

## Medical Education Institute Inc. (MEI): Patient Concerns and Recommendations on the MIPPA Proposed Rule

PLEASE NOTE: These are DRAFT comments that will be updated and submitted following the CMS Town Hall Meeting in Baltimore on October 23, and prior to the November 16 submission deadline. Please feel free to copy or echo any of these comments that are of value to you or your organization, and we will do the same with considerations we haven't yet included. In this way, CMS will obtain a better sense of community concerns and how to address them. Please address any questions or suggestions about these comments to Doris Schatell, Executive Director, at [schatell@meiresearch.org](mailto:schatell@meiresearch.org).

MIPPA Section	MEI Patient Concerns & Recommendations
<p><b>413.195: Limitation on review</b> Refers to Section 1881(b)(14)(c) and the preamble states: “In this notice we are proposing to establish an ESRD PPS which relies on a per treatment unit of payment. We propose to continue the present per treatment basis of payment in which ESRD facilities would be paid for up to three treatments per week, unless medical necessity justified more than three weekly treatments. ESRD facilities treating patients on PD or home HD would also receive payments for up to three treatments for each week of dialysis, unless medical necessity justified the furnishing of additional treatments.” (needs to be in correct type)</p>	<p><b>Patient concern 1:</b> Patients want to live as long and as well as possible. Some in the renal community have expressed concern that CMS has put cost before patient health and well-being by not routinely reimbursing for more frequent treatments until results of the \$10 million Frequent Hemodialysis Network (FHN) study are published (already delayed &gt;1 year). We wonder how many patients would have kept their jobs, had fewer complications and hospitalizations, had better health-related quality of life—and survived instead of died—had CMS accepted data from multiple clinical trials and <i>routinely</i> reimbursed for 1-3 additional treatments per week during the study period.</p> <p>Even if the results of the FHN study confirm data from other studies, it appears from the rationale in the preamble that the ESRD PPS will continue to limit treatments to three times weekly <b><i>unless medical necessity justifies extra treatments—placing an additional burden on already overstretched nephrologists.</i></b> Short, thrice-weekly hemodialysis treatments evolved from a historical accident,<sup>i</sup> are <i>not</i> evidence-based, and should not remain the default treatment in the face of compelling evidence that the 2-day treatment gap contributes to thousands of needless deaths in the U.S. each year, as sudden cardiac death rates soar to 50% higher than expected on the day after the 2-day no-treatment gap,<sup>ii</sup> and <i>triple</i> in the 12 hours prior to the next treatment after that gap.<sup>iii</sup></p> <p><b>Recommendation(s):</b></p> <ul style="list-style-type: none"> <li>■ State in this policy that if FHN findings demonstrate that daily and/or nocturnal hemodialysis improves blood pressure, LVH, nutritional status, anemia, quality of life, and vascular access, <b>reimbursement for &gt;3 treatments per week will be allowed at the bundled rate plus any other adjustments provided in the final reimbursement policy, <i>without</i> additional medical justification.</b></li> </ul> <p><b>Patient concern 2:</b> Patients on peritoneal dialysis (PD) need dialysis 7 days a week. Medicare currently reimburses for 3 hemodialysis-equivalent treatments. <b><i>The statement in the preamble fails to mention</i></b></p>

