KIDNEY CARE PARTNERS

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: Medicare Program; End-Stage Renal Disease Quality Incentive Program Proposed Rule

Dear Dr. Berwick:

Kidney Care Partners appreciates the opportunity to provide the Centers for Medicare and Medicaid Services (CMS) with comments about the Proposed Rule for End-Stage Renal Disease Quality Incentive Program (Proposed Rule).[1] KCP is an alliance of members of the kidney care community that includes patient advocates, dialysis care professionals, providers, and manufacturers organized to advance policies that improve the quality of care for individuals with both chronic kidney disease (CKD) and irreversible kidney failure, known as End Stage Renal Disease (ESRD).

Quality has always played a central role in the KCP agenda. In late 2005, KCP launched the Kidney Care Quality Initiative to facilitate the development of recommendations that would allow for the implementation of a pay-for-performance program within the Medicare ESRD Program. KCP worked closely with the Congress and CMS officials in that effort.

As part of this initiative, KCP was a founding member of the Kidney Care Quality Alliance (KCQA), of which CMS served as a liaison. Members of the kidney care community and health care community-at-large joined together to form the KCQA.[2] Its goal is to involve patients and their advocates, health care professionals, providers, manufacturers, and purchasers in the development of performance measures at the facility and physician levels to evaluate and improve the quality of care for individuals with chronic kidney disease. The KCQA also focuses on developing data collection and aggregation strategies and promoting transparency through the reporting of performance measures to

[1] See 75 Fed. Reg. 49215.

[2] A complete list of the Members of the Alliance is included as Attachment A.

consumers, patients, care professionals, dialysis facilities, and others in the kidney care community to inform choice and improve outcomes.

As its initial project, the KCQA oversaw the development of adult clinical and quality of life measures that could be used in a pay-for-performance program. The Alliance submitted these "starter measures" to the National Quality Forum (NQF) in 2007 and received endorsement for several of them. We also worked closely with CMS through the NQF process and the final measures related to adequacy of dialysis, among other things, reflect discussions and agreements between the two organizations.

Thus, we are pleased that CMS has published the Proposed Rule that addresses many of the proposals we have developed and discussed with the Agency during the past five years. Generally, we are pleased with many aspects of the Proposed Rule in terms of how the first year of the quality incentive program (QIP) will operate. However, we have serious concerns that we highlight in this letter. We have divided our comments into two main categories (1) the first year of the QIP and (2) future considerations.

I. First Year

Specifically, we suggest with regard to the first year of the QIP that CMS:

Consistent with Medicare Payment Advisory Commission (MedPAC) and Institute of Medicine (IOM) recommendations, not take savings from the Medicare ESRD Program through the QIP.

Modify the proposed structure of the QIP by setting the maximum penalty at one percent and reducing the payment reduction increments to 0.25 percent for the first year of the QIP.

Establish clear guidelines as to how facilities opened for less than one year and small facilities will be treated under the QIP.

Use the most recent data for establishing the facility-specific performance standard as well as the national performance standard, not 2007 and 2008 data, respectively.

Replace the URR measure with the Kt/V measure for adequacy of dialysis as soon as possible.

II. Future Considerations

Specifically, we suggest with regard to the future considerations of the QIP that CMS:

> Provide additional detail and the opportunity to work closely with the Agency on future measure development, the weighting of measures, and the establishment of performance standards and apply the Special Rule for setting performance standards for at least the first year of a new measure.
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> Describe how it will address between-laboratory variation in subsequent years.
>
> Describe how it plans to incorporate improvement into the QIP in subsequent years.
>
> Address the ongoing concerns related to CROWNWeb as quickly as possible.

II. First Year

A. Consistent with Medicare Payment Advisory Commission (MedPAC) and Institute of Medicine (IOM) recommendations, CMS should not take savings from the Medicare ESRD Program through the QIP.

The QIP should not be viewed as a cost-saving program. Rather, it is meant to incentivize dialysis facilities to perform better when compared to established performance standards. In that spirit, we urge the Agency not to construct the QIP in a manner that would result in a substantial reduction in the aggregate payments made through the Medicare ESRD program. The margins under which dialysis facilities operate are already minimal, as MedPAC recently noted:

> On the basis of 2008 payment and cost data, we project that the 2010 aggregate margin will be 2.5 percent. This estimate reflects the 1 percent composite rate update in MIPPA, effective January 1, 2009, and January 1, 2010. This projection for 2010 does not take into account the 2 percent reduction in total spending that MIPPA mandated to begin in 2011 under the new dialysis payment method. We did not include the 2 percent reduction in our projection because CMS has not yet finalized the regulatory provisions to implement the new payment method. In addition, providers' response to the new payment method is unknown. Including ESRD drugs now separately paid for under Part B in the new payment bundle may lead to better management of drug therapy, which may lead to improvements in the efficiency of care.[3]

Removing additional funding from the program will not help beneficiaries and will only create more pressures on facilities struggling to meet the performance standards.

