



NORTHWEST
KIDNEY CENTERS

September 24, 2010

Dr. Donald Berwick
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 314G
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-3206-P: Proposed Rule for the End Stage Renal Disease Quality Improvement Program (QIP)

Dear Administrator Berwick,

Thank you for the opportunity to submit comments on the ESRD QIP Program. Northwest Kidney Centers is the world's first out-of-hospital dialysis program, based in Seattle Washington, founded in 1962. We are a non profit organization. Last year in our 14 facilities and 230 homes, we provided over 150,000 Medicare-funded dialysis treatments. Over 16% of our patients are on home therapy. We work closely with 40 nephrologists who follow patients at our facilities. Because we provide care to 0.5% of US dialysis patients, we consider ourselves a Small Dialysis Organization (SDO) provider.

GUIDING PRINCIPLES FOR OUR SUGGESTIONS

We share with Congress and CMS the intention for QIP to be successful, to encourage improved quality and outcomes for our patients. QIP is the first pay for performance program within fee-for-service Medicare. Thus we anticipate the ESRD QIP will come under much scrutiny. It is important to make it as successful as possible.

Our suggestions to CMS in this letter are guided by the following principles:

Keep QIP straightforward and simple at the outset. Avoid complexity so the initial QIP experience can be analyzed and understood.

Make changes based on initial experience. At the outset we assume QIP will not be fully refined nor will it encompass the full set of quality measures that Congress envisioned. Continuous quality improvement should apply to QIP.

Do no harm. Avoid significant QIP payment cuts to facilities that might put patient care at risk. At the outset, CMS should modulate the cuts until the QIP structure is refined and validated.

Use the best evidence to select and structure QIP. Unfortunately we have many gaps in knowledge in our field. Even with agreed upon measures, ensure the benchmarks are reasonable given the variation in patient condition.

Consider the impact on programs serving home dialysis patients. A “in center hemo-centric paradigm” dominates our field. To meet Congress’ and CMS’s intent to support home therapy, we urge CMS to consider the rule in light of the impact on home peritoneal and hemodialysis patients, many of whom are followed by Small Dialysis Organizations.

POSITIVE ELEMENTS OF PROPOSED QIP RULE

Northwest Kidney Centers is pleased with many aspects of the final bundling rule relating to QIP and the proposed QIP rule.

We support CMS’s proposal to:

Use three well defined measures as the basis of initial QIP. The final bundling rule defined the three QIP measures: Hgb less than 10, Hgb greater than 12 and URR greater than 65%. The three measures are few in number, collected and reported today on Dialysis Facility Reports and Dialysis Facility Compare. We can work to improve outcomes in these areas. We support CMS’s intention to replace URR with Kt/V as soon as reasonable and recommend setting specific standards not only for the formula used but also when the sample is drawn and how it is handled, which can affect results.

To weight Hgb less than 10 at 50%, Hgb greater than 12 at 25% and URR greater than 65% at 25%. Incentives regarding IV medication use change under bundling. EPO utilization may fall. It is appropriate for patient protection to weight Hgb less than 10 at 50%. This sends a strong signal to facilities to make sure enough EPO is being given to meet patient needs.

To use two performance standards to support improvement as well as achievement: the lesser of the facility rate or the national average for each measure. It is extremely important for the QIP program, on an ongoing basis, to allow facilities to avoid penalty if they are steadily improving their quality even if it does not meet the national average. CMS appropriately offers two benchmarks for each measure-comparison against the facility itself or the national average.

Use the Dialysis Facility Report (DFR) methodology and information for QIP. All facilities annually receive their DFR reports and have quality data available within seven months of year end. UM-KECC uses a refined analysis and continues to make improvements in reporting. DFR reports exclude many patient claims that would skew data. The state, network and national data are available for the facility to compare itself.

Eliminate home hemodialysis and home peritoneal dialysis patients from the URR measure. The final bundling rule stated at least six times that the URR measure would apply to only in center hemodialysis patients. This is correct as URR is an inappropriate measure for patients on peritoneal dialysis. As well, most home hemodialysis patients in the US utilize frequent therapy (more than 3 times a week treatment- nocturnal or during the day) and the URR measure is incorrect for this therapy regimen. It is straightforward to eliminate all home hemodialysis patients from the DFR

and QIP calculation instead of the current process used by UM-KECC to examine claims to selectively compute whether a patient was on frequent therapy or not.