	<p><i>that PD reimbursement is at the equivalent of 3 hemodialysis treatments a week.</i></p> <p><b>Recommendation(s):</b></p> <ul style="list-style-type: none"> <li>■ Anywhere that PD reimbursement is mentioned in the ESRD PPS, it should <b>state that Medicare reimburses for PD at the rate of 3 hemodialysis-equivalent treatments a week.</b></li> </ul>
<p><b>413.215: Basis of Payment</b>  (b) The per treatment payment amount is the product of the per treatment base rate described in § 413.220 plus the applicable adjustments described in § 413.231 through § 413.237 of this part.</p>	<p><b>Patient concern 3:</b> Patients have been concerned that if the bundle established a weekly or monthly payment, it would create problems for patients who travel, are hospitalized or transfer in mid-month. We were very pleased to see that CMS chose to retain the per-treatment payment schedule.</p> <p><b>Recommendation:</b> <b>Maintain per-treatment payment.</b></p>
<p><b>413.232: Facility-level adjustments</b>  (b)(1) Furnish less than 3000 treatments in each of 3 years preceding the payment year.</p>	<p><b>Patient concern 4:</b> If clinics receive a 20% increase for small volume based on number of treatments (&lt;3000 treatments), <i>they may be motivated to offer patients fewer treatments to ensure that they remain under the threshold.</i></p> <p><b>Recommendation(s):</b></p> <ul style="list-style-type: none"> <li>■ Calculate small clinics on the basis of patient census (i.e., 20 or less), <i>not</i> number of treatments.</li> <li>■ Reduce the 20% increase to the minimum permitted by law: 10%.</li> </ul>
<p><b>413.235: Patient-level adjustments</b>  (a) CMS adjusts the per-treatment base rate for adults to account for patient age, patient sex (female), body surface area, low body mass index, onset of dialysis (new patient), and co-morbidities, as specified by CMS.</p>	<p><b>Patient concern 5:</b> Including the wide array of case-mix-adjusters in the proposed ESRD PPS bundle creates an inequity for patients, in that <i>some will have much higher bundled payments per treatment than others—and will subsequently have higher coinsurance payments.</i></p> <p>A 44-year old patient will pay almost 20% more coinsurance than a 45-year old patient. Women would pay 13.2% more than men. Medicare-eligible patients in their first 4 months of treatment would pay 47.3% more. In a facility that obtains a comorbidity adjustment, patients would pay more. Assuming that patients have Medicare as the primary payer, no changes in adjustment factors during the year, and receive the number of treatments specified below, these examples from the proposed rule would leave patients with the following coinsurance liability:</p> <ul style="list-style-type: none"> <li>■ <b>Example 1</b> (John, age, high BSA): 20% of <b>\$231.52/treatment</b> or <b>\$7,223.42</b> that year</li> <li>■ <b>Example 2</b> (John, new, age, high BSA): 20% of <b>\$341.03/treatment X 52 + \$231.52/treatment X 104</b> or <b>\$8,778.88</b> that year</li> <li>■ <b>Example 3</b> (John, age, high BSA, outlier): 20% of <b>\$2,992.05</b> for 9 treatments (Jan) + <b>\$231.52 X 144</b> treatments or <b>\$7,266.19</b> that year</li> <li>■ <b>Example 4</b> (Mary, gender, high BSA, Hep B, upper GI bleed, low volume clinic): 20% of <b>\$438.40/treatment</b> or <b>\$13,678.08</b> annually</li> <li>■ <b>Example 5</b> (Agnes, gender, high BSA, low BMI, cardiac arrest): Agnes would pay 20% of <b>\$229.03/treatment</b> or <b>\$7,145.74</b> annually</li> </ul>

- **Example 6** (Jonathan, age, HIV/AIDS, DM, PD): 20% of \$202.10/treatment or \$6,305.52 that year
- **Example 7** (Timmy, age, DM, outlier): Timmy would pay 20% of \$262.10/treatment or \$8,177.52 that year

Some may have been concerned that facilities would cherry-pick healthier patients. Instead, facilities may be motivated to have patients with as *many* adjusters as possible—whether or not they have the appropriate number of qualified and trained staff or ability to care for more complex patients. ***Due to increased reimbursement with adjusters, patients without Medicare supplement coverage could face greater financial hardship—or even involuntary discharge for nonpayment.***

**Recommendation(s):**

- **To the extent permitted by Congressional intent, simplify the case-mix adjustment model** to reduce patient-level variability in cost.

**Patient concern 6:** The overall complexity of the new per-patient ESRD PPS bundle calculations appear to be potentially overwhelming for clinics. We believe there is a risk of ***reducing the staff time available to provide direct patient care***, if medical professionals must review patient records and track changes in the case-mix adjusted bundle by themselves. CMS acknowledges that the equation explains less than half (just 46%) of the variance for composite rate services.