[3]MedPAC, "Outpatient dialysis services: Assessing payment adequacy and updating payments," *Report to the Congress: Medicare Payment Policy* 133 (March 2010).

KCP acknowledges that Congress mandated that the QIP include payment reductions. However, it did not indicate that CMS would be prohibited from taking the funds that result from these reductions and putting them back into the system by giving them to high-performing facilities (those that attain the performance standards and/or demonstrate substantial improvement). Such payments would increase the incentives to attain performance standards and improve performance, while ensuring that there is adequate funding to the program as a whole.

Health care policy thought leaders support the idea that quality programs that link payment to performance should not be used to obtain program savings. MedPAC recommended that quality programs not be used as a way to create savings for Medicare. When MedPAC described how it would construct a quality program, it focused on a withhold structure that redistributed funds through a reward pool within the program. "Although savings could accrue from improved quality, the goal of our recommendations is improved quality, not saving dollars. Therefore, the Commission intends for all of the withheld dollars to be distributed."[4] The Institute of Medicine has made similar recommendations.[5] Other value-based purchasing programs that have been the subject of demonstration projects or are scheduled to be implemented by CMS in the near future also include a positive incentive structure. Our members would welcome the opportunity to work with the Agency on the details of structuring such incentives in the QIP.

B. CMS should set a maximum penalty of one and reduce the increments for the payment reductions to 0.25 percent for the first year of the QIP.

We applaud CMS for moving from nine to five tiers in terms of evaluating facilities and urge it to maintain this proposal in the final rule, although in the future we hope to work with the Agency to further refine the distribution of facilities in this grouping. However, KCP's primary concern is that CMS has proposed to apply the maximum penalty for the first year of the QIP. Because CMS has set the performance period in a manner that is not consistent with MIPPA; has not addressed other questions, such as how to deal with between-laboratory variation that results in different performance scores when none exist; and has not addressed a variety of other issues, we urge the Agency to minimize the impact of these problems by reducing the increments for the payment reductions and setting a maximum penalty at one percent.

KCP strongly objects to the proposal to implement a full two percent payment reduction at this time. The authorizing statute states that payments "shall be reduced by up to 2.0 percent, as determined appropriate by the Secretary."[6] The statute does not require that

[4]MedPAC, "Strategies to improve care: Pay for performance and information technology," *Report to the Congress: Medicare Payment Policy* 184 & 187 (March 2005).

[5]See, e.g., Institute of Medicine, "Crossing the Quality Chasm: A New Health System for the 21st Century" (March 1, 2001).

[6]42 U.S.C. § 1395rr(h)(emphasis added).

payments for any category of facility performance be reduced by a full two percent. CMS can accomplish this modification by reducing the interval in payment reductions from 0.5 to 0.25 (which CMS had outlined in the ESRD PPS). Using a 0.25 payment reduction interval will allow CMS to maintain its proposed point structure, which KCP supports for the first year, and lower the maximum penalty at the same time.

We agree that the QIP should establish meaningful incentives; however, given that 2012 will be the first year of the QIP – and it will be the first value-based purchasing program in Medicare – there are likely to be challenges that will need to be worked out. Implementing the greatest possible penalty will not provide appropriate incentives until everyone in the community, including CMS, understands how the QIP works in the everyday environment of dialysis facilities.

1. CMS should set the maximum penalty at one percent because it has not complied with MIPPA in setting the performance period.

While we appreciate that the Agency must set a performance period that allows it to apply the penalties of the QIP by January 1, 2012, we are extremely concerned that the proposed performance period does not meet the requirements of the authorizing statute. We recognize that the Agency may not be in a position to address this problem at this time. Because of that reality, we strongly urge the Agency to set the maximum penalty at one percent so that any harm created by the inappropriate performance period can be mitigated.

While CMS focuses on the language in MIPPA that requires payment reductions to begin for services furnished on or after January 1, 2012,[7] it appears to ignore subsequent language that requires the Agency to "establish the performance standards … prior to the beginning of the performance period for the year involved."[8] When interpreting a statute, the Agency must read the statute as a whole.[9] It must also look to the plain meaning of the text.[10] In setting the performance period as 2010, the Agency has not met the plain meaning requirement of the statute to establish the performance standards for the year prior to that of the performance period. The clause "for the year involved," clearly modifies "performance period" and, thus, requires the Agency to establish the performance standards the year before the year of the performance period. In other words, CMS would have to

[7] Id.

