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December 14, 2009

Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building
Room 445-G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1418-PL Medicare Program. End-Stage Renal Disease (ESRD) Prospective Payment System Proposed Rule

Dear Acting Administrator Frizzera,

As a practicing nephrologist with nearly 32 years of practical experience in the management of patients with ESRD I am pleased to have the opportunity to provide CMS with comments about the Proposed Rule for the End Stage Renal Disease Prospective Payment System.

My comments will focus on the following selected areas and are presented for convenience in the order presented in the Table of Contents:

- The Basic Case-Mix Adjustment
- Other Drugs and Biologicals and Their Oral Equivalents
- Diagnostic Laboratory Tests and Other Items and Services
- Home Dialysis Patients (Method I and II) and Self Dialysis Training

The Basic Case-Mix Adjustment

CMS is to be applauded for distinguishing that there are variations between patients, and that some require more labor and supply resources. Therefore, there should be distinctions in payment. The University of Michigan Kidney Epidemiology and Cost Center was contracted to develop the case-mix adjustment model in preparation for an expanded bundle (Hirth, et al. Results on Research on Case-Mix Adjustment for an Expanded Bundle, February, 2008, Contract HHSM-500-2006-00048C). Their model was developed based on Medicare Claims, Medicare cost reports and Independent Renal Dialysis Facility Cost Reports and Hospital Cost Reports up to 2004. Patient co-morbidities were based on CMS Form 2728 and data on Medicare claims. Their model was based on the utilization of patient variation in both case-mix and resource use. While they felt their model was feasible, they expressed concerns that providers could inadvertently be rewarded for poor outcomes. They felt it feasible on the bases on existing CMS data but that implementation challenges existed.

Their model did not create a multiplier for race. However, given that home medications used in dialysis patient are being considered to be part of the bundle, and that some races have differences in their needs for various medications, it seems that this variable should be added.

The implementation issue is problematic. Modifying claims data to account for co-morbidities may not be specific enough. Information technology at the level of the provider, and possibly CMS, is still not sophisticated enough to mine current databases, parse for specific variables and create reports that will be optimal to satisfy the Proposed Rule's requirements. Therefore, nurses and other dialysis personnel will be burdened with this challenge. My concern is that this reporting burden will detain them from their duties to patients.

Premature attempts to implement this model could have an adverse impact on its acceptance and usefulness. It would be prudent to delay implementation until software systems can adequately handle this without increased burdens on nurses. Bringing it out in selected markets will make it more feasible to make necessary refinements.

Other Drugs and Biologicals and Their Oral Equivalents

The Proposed Rule (FR 74:187, 50006) states "Section 1881(b)(14)(B)(iii) of the Act specifies that other drugs and biologicals that were furnished to individuals for the treatment of ESRD and for which payment was made separately under this title, prior to the implementation of the ESRD PPS, and their oral equivalent forms, must be included in the ESRD PPS payment bundle. Given the reference to ''this title,'' we interpret clause (iii) as requiring the inclusion in the ESRD PPS payment bundle all drugs and biologicals that were separately billable prior to the implementation of MIPPA under title XVIII of the Act. Therefore, we believe the ESRD PPS payment bundle would include all drugs and biologicals formerly separately payable under Medicare Part B and Part D."

While one must respect the above interpretation, it does not explain why the authors of the original legislation would have specifically stated "and their oral equivalent." Were they to have meant to expand the bundle to include drugs that were not being

given intravenously they would not have included that phrase. One must also assume they would have specified Part D.

There are presently multiple reasons why the oral medications that do not have an iv equivalent should not be included in the expanded bundle:

The new KDIGO Guidelines (http://www.kdigo.org/) have been published and suggest that all patients be screened for vascular calcification. Those who have evidence should not be placed on a calcium binder. The new guidelines also stress normalizing the serum phosphorus. Currently the approximate retail price from www.drugstore.com for a popular non-calcium binder is $62.99 for thirty 800 mg tablets ($2.10 per tablet)The average dose is 3 tablets with each meal, 9 per day, 365 days per year. This equates to 3285 tablet per year – costing $6,898.50 per year. This translates to $44.22 per treatment.

