August 31, 2013

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Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave. SW
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RE: CMS-2013-0150-0002: Medicare Program: End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies

Home Dialyzors United is the largest dialyzor-based, home hemodialysis organization in the nation, supporting and advocating rehabilitative dialysis for all. We appreciate CMS’s willingness to listen to patients like us as we are the beneficiaries of the ESRD Prospective Payment System. We have all taken different paths to Chronic Kidney Failure, but we now all share the same journey. Living with kidney failure is not easy. In fact, it’s a hard life, but we have come to accept it and do our best. That’s why we dialyze at home. We dialyze more frequently than those on conventional hemodialysis, and oftentimes much longer. Our kidneys don’t function 24/7 like most people, but we have learned a new “normal”. Home dialysis has allowed many of us to return to work, thus allowing us to pay our taxes and save the system from growing disability payments. For most, it affords us the chance to be better parents, grandparents, friends and an asset to our communities.

The original intent of the Medicare entitlement program was to rehabilitate and allow as many people as possible to do home dialysis. However, somewhere along the way we have become lost. Rather than rehabilitating and restoring lives, we have created an atmosphere that fosters debilitation. The U.S. mortality rate is the highest, outcomes the lowest and cost the greatest in the industrial world. Yet we’re the richest nation. Now Medicare finds itself in the position of growing deficits with skyrocketing expense. We need to get back to square one and start all over, but that’s going to take a lot of work. Considering the renal industry continues to consolidate at an ever increasing rate, we are controlled by a seemingly indifferent duopoly which emphasizes greater profits over quality care and better outcomes. We need to get back to a focus on quality care and improving outcomes, but how do we do that when the lines have already been drawn in the sand and deeply entrenched for the status quo!

Therefore, Home Dialyzors United would like to add our comments to the ongoing discussion. Who better than patients themselves? We the patient, not the providers, are most impacted by the decisions CMS makes. The two largest are making millions in profit per year. It’s a business with them. Though doctors may be more sympathetic, they don’t have to live with the consequences of kidney failure. No, it’s the patients who live with the condition day in and day out. It is families and friends who see loved ones cope and suffer. Our input should receive the highest consideration.

HDU believes the overall payment system for dialysis, encompassing both the PPS and QIP, should emphasize “pay for performance”. We don’t believe it does and therefore consideration should be given to restructuring the overall system. While stressing “performance” we envision a system which is constantly challenging providers to increase patient care and outcomes. Each year we should expect
services, care and outcomes better than the last. We anticipate a system which motivates providers to attain those values in order to earn their individual goals, whether it is to increase profits or satisfy community objectives.

We don’t believe the current PPS and QIP accomplish those aims. In order for that to happen, we believe Congress must review the specifics of MIPPA and amend it to have a much higher withhold on the QIP side to make the totality of the measures meaningful. We also believe CMS must also review the individual measures to make each one stand on its own and challenge providers to attain. We don’t believe this is the current situation with many measures to easy to achieve or have little impact on patient outcomes.

**Prospective Payment System**

Unfortunately, the fears brought up before the original PPS rules were finalized in 2009 have come to fruition. In 2009 we commented on making the PPS work for patients, including issues of accessibility, have many of the same issues and more.

Regarding the current proposed rules change, we wish to address what affects home dialyzors as well as those in-center. There are several issues which particularly affect home hemodialyzors and those wishing to pursue the modality.

The other hot topic that requires comments this year is the proposed 9.4% net reduction in the PPS. Unfortunately, we find ample evidence for CMS to make these cuts although we fear dialysis patients may be harmed.

**Home Hemodialysis Training**

Simply put, we are disappointed with the reimbursement for training of approximately $36 per session, meant to cover one hour per session of a nurse’s time. Though the current training payment for peritoneal dialysis is likely sufficient, the payment for home hemodialysis training is woefully inadequate. This creates a disparate barrier to dialyzors getting access to home hemodialysis. As home hemodialyzors who have gone through training we know how intensive training is and how much time nurses have spent with us. We estimate they spend an average of four to five hours per day over the training period.

We have already heard of centers rethinking whether they will start or continue with their home programs. Considering the reimbursement, it’s no wonder only about 25% of dialysis centers are certified for home dialysis,, but far fewer offer home hemodialysis. This does not just affect those who want to start home dialysis, but those already doing it.

By keeping training reimbursement outside of the bundle, CMS can be assured it is getting its money’s worth and not see it abused as has happened with the inclusion of specific dollars for ESAs and biological. Home hemodialysis has been effectively shown to be the modality which has the greatest survivability with the best quality of life. The percentage of patients returning to gainful employment is the highest. Home hemodialysis puts us back on the path of the original intent for the provision of dialysis. With its best outcomes it is what the dialysis system was meant to be.