[8] Id. (emphasis added)

[9] United States v. Morton, 467 U.S. 822, 828 (1984) ("In sum, '[w]e do not . . . construe statutory phrases in isolation; we read statutes as a whole.'").

[10] Tyler v. Douglas, 280 F.3d 116, 122 (2d Cir. 2001)(describing the "plain meaning" rule that courts "look first to the plain language of a statute and interpret it by its ordinary, common meaning. If the statutory terms are unambiguous, [its] review generally ends and the statute is construe according to the plain meaning of its words." (internal quotation marks and citations omitted)).

have established (by issuing a final rule) the performance standards in 2009 if it wanted to set the performance period as 2010.

Additionally, selecting 2010 as the performance period when more than 3/4 of the year has elapsed does not give facilities sufficient notification of the standards to which they will be held to allow them to respond through appropriate changes in their operations. The purpose of any value-based purchasing or pay-for-performance program, of which the QIP is one type, is to link financial incentives to provider performance. A program accomplishes this goal by establishing specific metrics and performance benchmarks, collecting data on these metrics, and rewarding or punishing providers that do not meet the benchmarks. Providers are expected to change how they treat patients based upon these incentives. Incentives do not work if there is no opportunity to educate health care providers and encourage changes in behavior prior to the period for which improvement is being measured and penalized.

We understand that the Agency on a practical level may feel that 2010 is its only option. If that is true, it should minimize the negative impact of using 2010 as the performance period by lowering the maximum penalty to one percent.

2. CMS should set the maximum penalty at one percent because it has not addressed the problem of between-laboratory variation for performance measures that rely on laboratory values, as do those for the QIP's first year.

Additionally, the maximum penalty should be less than two percent because the bias of between-laboratory variation has not been addressed in the establishment of the measures, weights, performance standards, or structural components of the QIP. Lessening the maximum penalty will not resolve the problem long-term, but at least in the short-term it makes the bias less disruptive to the community.

While we understand the Agency's desire to implement a straightforward approach for the first year of the QIP, we are concerned that it has over-simplified the process and ignored the critical problem of between-laboratory variation. "[P]oor comparability of analytical results that originate from different laboratories using different methods" is one of the primary causes of laboratory variation.[11] This between-laboratory variation also has been observed in a series of studies undertaken by R. Neill Carey, Ph.D.; James O. Westgard, Ph.D.; and Sten A. Westgard, MS.[12] In their most recent report, the researchers concluded

[11]M. Panteghini, "Traceability, Reference Systems and Result Comparability," 28 Clin. Biochem. Rev. 97-104 (2007).

[12]James O. Westgard, et al., "Comparability of Laboratory Tests, Westgard QC, Madison, WI, prepared for Spectra Laboratories" (2008); R. Neill Carey, et al., "Study of Bias among Laboratories for Tests Used in Monitoring End Stage Renal Disease, Westgard QC, Madison, WI, prepared for Spectra Laboratories" (2009) [hereinafter "Study Bias"]; & R. Neill Carey, et al. "Impact of Laboratory Analytical Bias on Proportions of Patient Populations Meeting K/DOQI Targets for Tests Used in Monitoring End Stage Renal Disease, Westgard QC, Madison, WI, prepared for the Participating Laboratories" (2009) [hereinafter "Impact of

that the results of their analyses "demonstrate that any measures proposed for use in Pay-for-Performance incentives should be carefully evaluated to assess the effects of between-laboratory method bias."[13] For example, they observed "significant biases" among laboratory tests relied upon to monitor patients with kidney disease, including those used to measure hemoglobin levels.[14] "Biases among laboratories arise from their lack of traceability from primary reference methods and primary reference materials down to the working methods and manufacturers' calibrators used for routine patient testing."[15]

Their work demonstrates that between-laboratory bias can dramatically affect any attempt to determine whether beneficiaries are meeting a specific metric and, in turn, whether or not a facility has achieved a specific performance standard. For example, the researchers found that the average bias and average percent bias for hemoglobin tests in its sample was 0.17 g/dL or 1.5 percent.[16] This finding means that if between-laboratory variability is not addressed in the QIP, it will be impossible to compare facilities to a performance standard or to each other. The problem remains even if a facility is comparing its current performance to past performance if it has changed laboratories or its laboratory has modified its practices in the intervening period.