Use claim submission for QIP and do not use CROWNWeb. As launched in February 2009, CROWNWeb is a huge burden for SDOs under the single user interface model. Our organization participated in Phase 1 of CROWNWeb so we have direct experience. To date CMS has made available the option of batch transmission of data to only three providers: the two LDOs and the largest SDO.

We believe our sophisticated information technology department has the ability to submit data electronically to a clearinghouse and/or to CMS. As well we believe the vast majority of SDO providers have electronic records and the capability to electronically send QIP information. Batching data is more efficient and accurate than data that is manually input. Manually input data costs the provider much more than electronic transfer of data.

It is not rational to require our organization to manually input data that is less accurate, detracts staff from patient care, and costs more money. Acting irrationally is, by definition, arbitrary and capricious.

We urge CMS to accept electronic submission of data from our organization and other SDO providers, perhaps through a clearinghouse model that uses the emerging standards of health information exchange. After that process is well tested, validated, and meets security requirements, then QIP data can be submitted through that system. In the meantime, we applaud CMS for using the claims format for collecting QIP measures.

RECOMMENDATIONS FOR CHANGES IN QIP RULE

CMS faces a conundrum in launching QIP. It is a matter of fair practice to announce measures before the performance year so facilities can change behavior to maximize performance. The final bundling rule was released on July 26, 2010 announcing the three QIP measures. The QIP rule will be released at the end of 2010 announcing benchmarks and weightings. Thus, ideally, the QIP performance year should be set for 2011.

However to compute the QIP penalty requires DFR data which takes seven months to compile and release which would be mid 2012. But MIPPA requires QIP to be implemented in 2012.

Thus we acknowledge that CMS proposes to set 2010 as the performance year even though fair notice cannot be given.

We propose the following changes to the QIP proposed rule:

Given the lack of advance notice of QIP measures and benchmarks, CMS should set the maximum QIP penalty in 2012 at 1% instead of the proposed 2%. MIPPA allows a penalty of “up to 2%”. We suggest that in the first year of QIP, given the lack of facility ability to change outcomes in the performance year, the penalty should be modulated.

To support a 1% reduction, the payment reductions using the Total Performance Score should be .25% instead of .5%.

The performance standard year should be 2009 national average instead of 2008. Given the shift in EPO utilization over the past several years as a result of the FDA black box warning and new scientific studies, it is highly desirable to use the most current data possible. Facilities received the 2009 data in July 2010 when we received our DFR reports. According to the report, in 2009 the national average for Hgb less than 10 is 3%, for Hgb greater than 12 is 16% and URR is 96%.

The facility's base utilization year should be 2009. For the same reason, the most current data should be used. As well, this change helps capture newer facilities (see below.)

Adjustments to QIP should be made for facilities not in existence in the benchmark year- national or facility specific. We have two facilities that were not in existence in 2007, the proposed facility benchmark year. We strongly believe that improvement as well as achievement should be part of the ongoing QIP structure. Thus, new facilities are penalized because they do not have a "lesser of" choice for benchmark. It may be very difficult for a new facility to meet or exceed a national benchmark. CMS should consider eliminating the QIP penalty for facilities until they have a one calendar year of data following Medicare certification and a DFR report with a facility- specific benchmark.

Adjustments to QIP should be made for facilities with small numbers of Medicare beneficiaries. We have a facility with 25 Medicare-funded patients. Over the course of the year, if even one of these patients has Hgb less than 10, we have 4% performance and would not meet the national average. Using statistical procedures, CMS should consider how to modify the benchmarks for this facility or simply eliminate the facility from a measure calculation based on small numbers.

CMS should direct the UM-KECC to publish the DFR guide to include specifics on calculations so facilities can model their QIP outcomes. On the CMS Open Door Forum CMS officials stated the URR on the DFR is a "12 month average." We contacted UM-KECC because the calculation methodology is not in the DFR Guide and were told it is the median (not mean) of 12 data points. Given the importance to facilities of modeling their QIP measures with multiple exclusions, the UM-KECC should provide full disclosure of all calculations in their online guide.