In addition, the regression model is based on data from the CMS 2728—which is *not* always completed by medically-trained staff (and probably *never* by a nephrologist, contrary to assumption made on the 10/15/09 Open Door Forum call), and may therefore contain missing, incomplete, or inaccurate data. These data *are never validated in any way*, yet care for a very vulnerable population is riding on them. ***We have grave concerns about the validity of a very complex case mix adjustment based on 2728 data.***

**Recommendation(s):**

- **CMS should calculate the per-patient rate** for clinics, based on data provided by clinics **or develop and provide an electronic calculator** to assure accuracy, level the playing field among all providers, and reduce the staff time required to perform complex mathematical calculations.
- **Simplify the case-mix adjustment model:** Divert additional funds to the base rate and include *only* factors that increase costs in the case-mix adjustment, to reduce the paperwork burden.
- **CMS should conduct a study of the medical training of facility personnel completing the CMS 2728 and routinely validate the CMS 2728 data** by choosing a random sample of completed forms from living patients and conducting interviews with patients and physicians and reviewing medical records.

### 413.237: Outliers

(a) The following definitions apply to this section.

(1) ESRD outlier services are separately billable items and services as defined in section 413.171 of this part and renal dialysis service drugs proposed for inclusion in the ESRD prospective payment system that currently are covered under Medicare Part D.

**Patient concern 7:** Including ESAs (and future oral versions of such) in the ESRD PPS bundle *creates a powerful disincentive for administering higher doses of these drugs*—which a small number of patients may temporarily require for optimal clinical outcomes (e.g., post-hospitalization). If reimbursement causes underutilization of ESAs to the extent that patients require blood transfusions, *they may become sensitized and less able to obtain a future kidney transplant*. This also has important ramifications for the U.S. blood supply. *Also, the proposed 2% maximum penalty for failing to meet anemia targets is an insufficient deterrent to prevent clinics from under-treating anemia—or even ceasing to provide ESAs at all.*

#### Recommendation(s):

- **Permit doses of ESAs sufficient to achieve higher-than-target hemoglobin (Hb) levels with medical justification**, i.e., for patients who are gainfully employed and paying taxes.
- **Increase the penalty for undertreatment (or non-treatment) of anemia to an amount commensurate with the anticipated cost of ESAs and iron.**

**Patient concern 8:** Including oral vitamin D products, phosphate binders, and calcimimetics in the ESRD PPS bundle *creates a powerful disincentive for administering lower instead of higher cost drugs—though the efficacy of the lower cost drugs, such as calcium-based binders may not be equivalent.*<sup>iv</sup> A meta analysis of calcium vs. non-calcium based phosphate binders found a trend toward lower all-cause mortality among patients who received (more costly) *non-calcium-based binders.*<sup>v</sup> Further, including these classes of drugs in the bundle may *discourage development of new, more effective drugs* to treat bone disease spectrum disorders in people on dialysis. Section 623(E)(1)(A) of the MMA states, “*Drugs and biologicals (including erythropoietin) furnished to end-stage renal disease patients under the medicare program which are separately billed by end-stage renal disease facilities (as of the date of the enactment of this Act)...*” Although CMS states on page 49228 of the Federal Register that this reading of the MMA is too constrained, if Congress had intended CMS to include Part D drugs that are neither provided by nor separately billed by dialysis facilities to Medicare in the ESRD PPS bundle, the MMA would have stated *explicitly* that Part D drugs should be included. It does not, and their inclusion creates an array of unintended consequences that can harm patients.

#### Recommendation(s):

- **Pull all oral medications out of the ESRD PPS bundle** so nephrologists can decide what is in the best clinical interests of their patients, without reimbursement intervening.
- **Track parathyroidectomy surgery and vascular calcification levels** if calcimimetics and phosphate binders are left in the ESRD PPS bundle.

**Patient concern 9:** To the extent that lower cost oral equivalents are available, there is a powerful incentive to prescribe these in place of intravenous formulations. This *increases the pill burden for dialysis patients—who already have the highest pill burden of any chronic illness, with a median of 19 pills per day<sup>vi</sup> (and lower health-related quality of life as a result) and are notoriously poorly adherent to oral medications.*<sup>vii</sup> Younger patients have even more trouble taking oral medications correctly than older ones<sup>viii</sup>—putting them at risk for long-term painful and costly complications such as vascular calcification and renal osteodystrophy.