Unfortunately, current regulations governing laboratories do not address this problem. The CLIA regulations provide specific detail on criteria that laboratories must meet in order to receive CLIA certification. For hemoglobin tests, laboratories must be tested at least three times per year and with at least five samples per testing event. Acceptable performance is the sample's actual value plus-or-minus seven percent.[17] This deviation allows for significant differences in results among different laboratories.

Currently, the issue of between-laboratory variation does not directly affect beneficiary care because physicians and other caregivers have the ability to adjust their prescribing behavior or other activities based upon their assessment of the laboratory upon which they rely. The QIP has no such professional judgment component built into it. Thus, even though it might be tempting to ignore between-laboratory bias in year one, the work of R. Neill Carey and his colleagues suggests that to do so would result in a quality monitoring program that lacks validity and reliability.

Additionally, if between-laboratory variation is not addressed in the QIP, it could result in unintended, negative treatment outcomes for beneficiaries. With the hemoglobin

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Laboratory Analytical Bias"].

[13] "Impact of Laboratory Analytical Bias" supra note 8, at 2.

[14] Id. at 3 & 30-31.

[15] Id. at 3.

[16] Study Bias, supra note 8.

[17] 42 C.F.R. § 493.941 (emphasis added).

measures, for example, dosing amounts could be adjusted in a way that could dramatically impact beneficiaries. Dosing changes should only be made for clinical reasons and not because the QIP has skewed beneficiary treatment because it does not take such bias into account.

To minimize the impact of this bias during the first year of the QIP, we strongly urge the Agency to set the maximum penalty at one percent. Doing so would provide for a meaningful incentive. However, it would also recognize that until the concerns about between-laboratory variation, as well as the others described in this section, are addressed, the penalty is reduced.

3. CMS should set the maximum penalty at one percent because it has not addressed other issues.

KCP also believes CMS should set the maximum penalty at one percent because there are a series of other issues that have yet to be addressed, including for example how dialysis provided in nursing homes or in-center to nursing home patients should be incorporated into the QIP. Additionally, there is no evidence that the QIP as proposed will work as anticipated. For these reasons as well as those mentioned previously, CMS should minimize the maximum penalty.

The complexity of the Medicare ESRD program makes it difficult to ensure that the QIP has adequately addressed all of the issues it should to ensure that the first year of implementation does not result in unintended consequences. For example, it is unclear how the Agency will address the unique situation of dialysis facilities that provide care to nursing home patients. This includes patients who are dialyzed in nursing homes or those transported from nursing homes to in-center hemodialysis facilities. CMS has not clarified how it will adjust for these patients who will likely always fall outside of the performance standards because of the complexity of their conditions. Including these patients in the patient pool for the QIP could greatly skew the results; yet we appreciate the importance of ensuring that this patient population receives quality care like all other patients. Until CMS has sufficient data on whether to risk adjust or otherwise ensure that facilities with high numbers of nursing home patients are not the ones that disproportionately receive a payment reduction, the maximum penalty should be one percent. CMS should work with the community to make sure that the measures, weights, and performance standards account for the unique needs of these patients.

Another reason to set the maximum penalty at one percent is because there is no pilot or transition phase to test the impact of the proposed QIP and address unintended consequences (such as the one noted above) before full implementation. Traditionally, CMS has transitioned modifications to payment systems. Although the QIP has a quality focus, it is in fact a modification to the ESRD payment system. To be clear, we are not suggesting that there must either be a pilot or phase-in; however, because there is neither testing of, nor transitioning into, the QIP, we recommend that CMS set the maximum penalty lower than that permitted by the statute so as to minimize the negative impact on facilities if there are unforeseen problems with the QIP.

C. CMS should establish clear guidelines as to how facilities opened for less than one year and small facilities will be treated under the QIP.

The Proposed Rule does not address how it will treat facilities that are opened for less than one year. According to a study performed by Medical Department of Fresenius Medicare Care, North America, the standard deviation when reporting quality measures decreases with a higher number of results, thus producing less variability.[18] Facilities opened for less than a year do not have the patient volumes necessary to ensure that the results are not skewed. Similarly, there is no "base" year against which to judge them. KCP strongly recommends that all facilities be included in the QIP, but given the unique circumstances of these facilities recommends that CMS require new facilities (those open for less than one year from the date of Medicare certification) to report measures, but not be included in the penalty aspect of the program until they have a full calendar year (from the date of Medicaid certification) of data available.