Nearly half of patient deaths in hemodialysis patients are from vascular calcification, and physicians are going to use this regimen in the approximately 60% of the 341,000 patients who are on hemodialysis. If these and other medications that demonstrate best clinical practice are used, and their pricing exceeds what is projected to be covered in the bundle, dialysis centers are going to have to cut their costs to other vital services

Furthermore, the administration of this program is going to have untoward effects upon the current system. Many dialysis centers are not equipped to handle and distribute home medications. It will be unwieldy to determine which medications were prescribed by primary care physicians or other providers, and which the nephrologist prescribed, and to then debit back costs to dialysis facilities.

In order to determine if this ambitious project can succeed, one should implement it in selected markets, and make certain that software and infrastructures can adequately support it.

Diagnostic Laboratory Tests and Other Items and Services

The Proposed Rule will underfund laboratory services provided by physicians as part of best-demonstrated practices unless funding is at 100%. This is specified by law (Social Security Act §1833 (a)(2)(D) (ii)" on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate for such tests;).

"Section 1881(b)(14)(B)(iv) of the Act requires that diagnostic laboratory tests not included under the composite payment rate (that is, currently separately billable laboratory tests) must be included as part of the ESRD PPS payment bundle. We propose to define such laboratory tests as laboratory tests that are separately billed by ESRD facilities as of December 31, 2010, and laboratory tests ordered by a physician who receives monthly capitation payments (MCPs) for treating ESRD patients that are separately billed by independent laboratories. Because many of the same diagnostic laboratory tests can be performed for both ESRD and non-ESRD patients, we believe that this approach for including laboratory services appropriately captures tests for inclusion in the payment bundle. "

The Proposed Rule also states “ESRD patients generally have many co-morbid conditions and are treated by other specialists for those conditions. As such, many of the same laboratory tests ordered by a physician to monitor a patient’s ESRD, could also be ordered by other physician specialists treating the ESRD patient for other medical conditions. Therefore, it is difficult to differentiate between an ESRD related laboratory test and a test ordered for another condition. While the ideal scenario would be to require that payment for all potential ESRD related laboratory tests be made only to the ESRD facility, ESRD facilities may not be able to control the ordering of tests by physicians not treating the patient’s renal disease. A consolidated billing approach could identify the source of a given laboratory test to allow separate payment when the test was not ordered in connection with the patient’s ESRD condition. In order to ensure proper payment in all settings, we are exploring the use of modifiers to identify those services furnished to ESRD beneficiaries, which are excluded from the proposed ESRD PPS.”

Often nephrologists assume the role of primary care physician as a convenience to patients, to minimize venous cannulations and simplify their care. On other instances, patients will have laboratory testing that is renal-related drawn outside the facility. A simplified solution would be to identify in advance those tests that are directly related to dialysis and provide for their ample reimbursement, regardless of the site where the blood is drawn.

Home Dialysis Patients (Method I and II) and Self-Dialysis Training

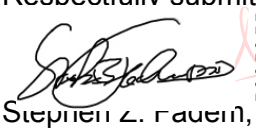
Patients who undergo peritoneal or home hemodialysis are more likely to remain employed and have a higher quality of life. Yet, it is not often discussed in the predialysis period, and most patients never are offered the opportunity to chose this modality. Efforts are underway to increase its use. To not offer fair compensation for training patients to undergo home treatments will seriously jeopardize our efforts to increase home utilization. We urge CMS to not forego the home dialysis-training fee.

Conclusion

In May, 2007, Avi Dor published an international study as part of the National Bureau of Economic Research Working Paper Series. This paper capered dialysis payment, services, incentives and outcomes in 12 countries. The ratio of HD to general population death rates was 15.57 in the USA, and slightly better only in Germany, France, Italy and the United Kingdom. It was markedly better in Japan, a country which does hardly any transplantation. The higher death rate was not adversely associated with serum albumin levels, Kt/V or hemoglobins. Reuse was much higher in the USA than elsewhere. What was striking was that payment per HD treatment in the US was $124.00, second only from Australia. Japan paid $192.00 per treatment. The higher the gross national income, the higher the incidence of dialysis. The study concluded that when ESRD expenditures were adjusted to account for the differences in purchasing power of medical inputs in the countries studied, variation in per capita expenditure on ESRD was substantially reduced. The adjusted ESRD expenditure per capita in the USA was below Germany, Belgium and the UK.

It is important to recognize that when CMS transitions to an alternate system of payment, it not inadvertently underfund the ESRD delivery system or overburden it with a payment infrastructure that will be difficult to implement and maintain.

Respectfully submitted:



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