**Disparate Access to Care**

We also believe there is a significant problem with accessibility to the home hemodialysis modality. Many patients aren’t able to get training scheduled for various reasons. We have heard of cases where patients with commercial insurance as their primary coverage are getting preferential treatment. Others are told to start with peritoneal even though they prefer home hemodialysis. The Conditions for Coverage are very specific. Each dialysis patient must be evaluated for
home or self-care dialysis. There must be a plan for home dialysis or documentation for the rationale as to why the patient doesn’t qualify. From independent surveys we know that the vast majority of in-center patients have never heard of home dialysis, especially home hemodialysis. In fact, a survey by the American Association of Kidney Patients in 2012 indicated that only 12% of patients reported being made aware of home hemodialysis, and only 34% reported being told about peritoneal. Obviously the Conditions for Coverage are not being followed as intended. Therefore, we urge CMS to strengthen its oversight of the Conditions for Coverage. We also insist dialysis centers provide all of the modalities CMS has approved for payment or facilitate the transfer to a convenient center that does offer the preferred modality.

In addition, the Conditions for Coverage The regulations (42 C.F.R. § 494.60(c)(4)) require patients to "be in view of staff during hemodialysis treatment to ensure patient safety." V407 goes further than the regulation by requiring facilities to provide constant visibility of home hemodialysis patients. This requirement also does not differentiate between new patients, who need constant supervision during training, and patients who have become competent as their training progresses. During the later phases of training, patients benefit from training that simulates the home environment by allowing patients to dialyze on their own with nurses available to help when needed. Home hemodialysis training is not done only during the set up period and teaching of self-cannulation and the ending of therapy with the pulling of needles and tear down. Most of the training takes place during the time the patient is performing dialysis. This is when the training nurse is teaching and simulating problems that can occur while on dialysis. This is far from idle time. The training nurse is occupied with the patient throughout the entire dialysis process.

What do patients want from their therapy? We want to live as normal a life as possible. We want our health to be restored as much as possible to what it was when our kidneys functioned. We want what the original supporters of the Medicare ESRD Program wanted and what Congress approved for us. We want to be employed and contribute to our community. We live in a world of “adequate” dialysis when we want optimal dialysis. We want to define our outcomes rather than have others do it for us. Simply put, we want a good quality of life.

Eliminate Requirement for Medical Justification: As home dialyzors, we understand there is a finite amount of money to go toward our therapy, but if we had our way we would rather see more money go toward therapy rather than bundled for medications unnecessary because we are using a better modality. The bottom line is that more money needs to be put toward more frequent dialysis. The requirement for medical justification only slows the process down, causing uncertain payment for providers and reducing access to care. Patients and their nephrologists should be able to decide what is best for the individual. For in-center patients we would urge that CMS do away with the “long weekend.” Studies have proven that more cardiac deaths occur the first day after wards. So why are we still imposing the dreaded long killer weekend on nearly 365,000 people?

Corporate Practice of Medicine: We are concerned about the corporate practice of medicine by dialysis providers. Where else has the responsibility of prescribing therapy and medication been taken out of the hands of physicians? While over 90% of nephrologists say they would prefer home dialysis if dialysis was necessary, 90% of their patients are relegated to a chair in-center. We have heard stories of many nephrologists desiring a patient start home hemodialysis, yet the center hasn’t allowed it or has not made staff available to train the patient. We know of major providers signing contracts with pharmaceutical companies for certain medication while the particular medications might not be the best for a particular patient. Many patients are suffering because changing prescribing practices of providing analog vitamin
D and iron, among others. We must put the responsibility of medicine where it belongs and that is in the hands of the individual physician and the patient they are prescribing for.

9.4% Reduction to the PPS

We are saddened we must agree CMS is justified in reducing the PPS payment by 12% due to the underutilization of ESAs and biological. CMS’s proposed 12% cut in the bundled payment rate—actually, a 9.4% reduction after CMS added in a 2.5% increase in its annual review of operational costs—is not based on an arbitrary review. Congress mandated in the American Taxpayer Relief Act of 2012 that the agency reduce the composite rate after two reports from the General Accounting Office and the Office of Inspector General criticized CMS for using old data from 2007 to determine payment for injectable drugs. The GAO report was required as part of the Medicare Modernization Act of 2008 that mandated CMS create the Prospective Payment System for dialysis care, and the OIG report was part of the agency’s planned investigations for 2013, a list of which is released each year.