Similarly, the Proposed Rule does not address how small facilities will be treated under the QIP. The variation problem noted above also applies in the case of small facilities. For example, if a facility has 50 patients and 1 patient does not meet the standard, that facility has 2 percent of patients not meeting the performance standard. If the facility had only 25 patients, it would be 4 percent. The small numbers problem clearly skews the results. Thus, we suggest that when evaluating small facilities, the Agency establish a statistically valid alternative for ensuring that small facilities are not penalized merely because of their size. KCP would welcome the opportunity to work with CMS to define "small facilities" and to develop the appropriate statistical methodology. We strongly believe such a system needs to be in place before the first year of the QIP is implemented to avoid economic instability for these facilities. We further note that Dialysis Facility Compare (DFC) and the Dialysis Facility Reports sent to institutions acknowledge this problem by not reporting on small numbers, whereas the Proposed Rule is silent in this matter.

D. CMS should use most recent data for establishing the facility-specific performance standard as well as the national performance standard, not 2007 and 2008 data, respectively.

We have noted previously our objection to the use of DFC 2007 and 2008 data in the context of the hemoglobin measures. The central purpose of value-based purchasing is to incentivize quality, while also providing patients, providers, purchasers, and the public with meaningful information. The use of 2007 and 2008 baseline information as compared to 2010 performance does not provide an accurate picture of the quality of today's care, given the changes in care related to anemia management, in particular. Thus, we recommend CMS avail itself of data from the most recent year before the performance period. If CMS uses 2010 for the performance period, it should use the 2009 data, which will be available at the time the program is implemented in 2012.

[18] Eduardo Lacson, Jr., et al., "Effect of Variability in Anemia Management on Hemoglobin Outcomes in ESRD" 41 Am. J. of Kidney Disease 111-24 (2003).

E. CMS should replace the URR measure with the Kt/V measure for adequacy of dialysis as soon as possible.

In our previous comment letter on the ESRD PPS, we encouraged CMS to adopt the Kt/V measure for evaluating adequacy of dialysis. As we noted in that letter, the Kt/V measure is more widely used within the clinical community to assess patient outcomes. Although CMS has been collecting Kt/V measure data on the claims forms since July 1, 2010, we understand that it may not have sufficient data to implement the measure for the first year. If it is truly not practical to make this change in year one, we strongly urge the Agency to adopt the Kt/V measure for the following performance period.

When it adopts this measure, we also encourage the Agency to indicate which of the existing Kt/V modeling calculators it will require facilities to use to ensure that the outcomes measured are consistent among facilities. Additionally, CMS should clarify whether patients with residual renal function are included or not, again to ensure consistency. Once these specifications are clarified, CMS should also make sure that they are taken into account when establishing the performance standard.

II. Future Considerations

KCP agrees that it is important to consider how the QIP will be structured in subsequent years and the processes that will allow for its evolution. Specific issues that need to be addressed include future measure development and adoption, the evolution of current weights and performance standards and the development of new ones, eliminating bias created by between-laboratory variation, incorporating improvement into the QIP, and addressing the incorporation of CROWNWeb as viable data collection system for all dialysis-related data. While we appreciate that there are future rulemaking opportunities, we encourage CMS to work with the community based upon the comments below to develop a plan that could be included in the final rule for the QIP and to provide an opportunity for comment on the plan at that time so that additional time is not lost waiting for a subsequent rulemaking. In addition, as long as CMS obtains data through claims and has not been able to implement a more complex measure reporting system, the issues identified in section I will continue. Thus, we encourage CMS to address these issues for any year in which claims-based measures are used.

Also, consistent with our previous comments, KCP recommends that the Agency commit to providing the community with two-year notice before making any modifications to the QIP. This timing will allow facilities to educate their workforce, as well as the independent physicians with whom they work, about the changes, to resolve questions related to the clarity of specifications and data reporting requirements, and to address any other issues that might arise regarding the modifications.

A. In the final rule, CMS should provide additional detail and the opportunity to comment on future measure development, the weighting of measures, and the establishment of performance standards.

CMS should provide more specifics about the processes it will employ to develop new measures, the weights for future years, and the establishment of modified or new performance standards. As described below, we strongly encourage the Agency to work with the kidney care community as it undertakes these and other activities related to the future implementation of the QIP.

a. CMS should establish and abide by a transparent and open process for future measure development that engages with the kidney care community.

Consistent with our ongoing dialogue with CMS, KCP remains deeply concerned about the process CMS appears to be using to develop and adopt the next generation of QIP measures. Historically, KCP has had a strong, positive working relationship with the Agency as it has developed policies that affect dialysis care. Thus, we have been surprised and troubled by the current actions related to the development of the next generation of quality measures. Our comments below are meant to highlight our concerns with the current process and to urge CMS to make sure that any process related to the evolution of the QIP be transparent and open.