**Recommendation(s):**

- **Pull all oral medications out of the ESRD PPS bundle.**
- **Track adherence to oral medications**, including serum phosphorus and calcium levels, calcium-phosphorus product, and intact PTH if these drugs are left in the ESRD PPS bundle.

**Patient concern 10:** Including oral medications in the ESRD PPS bundle creates a 20% coinsurance *per treatment* for patients for these medications. Previously, under Medicare Part D, those with limited income and assets have been eligible for extra help (estimated at \$3,900 in 2009)<sup>ix</sup> so they could pay a small fee (\$1.10 to \$6.00) for *an entire month's supply* of each covered drug.<sup>x</sup> CMS attributes only \$14 of the bundle to Part D drugs, a figure that we strongly suspect is a gross underestimate of their real cost. In addition to using two year old data on drug costs, CMS states on page 49941, “... *the payment total for former Part D drugs only includes data for the 66.73 percent of ESRD beneficiaries who were enrolled in Part D... we do not have patient-specific information on the cost of drugs (part D equivalent drugs) for the remaining third of ESRD beneficiaries who do not have Part D coverage. To the extent these beneficiaries have drug coverage through their employer or other insurance, we do not have access to specific usage or payment information for these medications.*”

*Even at \$14 per treatment (CMS estimate for Part D drugs, plus \$9 for labs), patients may anticipate paying 20% of \$23, or \$4.60 per treatment—or \$716.60 per year in additional drug and lab test) co-pays at 3 treatments per week if they don't have other coverage. Patients who dialyze more often than thrice weekly (with medical justification) could be responsible for as much as \$1,435.20/year for coinsurance.* This burden may not only be onerous, but as Part B drugs, any out-of-pocket costs will not count toward the Part D coverage gap.

**Recommendation(s):**

- **Pull all oral medications out of the ESRD PPS bundle.**
- **Increase the dollar amount paid for pharmaceuticals.** Table 35 on page 49998 states that according to cost reports, the weighting of pharmaceuticals in the bundle should be 28.775%. The \$14 payment translates to only 7.048% of the bundle—a 75% underestimate. The downside of this

recommendation would be that patients would pay an even *higher* coinsurance.

- **Have GAO conduct a study on the *actual cost* of oral dialysis medications, including those paid by employers that receive the Part D retiree drug subsidy for dialysis patients *prior* to including them in the bundle, so the amount can more accurately reflect experience. Increase the amount allocated into the bundle for oral medications if they remain in the bundle.**
- **Track patients' coinsurance expenditures if oral medications remain in the bundle.**

**Patient concern 11:** Including dialysis oral medications in the ESRD PPS and requiring patients to obtain them solely through their dialysis clinics (or a pharmacy under contract with a clinic) ***effectively turns dialysis patients into second class citizens.*** Under the proposed rule, dialysis patients would be treated differently than other Medicare beneficiaries who can obtain covered Part D drugs from *any* pharmacy on their plan. Including these drugs in the ESRD PPS bundle also means that there is no longer a 1:1 correspondence between patients' costs and medications taken: ***patients who do not need and are not prescribed these drugs must still pay the 20% coinsurance for them.***

**Recommendation(s):**

- **Pull all oral medications out of the ESRD PPS bundle.**

**Patient concern 12:** Including dialysis oral medications in the ESRD PPS ***eliminates patient protections under Medicare Part D for Medication Therapy Management (MTM)***—necessary for a complex patient population such as this one—***and additionally denies them the opportunity to have all of their drug interactions tracked, as their medications will likely be distributed by more than one provider/supplier.***

**Recommendation(s):**

- **Pull all oral medications out of the ESRD PPS bundle.**

**Patient concern 13:** Section 623(E)(1)(B) of the MMA states, "Clinical laboratory tests related to such drugs and biologicals..." ***Congressional intent was apparently to include only such lab tests as were directly related to the use of IV drugs such as erythropoietin and vitamin D, NOT all laboratory tests.*** Including other laboratory tests in the ESRD PPS bundle creates the potential for disincentives to order such testing as often as it may be necessary. If a patient's nephrologist also acts as the primary care physician, he or she again becomes a *second class Medicare beneficiary*, able to obtain certain lab tests only within the dialysis clinic payment structure—or must obtain services from other physicians at additional cost to Medicare and him or herself.