Both of these reports said the same thing: Once the bundle took effect in 2011 and dialysis drug payments were included, providers started reducing use of these costly drugs almost immediately, particularly anemia drugs like Epogen (the latest data from the Dialysis Outcomes and Practice Patterns Study’s Dialysis Practice Monitor shows a drop of close to 30% since the bundle took effect). Yet CMS never made an adjustment to the bundled payment. So providers received payment for drugs they weren’t using. The GAO report said the extra cost to Medicare was between $660-$880 million.

In addition to getting the same money for using less drugs, renal providers received three consecutive increases in the base composite rate for dialysis treatments in 2012, 2013, and now one for 2014 — based on CMS’s annual review of a market basket of costs to provide care. Annual increases to the composite rate were few and far between in the years prior to the bundle.

In fact, CMS gave the industry a rate increase for 2014 even after the Medicare Payment Advisory Commission withdrew its recommendation to Congress that clinics deserved a similar-sized increase.

So now the industry is being told they have to give some of that back. Facing cuts they basically brought upon themselves, dialysis providers and advocacy groups, including patient organizations dependent on industry funding, are saying that patient care will suffer, that dialysis centers may close, and that staff will be reduced. In fact, they are saying that life-saving therapy is at risk.

Uneven Playing Field

Although all sized dialysis centers, both for-profit and non-profit, are guilty of underutilizing ESAs and biological, one particular LDO is the biggest offender. Not only is this company able to benefit from economies of scale in its purchases, but also has a long-term contract with Amgen for the purchase of its ESAs and less likely to be affected by price increases, such as the recent average 5% increase. HDU also did not have all of the pertinent data to ascertain whether all providers equally share in the same percentage of the underutilization. In the event non-profits and SDOs proportion of the underutilization was below that of one or both of the LDOs, it would seem unfair they be assessed the same reduction percentage.

Interestingly, it is the non-profits and SDOs that seemingly provide better care and outcomes for its patients. Two recent studies prove this out.
In the article, “Patient care staffing levels and facility characteristics in U.S. hemodialysis facilities” published in June in the American Journal of Kidney Diseases, researchers noted that “ratios of RNs and LPNs to patients were 35% (P < 0.001) and 42% (P < 0.001) lower, respectively, but the PCT to patient ratio was 16% (P < 0.001) higher in for-profit than nonprofit facilities (rate ratios of 0.65 [95% CI, 0.63-0.68], 0.58 [95% CI, 0.51-0.65], and 1.16 [95% CI, 1.12-1.19], respectively)."  

We also learned from the Agency in Health Care Research and Quality in December 2011 that, “Compared with the nonprofit chain, mortality risk was 19 percent higher at one for-profit chain and 24 percent higher at a second for-profit chain. Overall, patients from for-profit facilities, regardless of chain status, had a 13 percent higher risk of mortality than non-profit facilities.”

If we are serious about providing patients better care and outcomes, we must insure that non-profits and SDOs are able to survive these difficult time. There must be a method for differential pay for these superior providers. It is just a matter of whether this is reflected in the PPS or QIP, or both. When Congress passed MIPPA in 2008, CMS was given latitude to adjust payment per the PPS based upon the size of the provider organization. In addition, the Regulatory Flexibility Act (RFA) allows CMS to assess the impact of the regulation on small entities. We firmly believe CMS clearly has the authority to adjust the payment to the SDOs.

Finally, to prop up the SDOs further, CMS should do what it can to increase the level of home dialysis, including home hemodialysis. The SDOs have indicated their 2012 average profit per treatment for home dialysis is $51, $81 and $51 for Home CCPD, CAPD and Hemodialysis respectively while only $14 for In-center. One measure to accomplish this is to increase the reimbursement for home hemodialysis training.

**Quality Incentive Program**

The QIP should not be easy for providers to attain. Instead, it should be a constant challenge in order to provide an ever increasing quality of care. We should never be satisfied with the status quo. We appreciate the fact CMS wants to add five more measures to the QIP. However, as long as Congress mandates a 2% withhold, we feel the more measures added dilutes the 2% withhold to the point that it effectively make the QIP counterproductive. Therefore, we urge CMS to put more emphasis on quality, focusing on those most important to improving the health status and outcomes of patients. We believe the CMS Quality Incentive Program for Chronic Kidney Failure Patients on Dialysis, commonly known as

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1 Am J Kidney Dis. 2013 Jun 27. pii: S0272-6386(13)00830-5. doi: 10.1053/j.ajkd.2013.05.007

2 Analysis of 2012 Small and Independent Dialysis Provider Revenues and Costs, Avalere Health, August 2013
the ESRD QIP, should establish performance measures for dialysis providers to afford patients the best possible care possible.