Generally speaking, we believe CMS should follow the technical expert panel (TEP) process that it has historically used for developing the CPMs or, alternatively, the process recently set forth by the National Quality Forum (NQF). As the CPMs and DFC demonstrate, quality metrics have improved substantially over the years. The community consensus in the process for developing and reporting these measures is an important part of this success. Both options would provide for transparency, consensus building, community input, and the opportunity for commenting for the QIP. By adopting either option, CMS would be building on a solid tradition.

If CMS were to follow the TEP approach, it should do so in an open and transparent manner. Once a TEP reaches consensus agreement on proposing a specific measure, the measure should be evaluated by a data-focused TEP to ensure that the information facilities need to provide is obtainable and reasonable. The TEPs should develop metrics that are measurable and achievable. After this, the TEP reports with the recommendations, including specifications, should be open for comment by the community. If commenters express concerns or other difficulties arise about a measure, the measure should be returned to the TEP for further evaluation. If measures receive consensus, they should be transmitted to the NQF for endorsement. Finally, the measures, along with the weights and performance standards, should be adopted through notice and comment rulemaking. This process allows for transparency and will help to create the necessary community support to ensure that the QIP succeeds in its mission to reward high-quality clinical care.

Another alternative would be to use the approach set forth in the NQF draft paper "Establishment of a Partnership for Applying Measures (PAM) to Improve Quality." KCP supports the creation of this consultative partnership and the expansion of its roles beyond reporting hospital and physician quality data; the NQF paper envisioned such an expansion. Under this approach, NQF (presumably), as part of new duties created through the Affordable Care Act, would be required to convene multi-stakeholder groups to provide input to the Department of Health and Human Services on the selection of measures for public reporting and payment programs. In preparation, the NQF Board adopted a plan for what is now referred to as PAM and requested public input on how to best implement the Partnership.

In addition to supporting these activities, we (1) encouraged expansion of the PAM's activities specifically to encompass the ESRD QIP and (2) recommended that the final document more strongly emphasize the importance of broad participation of knowledgeable individuals with an understanding of the practical applications of measures and data elements to ensure that the selected measures are feasible. The scope of PAM's activity is entirely consistent with being able to provide input on how the QIP should evolve.

We recognize that the TEP process we propose is similar to the process CMS has outlined in its current measure development. However, we are concerned that in practice, it appears that the current process has turned into an exercise that is not a transparent, consensus building one. Specifically, our members have raised concerns that the TEP input was not taken into account when the measures were finalized to submit to the NQF. There are also concerns that there was not sufficient public input following the TEP process before the measures were submitted to NQF. Finally, it has been difficult to access the TEP reports. Although initially posted, they have been removed from the web with no explanation or timing as to when the documents will be available again. Given that this round of measure development seeks to increase substantially the number of measures that could be applied to the QIP by perhaps more than 10 fold, our members are deeply concerned about the lack of transparency and the questions raised regarding the manner in which TEP member comments and concerns were handled.

Furthermore, it troubles us that CMS plans to increase the number of measures for the second or third year of the QIP exponentially. KCP supports a robust QIP program and recognizes that the CPMs contain many reporting measures. The CPMs have been a good reporting tool, as has DFC. However, there has not been the same attention to detail with these programs that must take place in the QIP. For example, measure specifications need to be precise and clear. There must be true medical consensus as to what should in fact be measured so that beneficiary outcomes are positively impacted. The reporting requirements must also be detailed to ensure that reporting is uniform across all facilities to ensure a level playing field. These are only some of the considerations that need to be addressed when CMS considers new candidate measures for the QIP.

The Agency should also take into account the burden of reporting new measures on facilities. Unlike hospitals or other health care providers, dialysis facilities can best be

described as a "one DRG" provider. This means it is not necessarily appropriate to compare the number of ESRD measures to those of other provider types. It is also important to recognize that most of the measures adopted in other quality reporting programs are process based measures, while the dialysis community has continually supported both outcomes and process-based measures. While we appreciate that it might be tempting to increase the number of QIP measures to look more like other provider programs, CMS should proceed cautiously.

KCP has significant concerns about how CMS plans to update both the measures and specifications for the QIP. Specifically, CMS notes: "We believe we have the authority to update specifications of quality measures in appropriate cases, such as when selected specifications do not result in useful or accurate information in comparing ESRD providers/facilities."[19] As CMS is aware, measure developers, and NQF, consider a change in specifications as constituting a different measure. KCP recognizes that not all specification changes will have a material impact, but the types of changes contemplated by this statement are clearly material. We strongly caution CMS from pursuing changes to specifications without first proposing them and achieving consensus through NQF or proposing them through rulemaking.