**Patient concern 14:** If all lab tests are included in the bundle there will be a 20% coinsurance for lab tests that have been covered at 100%. This could place a financial burden on patients.

	<p><b>Patient concern 15:</b> If patient wants to travel, policies at many destination clinics often require recent results for Hepatitis B, increasing the burden on the home clinic and the patient with the result that clinics may discourage patients from traveling.</p> <p><b>Recommendation(s):</b></p> <ul style="list-style-type: none"> <li>■ <b>Include in the ESRD PPS bundle <i>only</i> laboratory tests used to monitor IV dialysis drug use.</b></li> <li>■ <b>Permit lab tests done for the purpose of patient travel to be separately billable.</b></li> </ul>
<p><b>413.241: Pharmacy arrangements</b> Effective January 1, 2011, the ESRD facility that enters into an arrangement with a pharmacy to furnish renal dialysis service drugs must ensure that the pharmacy is located such that it has the capacity to provide all classes of renal dialysis service drugs to patients in a timely manner.</p>	<p><b>Patient concern 16:</b> <i>IF oral medications remain in the ESRD PPS bundle, the requirement for conveniently located pharmacies is a plus for patients.</i></p> <p><b>Recommendation(s):</b></p> <ul style="list-style-type: none"> <li>■ <b><i>IF oral medications remain in the ESRD PPS bundle, retain this provision as well.</i></b></li> </ul>
<p><b>414.330 Payment for home dialysis equipment, supplies, and support services.</b></p>	<p><b>Patient concern 17:</b> Prior to the ESRD PPS bundle, the Medicare reimbursement for home dialysis training was limited to the composite treatment rate plus <b>\$12</b> per training session for continuous ambulatory peritoneal dialysis (CAPD) and <b>\$20</b> per training session for automated PD (APD) or home hemodialysis (HD). <i>The \$20 add-on payment per training session for home HD fell woefully short of the estimated actual staff time costs of \$130 per session, per the General Accounting Office report of May, 2009.<sup>xi</sup></i> (For PD, Medicare allowed 15 training sessions; for home HD, Medicare allowed 25 training sessions without medical justification). The GAO reported that most clinics required 5-10 training sessions for all types of PD and 20-30 for home HD.</p> <p>In the preamble to the current proposed rule, CMS states: <i>“Because we are proposing that training costs under the ESRD PPS would be treated no differently than any other overhead expense, an explicit adjustment to the bundled payment for HD and PD training expenditures would not be necessary.”</i></p> <ul style="list-style-type: none"> <li>■ Dialysis Facility Compare reports that there are <b>5,258</b> clinics in the U.S. As of October 15, 2009, the <b>Home Dialysis Central</b> database, which contains clinics that <i>actively train patients for home treatments</i>, identified: <ul style="list-style-type: none"> <li>➤ <b>2,158</b> clinics (41%) that train patients for PD</li> <li>➤ <b>765</b> clinics (14.5%) that train patients for conventional home HD (3 times a week),</li> <li>➤ <b>533</b> clinics (10.1%) that train patients for short daily home HD</li> <li>➤ <b>272</b> clinics (5.2%) that train patients for nocturnal home HD</li> </ul> </li> </ul> <p>While “overhead” is not defined in the proposed rule, we strongly disagree that a service provided by well</p>

under half of all clinics should constitute “overhead” for all of them—***to do so would have the effect of penalizing clinics that offer home training, while rewarding those that do not.***

On page 49952 of the *Federal Register*, 9/29/09, CMS states, “We found that there was a drop in separately billable payments after the first 4 months. These higher costs for new patients may be due to stabilization of the patient’s condition; administrative and labor costs associated with the patients being new to dialysis either in-center or home setting; ***or initial costs incurred to train patients and their caregivers to perform home dialysis.***” Thus, CMS acknowledges that the costs of home training are NOT usual care. Instead of promoting home therapy as CMS expected, with current reimbursement policies for home dialysis, rates have *declined* over the last decade. In addition:

- The only national, random study of modality awareness, the Dialysis Morbidity and Mortality (DMMS) Wave 2 study (1996), found that only 24.6% of in-center patients were aware of home HD, and just 25.3% knew of CAPD (20% knew of CCPD).<sup>xiii</sup> The new Conditions for Coverage that took effect on April 15, 2008 *now* require options education once patients begin dialysis. However, we doubt that there has been 100% penetration of modality education sufficient that patients would choose a home treatment *during the first 4 months of dialysis*—particularly since an estimated 40%-50% of patients begin dialysis in the U.S. with less than 3 months advanced warning that they will need it, leaving little time for predialysis modality education.
- The clock starts ticking when a Medicare patient is admitted to the dialysis clinic. Patients may be too frightened, unstable, or uremic during the first 4 months to choose to train or successfully complete a home training program. ***If they miss that window under this proposed rule, their facility might not offer them the opportunity to home train later, with no training reimbursement.***
- Typically, the type of home dialysis that might be initiated during the first 4 months of treatment would be PD, not home hemodialysis, which requires longer, more costly training and the potential for home modifications that could cost up to \$1,500.
- Even if patients *do* opt to train for home hemodialysis within the first 4 months, there may not be a training slot available at any nearby certified training facility.
- ***Under this proposed rule, facilities have no incentive to train patients for home dialysis—ever—because they will be paid at the higher rate whether or not they train patients. Their profits will be higher if they don’t.***

Failing to provide clinics with a reasonable separately billable payment for home HD training has *already* hampered growth in home dialysis, and this proposed policy creates a very real risk that clinics will cease to train patients for longer and/or more frequent home HD, which have been shown to improve health-related

	<p>quality of life,<sup>xiii</sup> reduce medication use<sup>xiv,xv</sup> and hospitalization,<sup>xvi,xvii,xviii</sup> and increase survival.<sup>xix,xx,xxi</sup></p> <p>On page 49931 of the Federal Register 9/29/09, the Proposed Rule states: “<i>We believe that including training and home dialysis costs in the ESRD PPS would provide increased flexibility to dialysis centers for greater use of less costly PD and alternative treatment regimens such as nocturnal dialysis, home hemodialysis using compact portable dialysis machines, and shorter but more frequent dialysis sessions.</i>” <b><i>We are unaware of any circumstance in which not reimbursing for a service encourages flexibility, innovation, or even provision of that service. Including home training in the ESRD PPS bundle would do a grave disservice to patients.</i></b></p> <p><b>Recommendation(s):</b></p> <ul style="list-style-type: none"> <li>■ <b>Make home dialysis training (for PD and home HD of all types) separately billable at a rate that reflects the actual cost of staff time.</b></li> <li>■ <b>Fund training by reducing the 47.3% payment adjustment for the first 4 months of treatment to 30%. Use the remaining 17.3% to create a pool for home dialysis training of all types.</b> At 105,000 new patients per year, if 60% are Medicare primary, 63,000 patients would be eligible for the new patient adjustment. For 52 treatments (4 months x 13 treatments), this \$93.96 adjustment is an estimated <b>\$307,812,960</b>. Reducing the adjustment from 47.3% to 30% means that the increase in payment for the first 4 months would be \$59.59 instead of \$93.96. The difference creates a pool of <b>\$112,596,120</b> for home training. Per the USRDS 2009 Annual Data Report, Table J.16, a total of <b>6,420</b> U.S. patients trained for some type of home dialysis in 2002, 7,312 in 2003, 7,330 in 2004, <b>7,350</b> in 2005, and <b>7,295</b> in 2006. Assuming that <b>8,000</b> patients would train in 2011, the \$112,596,120 pool/year should accommodate paying clinics the actual staff time for home HD (and some reasonable amount for PD) training —\$130 per training session (a 65.4% increase) and the pool would grow each year as the population of dialysis patients does. Creating such a pool would allow for a training reimbursement rate that would appropriately compensate clinics for the time and effort it takes to train patients for home treatment, and create an incentive to train more.</li> <li>■ <b>Reimburse clinics for training after a patient has successfully dialyzed at home for 6 months or received a kidney transplant, whichever comes first.</b> In this way, a training payment can create a policy incentive for effective training and support for successful home retention.</li> <li>■ <b>Limit training days to the current level (unless medically justified), as most clinics appear to be able to complete training in that time period.</b></li> </ul>
<p>Section 1881(h)(4)(A) of the Act requires the Secretary to establish performance standards with respect to</p>	<p><b>Patient concern 18:</b> The death rate in dialysis is high, and has remained essentially unchanged for almost two decades. Anemia and hemodialysis adequacy have each been individually monitored and tracked for over a decade with little</p>