The initial intent of the Medicare entitlement program for dialysis was to rehabilitate patients with the goal of reentering society in a functional manner, including employment. We understand priorities change and we must remain flexible, but the U.S. dialysis system has dismally failed this rehabilitative goal. Today, roughly 80% of dialysis patients between the ages of 18-54 are unemployed with only 3% employed due to rehabilitative efforts, and 19% of dialysis centers opened with new shifts after 5:00pm. However, rehabilitation goes further than employment. With the skewing of dialysis patients toward older ages, it can mean as little as restoring a more meaningful relationship with family and community. The goal should be to restore people to living purposeful lives. Anything less than that is simply not good enough. Therefore, we believe measures should go beyond clinical values, and must include quality of life and psychosocial values.

Since we are primarily advocates for home dialysis, we strongly believe home dialysis must not be ignored in any quality incentive program. In the early 1970’s, congressional committees went as far to propose 50% of all dialysis be performed at home. Today, only about 10% is done there. Yet, multiple surveys of nephrologists and other renal professionals indicate 90% of them would not do conventional hemodialysis in-center. Congress has mandated CMS develop reimbursement mechanisms to incentivize home dialysis. We believe any quality incentive program should also work toward the goal of closing the gap between providers and their patients regarding doing dialysis in the home environment.

Anemia

Currently, the one measure for anemia is a hemoglobin level of over 12g/dL with the discontinuance of the under 10g/dL. We opposed the measure of 12g/dL when it was first proposed and approved. One of the stated reasons for bundling erythropoietin stimulating agents (ESA’s) payments into the PPS was ostensibly because ESA’s were being overdosed due to the profits built into its use. With the passage of MIPPA and the subsequent ESRD PPS, prescribing ESA’s changed from being a profit center for providers to one of being a cost center. Thus the underutilization of ESA since just before the introduction of the PPS in 2011 and the resultant proposed reduction this year. We feel if any measure should exist it should be a lower limit of 10g/dL for the safety and wellbeing of patients.

Interestingly, the current proposal still maintains the upper limit of 12g/dL, which we believe is not a performance measure at all because providers are looking toward reducing cost. Our concern is without a lower limit an invitation for providers to underdose exists. The probability of too low of a hemoglobin measure and its inherent anemia may be more dangerous, if not more than the higher Hgb levels. The setting of an appropriate Hgb should be between the patient and the doctor. If any generality can be made it is that there needs to be a minimum limit and not a maximum limit. We are experiencing the increase blood transfusions by approximately 20%. As you know, each time a dialysis patient receives a transfusion, his/her antibodies go up, and that can become an issue if the person desires a transplant. In addition, without having a lower limit, CMS is giving the green light to providers to underutilize.

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3 Table 20-ESRD Network Program 2011 Summary Annual Report

4 USRDS 2011; NY Times, May 11, 2012, Unintended Consequences for Dialysis Patients as Drug Rule Changes
It is the patients’ lives which are affected by low anemia. We know what it’s like. It should be between patient and physician as to what the dose should be. Also, those who have a natural Hgb of greater than 12 without the use of ESA’s should not skew the center’s score. Let us decide what the benefits and risks are.

CMS is proposing one more reporting measure regarding anemia, which is to account whether patients are receiving informed consent for anemia treatment. While we agree informed consent should be given for anemia treatment, it should also be given for other aspects of dialysis. Quite frankly, we believe informed consent is much more important regarding the choice of modality. We have counseled many more patients because they have not been given proper informed consent pertaining to home dialysis. In fact, many patients have never heard of home dialysis. This has a much greater impact on a patient’s longevity and quality of life. Regardless, we do not believe more reporting measures should be added to the QIP.

**Adequacy**

CMS is proposing keeping dialysis adequacy measure based on Kt/V for in-center, peritoneal and pediatric patients. Home hemodialysis patients are excluded for this as in the past. However, we believe Kt/V is a poor measure of adequacy. In fact, we’re opposed to the concept of adequate dialysis in the first place. We favor the approach of optimal dialysis. Dialysis is not something one should get to just survive regardless of quality of life. A good life goes hand in hand with quality. We don’t understand why the minimum level of “getting by” is the marker by which we should accede.