KCP has always sought to work constructively with the Agency to implement new and innovative programs to help improve beneficiary care. We hope to continue to do so in the context of the QIP as well and we stand ready to assist in the development and adoption of new measures in the future.

b. CMS should provide for a community-based consensus process for the development of new measures; it should adopt weights for such measures through notice and comment rulemaking.

KCP urges CMS to use a community-based consensus process to develop the weights for future measures. Until we know the specific measures that will be adopted for a subsequent performance year, it is impossible to describe how they should be weighted. Generally speaking, weights should be selected so as to drive better quality and improvement. Because of the moving nature of this target, we recommend that CMS establish a technical expert panel that includes physicians, nurses, dialysis facility representatives, and patients to evaluate the set of QIP measures and to develop appropriate weights for them. This panel should meet regularly to assess the current weights and consider how to adjust weights as new measures are incorporated into the QIP. They, as well as the community at large, should have access to aggregate performance data to allow for thoughtful decision-making. Such weights should be open to public review and comment and then adopted through notice and comment rulemaking. By using such a process, CMS will ensure it has appropriate expert input and transparency.

[19] ESRD PPS Rule, 75 Fed. Reg. at 814.

c. When implementing new performance standards, CMS should develop them in consultation with the kidney care community and apply the Special Rule during at least the first year of a new measure.

CMS should also use an open and transparent process for modifying existing performance standards and adopting standards for new measures. When modifying current performance standards, we urge the Agency to do so in consultation with the kidney care community. The Agency should establish initial performance benchmarks for new measures it adopts in consultation with the community, as well.

Also, we recommend that the Agency apply the Special Rule when establishing any new performance standard. There is nothing in the authorizing statute that would prohibit the Agency from doing so. Applying the Special Rule to new measures would provide the community, as well as CMS, with the opportunity to adjust to the new measure in the least disruptive way possible and ensure stability of care.

CMS should also address the time lag problem with its data. A delay in data does not establish a good foundation for improving quality because it is too far removed from the actions that resulted in the outcomes. As close to real-time feedback is essential to effectuating real change.

Finally, we encourage the Agency to work with the community to establish a shorter penalty period. The proposed annual penalty period does not recognize that facilities may improve more quickly. For example, if a facility is penalized for not attaining the performance standard in the performance period, that penalty applies to payments for an entire year. It does not account for the fact that the facility may have improved its behavior within the first quarter of the year in which it receives the penalty. We recognize that current data systems do not allow CMS to have the ability to adjust the penalty period more frequently, but we encourage the Agency to keep this request in mind as it develops new systems.

B. CMS should describe how it will address between-laboratory variation in subsequent years.

As noted in Section II of this letter, KCP remains concerned about how documented between-laboratory variation will be addressed in the QIP. The Agency should make addressing this problem a priority. For example, measures could incorporate a standard deviation that would account for laboratory variation observed during the testing phase of such measures. They could be updated annually to adjust for observed changes in the variation. A similar approach could be taken with performance standards so that they are set using a range that would account for such variation. As the community gains more experience with the structure of the QIP, there may be structural modifications that could be made to address this bias as well. KCP stands ready to assist the Agency in developing appropriate solutions to this problem. We urge the Agency to set forth in the final rule and

to provide an opportunity to comment on how it plans to address between-laboratory variation not only in the first year, but also in the future.

C. CMS should describe how it plans to incorporate improvement into the QIP in subsequent years.

KCP remains disappointed that CMS has chosen not to address improvement in the first year of the QIP. Our initial proposal for a value-based purchasing/payment-for-performance system in the Medicare ESRD program advocated for rewarding both attainment and improvement. This approach is also consistent with recommendations MedPAC has made to Congress on the design of such program.[20] MedPAC recognizes that the best way to help improve quality for all beneficiaries is to reward both attainment and improvement.[21] It would also be consistent with the statutory mandate CMS is implementing. Rewarding both is particularly important given that the structure is penalty-centered. For example, points should be awarded to facilities that demonstrate improvement in a measure over the previous year. Because each measure is unique and has its own challenges, improvement should be defined for each measures as part of the development, weighting, and performance standard consensus process. The Agency would award points for improvement that would be incorporated into the total score. We urge the Agency to describe (and provide an opportunity to comment on) how it will incorporate improvement into the QIP in subsequent years.