the measures selected for the QIP for a performance period with respect to a year. Section 1881(h)(4)(B) provides that the performance standards shall include levels of achievement and improvement, as determined appropriate by the Secretary... in our model, for the first performance period, we would establish a performance standard for the proposed anemia management and hemodialysis adequacy measures based on the special rule in Section 1881(h)(4)(E). This provision requires the Secretary to “initially” use as a performance standard for the anemia management and dialysis adequacy measures the lesser of a facility-specific performance rate in the year selected by the Secretary under the second sentence of section 1881(b)(14)(A)(ii), or a standard based on the national performance rate for such measures in a period determined by the Secretary.

resultant change in the death rate. The proposed QIP is quite limited. ***We believe a higher standard—looking at multiple key clinical indicators simultaneously—is essential.*** Both of the recommendations below make use of clinical performance measures *that are well-accepted in the community and already routinely collected*; the difference is that looking at them *together* offers a more well-rounded clinical picture that suits Congressional intent and could make a real difference to patients.

**Recommendation:**

- **Exclude patients who are not receiving ESAs** when determining percent of patients whose hemoglobin levels > 12 g/dL.
- **Adopt the Practice-Related Risk Score (PRS) as a QIP standard.** The PRS is a composite, *facility-level* index of four key dialysis quality measures; the percent of patients with: 1) Kt/V  $\geq$  1.2; 2); Hemoglobin  $\geq$  11 g/dL; 3) Albumin  $\geq$  4.0 g/dL; and 4) A central venous catheter for dialysis access. The PRS was developed by the Arbor Research Collaborative for Health using data from the Dialysis Outcomes and Practice Patterns Study (DOPPS). In a 12-country study, “changes in the PRS over time were significantly correlated with changes in the standardized mortality rate (SMR). The PRS ranged from 1.0 to 2.1. Overall, the adjusted relative risk (RR) of death was 1.05 per 0.1 points higher PRS (P < 0.001).”<sup>xxii</sup>
- **Adopt a patient-level all-CPM index as a QIP standard.** Using data from 15,287 patients who were part of the 5% random clinical performance measure (CPM) data collection, Rocco et al<sup>xxiii</sup> devised an individual, *patient-level* target CPM index that is quite similar to the PRS. Composed of **Adequacy** (single-pool Kt/V urea of  $\geq$  1.2); **Anemia** (Hemoglobin  $\geq$  11 g/dL); **Albumin** ( $\geq$  40 g/L with bromocresol green or  $\geq$  37 g/L with bromocresol purple); and **Access** (use of an arteriovenous fistula), use of this index demonstrated that *6% of patients met no clinical targets*, 24% met one target, 39% met two, 24% met three—and *just 7% met all four targets*. During the study period, 8,364 patients were hospitalized, and 3,062 died. The risk for death increased with each additional unmet target. “Adjusted hazard ratios were 4.6 (95% CI, 3.3 to 6.4), 3.5 (CI, 2.6 to 4.7), 2.6 (CI, 1.9 to 3.5), and 1.9 (CI, 1.4 to 2.6) for 0, 1, 2, or 3 targets met, respectively, compared with meeting 4 targets.”
- **If CMS persists in including oral Vitamin D and phosphate binders in the bundle, CMS must include measures for mineral and bone disorder (MBD) in the QIP.** Otherwise, dialysis facilities striving to maintain their profit margin will choose cheaper alternatives or *not provide these drugs at all*. Depending on the delay in the quality data collection, it could be months or years before the change in practice patterns and outcomes is learned, and countless patients could be harmed in the interim.

**References**

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