There are many disadvantages to using Kt/V:

- Urea is not associated with toxicity.
- \( Kt/V \) does not take into account the role of ultrafiltration.
- It is only a point in time measurement

We believe other measurements of adequacy must be developed. One such measurement might be UFR (ml/hr/kg). Such a measure takes in consideration time on the dialysis machine, interdialytic weight gain and has a direct correlation to cardiac and all purpose risk of mortality.

**Proposed Vascular Access Type Measure**

We firmly believe the placement of autogenous Arteriovenous fistula provides for a safer and better dialysis therapy. Therefore, where possible, it should be promoted. However, we also realize there are situations where a fistula cannot be placed. Those who have failed fistula in the past, or must use a graft, should not be penalized for requiring the use of a catheter. Should providers be held accountable? In many cases, it may be difficult to discern whether it was the provider who dissuaded the placement of the fistula, or whether they were responsible in some way for the slowing of maturity. We have nephrologists and vascular surgeons for a reason. We can’t ignore their responsibility regarding placement of the AV fistula. In some cases, catheters are used simply because of poor planning while the patient is predialysis.

**Infection Control**
Since dialysis patients are subject to infections caused by many and varied reasons, and not just due to issues directly related to their therapy, any measure developed must target the cause of the infection if providers are to be held accountable.

**Measuring Hypercalcemia**

As important as it might be to measure total uncorrected serum calcium greater than 10.2 mg/dL, we believe it is one more clinical measure which would contribute to the dilution of the effectiveness of the QIP.

**Proposed Patient Experience of Care Survey Usage Measure**

Congress mandated in MIPPA that a measurement of patient satisfaction and quality of life should be established. CMS has designated the In-center Hemodialysis Consumer Assessment of Healthcare Advisors (ICH CAHPS) survey tool to be implemented to accomplish that goal. However, simply performing surveys does not equate to improving patient experience and quality of life. Patients have answered surveys for years, actually decades, and they continue to get more debilitated. CMS is not proposing a measure for actual performance based on the survey results. We are also disappointed because the ICH CAHPS survey has been designed for thrice weekly in-center patients and does not consider the experience of patients at home. We encourage CMS to implement a patient satisfaction mechanism that reflects the experience of all patients. But that means a total redesign. We feel the current ICH CAHPS designed in 2009 does not reflect the patient experience due to their dialysis therapy. The following questions are examples of what would give a better idea as to whether patients are satisfied with their therapy.

1. Do you cramp during your therapy?
2. Do you get nauseous during your therapy?
3. Does your blood pressure crash during your therapy?
4. Do you have a long recovery time after your therapy?
5. Are you dehydrated from your therapy and does that cause you to drink too many fluids afterward?

In addition, it is our experience that dialysis patients don’t necessarily answer such surveys honestly. Oftentimes they will not answer questions to the negative for fear of retaliation from the provider. This brings into question the validity of any such survey.

**Proposed Mineral Metabolism Reporting Measure**

We believe it is extremely important to control the factors that contribute to bone mineralization. However, CMS is proposing providers simply monitor phosphorus on a monthly basis. They are already required to do that. We don’t understand the purpose of the proposed rule as it stands. There are no requirements for actual control and outcomes. It is imperative that they must be put in place. Otherwise it becomes a matter of providers going through the paces, without actually bettering a patient’s health.

**What’s Missing**
We first want to propose new performance measures which have not been proffered by CMS. We understand that CMS will have to track more information on a yearly basis from individual dialysis centers in order to make these measures possible.

1. Track and report on whether a particular dialysis center offers home hemodialysis and peritoneal dialysis.
2. Track and report on whether a particular dialysis exceeds the average of percentage of patients between the ages of 18-54 employed.
3. Track and report on whether the dialysis facility, if in-center, has shifts starting after 5:00pm. This would allow more people to return to the workforce.

We concur that certain clinical markers must be present in any performance measures to assure more healthful outcomes, but need to balance the clinical with the psychosocial in order to impact the total patient.

In conclusion, we understand and appreciate how much effort has gone into developing the proposed rule changes. However, we want to be sure that the patients’ voices are heard going forward. We don’t have the resources of providers, pharmaceutical companies and other renal businesses; we simply don’t have the same access they do. But the Medicare ESRD Program is about us. We’re the ones carrying the real load. We’re not into dialysis for the money. Our only concern is our self defined quality of dialysis. We’re here because we have to be — in order to sustain our lives. We urge CMS to listen to our voices. It’s all about the patient.

Respectfully,

Richard Berkowitz
President and Founder
Home Dialyzors United

cc: Laurence Wilson
Jean Moody-Williams