D. CMS should address the ongoing concerns related to CROWNWeb as quickly as possible.

Finally, we would be remiss if we did not address the ongoing concerns with the implementation of CROWNWeb. We are pleased that CMS decided not to implement the program all at once, but instead has developed a phased-in approach. That said, our members remain troubled that the issues around batch-processing and clarification of reporting standards (including measure specifications) have yet to be resolved. The kidney care community strongly supports a single data collection system to reduce the unnecessary duplication that exists today. However, these issues must be addressed quickly if CMS plans to rely upon CROWNWeb as the primary system.

The issue of clarity with regard to the specifications and data submission requirements must also be resolved. If not, it too will lead to QIP results that are not comparable as different dialysis facilities apply different interpretations of the specifications and data submission requirements. The Proposed Rule notes the progress CMS has made with CROWNWeb during Phases I and II. While we are heartened by this progress, we are concerned that CMS has not taken into account the experience that a measured, phased-in approach is an absolute necessity for the program's integrity. Specifically, CMS indicated at its last Open Door that the national CROWNWeb roll-out would contain more new data

[20] MedPAC, supra note 5, at 184.

[21] Id. at 187.

elements that are undefined and untested at a time when issues remain to be resolved in the final, upcoming testing phase.

We also remain very concerned about the inequity of data submission methods anticipated when CROWNWeb is deployed nationally in 2011. CMS appears to be on a path that would allow only some dialysis facilities to submit data through batch-processing. This approach would result in a bifurcation of data submissions – some electronically and some manually. There is no evidence that electronic and manual submission will produce comparable results. Given the influence of human error and discretion, it would be inappropriate to conclude that they will not. If left unchanged, such discrepancies will create inappropriate bias in the QIP collection effort. To date, there are no available audit data that demonstrate that statistically reliable information (e.g., calculation of a Kappa score) for the myriad data elements required is obtained regardless of the method of transmission. Without such evidence, there is no demonstration of a level playing field between performance results for data submitted through batch submission versus those submitted through manual entry. We strongly object to any suggestion that CMS can assume they are equivalent when evidence from other fields finds that the method of data entry/transmission has significance in the calculated results. We also strongly believe that all data submissions to CROWNWeb should be in electronic format. Requiring all providers to manually enter data into CROWNWeb would be inefficient and would increase the likelihood of human error.

KCP remains committed to working with CMS to resolve these issues as quickly as possible as these problems must be addressed if the QIP is to be implemented successfully.

IV. Conclusion

We appreciate the opportunity to share our comments and recommendations with you. Please do not hesitate to contact Kathy Lester at 202-457-6562 if you would like to discuss them in detail or have any questions.

Sincerely,

Kent Thiry
Chairman
Kidney Care Partners

Abbott Laboratories
Affymax
AMAG Pharmaceuticals
American Kidney Fund
American Nephrology Nurses' Association

American Renal Associates, Inc.
American Society of Diagnostic and Interventional Nephrology
American Society of Nephrology
American Society of Pediatric Nephrology
Amgen
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
California Dialysis Council
Center for Dialysis Care
DaVita, Inc.
DCI, Inc.
Dialysis Patient Citizens
Fresenius Medical Care North America
Fresenius Medical Care Renal Therapies Group
Genzyme
Kidney Care Council
National Kidney Foundation
National Renal Administrators Association
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage
Mitsubishi Tanabe Pharma America
Renal Advantage Inc.
Renal Physicians Association
Renal Support Network
Renal Ventures Management, LLC
sanofi-aventis
Satellite Healthcare
U.S. Renal Care
Watson Pharma, Inc.

Attachment A

Kidney Care Quality Alliance Members

Abbott Laboratories
Affymax
AMAG Pharmaceuticals American Health Care Association
America's Health Insurance Plans
American Kidney Fund
American Nephrology Nurses' Association
American Regent, Inc.
American Society of Diagnostic and Interventional Nephrology
American Society of Nephrology
Amgen, Inc.
American Society of Pediatric Nephrology
Baxter Healthcare Corporation
Board of Nephrology Examiners and Technology
California Dialysis Council
Centers for Dialysis Care
Centers for Medicare and Medicaid Services
DaVita, Inc.
DCI, Inc. Dialysis Patient Citizens
Forum for ESRD Networks
The Federation of American Hospitals
Fresenius Medical Care Renal
Therapies Group Kidney Care Council
Fresenius Medical Care North America Medical Education Institute
Genzyme
National Kidney Foundation
National Medical Association
National Partnership for Women and Families
National Renal Administrators Association (NRAA)
Nephrology Nursing Certification Commission
Northwest Kidney Centers
NxStage Medical
Renal Advantage, Inc.
Renal Care Group
Renal Physicians Association
Renal Support Network
sanofi-aventis
Satellite Health Care
Society of General Internal Medicine
U.S. Renal Care
Watson Pharma, Inc