CMS should direct the UM-KECC to recalculate and restate the national and performance specific benchmarks for the selected benchmark years (hopefully 2009) to exclude all home hemodialysis patients for the URR measure. For QIP we need accurate benchmarks. The DFR is not accurate because only home hemodialysis patients with greater than 5 treatments/week on the claim are excluded. All home hemodialysis patients should be excluded per the final bundling rule.

CMS should direct UM-KECC to exclude dialysis patients who have active malignancy and anemia as demonstrated by the Hgb <10 measure. Cancer may

cause anemia through iron loss and a variety of other mechanisms that can induce significant resistance to ESA treatment, necessitating higher doses.

Recent literature [Solomon et al, N Engl J Med. 2009 Nov 19;361(21):2019-32; Pfeffer et al, N Engl J Med. 2010 Sep 16;363(12):1146-55; Szczech et al, [Kidney Int.](#) 2008 Sep;74(6):791-8] points to an important relationship between high ESA doses to raise Hgb in patients who do not respond well to it (i.e., who do not “attain target”) and the development of major cardiovascular complications, particularly strokes. UM-KECC has data on comorbidities; we suggest that in addition to other exclusions, the DFR exclude patients with a diagnosis of active cancer from this measure. Such an exclusion could, in fact, potentially improve safety by eliminating the need to attain difficult Hgb targets with high ESA doses in patients for whom such doses might actually pose risk.

To monitor patterns of care including the use of home modalities, CMS should update the revenue codes for ESRD to distinguish home hemodialysis from in center dialysis on the ESRD claims. UM-KECC and others must go to the condition code level on the claim to accurately identify the modality of hemodialysis which is being provided. Updating the revenue codes for home hemodialysis is important in the implementation of the ESRD QIP and will improve the accuracy of the data reported in the Dialysis Facility Report. New revenue codes would also facilitate CMS’s intended goal of tracking the impact of the bundle on home dialysis. Finally, this would allow the USRDS to distinguish between modalities in analyses of ESRD outcomes and practice patterns.

Future QIP measures should be selected with broad input from the renal community as well as NQF and be adapted to actual program practice. Measures such as quality of life and patient satisfaction are extremely hard to define and to set targets. A measure like “percent of home patients at the facility” would be distorted by regional home programs like ours where two facilities are recorded as following home patients and the rest have none. However we have a large home program with 16% of our patients in one county on home therapy. Facility specific instead of organization specific data could distort QIP results.

Be extremely cautious in moving from national performance rates as the performance standard and identifying absolute standards for performance goals. High goals are worth working toward i.e. eliminate hemodialysis catheters or eliminate access infections. To set a performance goal that is more achievable at the outset will take much input from ESRD clinical professionals.

Be extremely cautious in setting floors for performance that will not allow the measure to be reduced and establishing performance standards that are higher than the floor. Include ESRD clinical staff and patient community input prior to making these decisions.

CMS should adopt the public reporting proposals in the rule, allowing 15 business days for reporting. It is acceptable to post a certificate with QIP results for the facility. Ideally the graphic charts now adopted by UM-KECC called “DFR Supplement” might be incorporated into this certificate as the facility results are then compared to state, network and national averages. As well facility trends over several

years are presented which would then include both benchmarks, facility-specific and national. (The proposed rule repeatedly mentions the national performance score benchmark but recall the facility specific improvement benchmark will be used and is equally important.) The DFC website is an acceptable location to publically report QIP results.

We suggest that CMS allows 15 business days for certificate posting to allow for personnel absences and time to orient facility staff to the results so they can appropriately respond to patient inquiries. CMS could educate beneficiaries about QIP via DFC, Network newsletters, open door forums, and other CMS specific communication tools.

To support meaningful conversations with patients about quality of kidney care, the Northwest Kidney Centers posts each Dialysis Facility Report for our 14 facilities on our website (nwkidney.org) along with the DFR Supplement to allow transparency and full disclosure of quality data on all reported measures. As a non profit, accountable to the community, we believe our patients and the public should have full access to this information.

In the future QIP rule, CMS should consider reporting multiple facility performance measures to the public yet focus the financial penalty to performance on select measures. As measures are added, the financial impact of poor performance on each will be reduced. However public reporting is an incentive in itself. CMS might consider developing facility specific reports which include multiple measures but limit the financial penalty to those quality outcomes which have the greatest risk of being affected by incentives embedded in bundling.

We appreciate the opportunity to comment on the proposed QIP rule.

Sincerely,

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