in standard deviation in the latest period shown, suggesting a slight widening of the distribution, the exact opposite of the desired effect.

The immediate impact of the EMP is more clearly seen in figure 4, which shows monthly data for the average in-center EPO dose and the average HGB. An immediate drop in dose is seen in April, while a drop in HGB follows in May 2006. The mean dose begins to rise in May, and continues to rise through August 2006. This suggests that physicians

Fig. 5. Movement among hemoglobin categories for 73,002 patients with at least one HGB value in each of three months (March 2006, May 2006, July 2006). The stacked bars containing solid colors represent the percent of patients categorized by their latest HGB in each month: pink for latest HGB <11, green for latest HGB in the target range of 11–12, blue for latest HGB >12–13, and yellow for HGB >13 g/dl. The two-tone bars represent patients who moved from one category to another, with the left-hand color chosen to denote the prior HGB category.



responded to reduced outcomes with higher EPO doses. After a 3-month fall, the monthly mean HGB returns to its March/April level in August 2006. One might expect that the higher dose observed in August 2006 will cycle back down in response to the rebound in HGB values.

One might ask why the company's strict enforcement of the mandatory dose reduction required by the EMP did not substantially reduce the percent of patients with HGB in that range. This can be best understood by examining the movement of patients among HGB categories, as shown in figure 5. This analysis includes 73,002 patients with at least one HGB value in each of three separate months (March 2006, May 2006, and July 2006). The stacked bars containing solid colors represent the percent of patients categorized by their latest HGB in each month: pink for latest HGB <11, green for latest HGB in the target range of 11–12, blue for latest HGB >12–13, and yellow for HGB >13 g/dl. The two-tone bars represent patients who moved from one category to another, with the left-hand color

chosen to denote the prior HGB category. While the percent of the subgroup of patients with latest HGB >13 g/dl dropped only slightly (21.1% to 20.2% to 19.2%), only 2.6% of the patients present in all 3 months remained in the HGB >13 group throughout. Further analysis reveals that the majority of these patients received little or no EPO.

In summary, 5 months of follow-up data show that the April 2006 EMP rules appear to have reduced the percentage of patients with a HGB of >13 g/dl slightly, but with the side effect of putting a greater percentage of patients into HGB categories of <11 g/dl. Given the observed intra-patient HGB variability, it is unrealistic to expect that the percentage of patients >13 g/dl will be reduced substantially using current anemia algorithms without increasing the percentage of patients with HGB <11 g/dl. Furthermore, it remains to be seen whether there will be an overall savings in EPO costs for dialysis patients as a result of the EMP. More up-to-date data will be presented at the conference in January 2007.

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