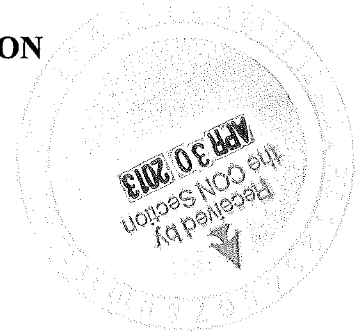
Public Written Comments

TAR RIVER DIALSYSIS FACILITY APPLICATION
Project # K-10099-13



Submitted By

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In its Tar River Application, BMA proposes to establish a new 10-station dialysis facility in Franklin County by transferring stations from two different Wake County facilities: BMA Zebulon and FMC Eastern Wake. BMA projects that a number of patients who are now receiving dialysis at these and other BMA facilities will transfer to the proposed Tar River facility.

However, the BMA Application should be denied because it fails to demonstrate conformity with Criterion 3, the Performance Standard Rule for dialysis facilities and with Criterion 5. The detailed analysis presented in these comments shows that BMA's assumptions about the projected patient transfers, as well as some fundamental assumptions about the revenues that the facility will generate, are completely unfounded and in fact are unreasonable in light of objective data that is contained right in the BMA Application, or is readily available to the CON Section. Since the BMA Application proposes an unneeded and financially infeasible facility, the development of this project also would create additional capacity that duplicates existing dialysis facilities and the application also should be deemed non-conforming with Review Criterion 6.

Finally, for all the above reasons, and also because BMA has once again chosen not to document arrangements with a developer in the application, this application should be deemed non-conforming with Review Criterion 4. BMA has not chosen the least costly or most effective alternative: It is proposing to develop and operate an unneeded, unprofitable facility and has not even made arrangements with a developer, even though it counts on the developer to acquire the site for the facility. For all these reasons, the application should be denied.

I. THE BMA APPLICATION FAILS TO DEMONSTRATE CONFORMITY WITH REVIEW CRITERION 3 AND THE PERFORMANCE STANDARD RULE.

A. Prior CON Analysis of the likelihood of Patient Transfers.

With the frequency and duration of dialysis treatments, dialysis patients often will choose to dialyze at the facility that is closest to where they live. In the Agency Findings for the prior application that proposed a Franklin County facility, reviewed as Project I.D. No. K-8798-12, and denied by the Agency in August, 2012, the analyst reviewed the residence information for the patients whom BMA had projected to transfer to the proposed facility, and compared 1) the distances from the zip code where each patient lived to the zip code of each patient's current dialysis facility with 2) the distances from the from the zip code of residence to the zip code of the proposed facility.

The analyst concluded that in many cases, the patient would be traveling farther to get to the proposed facility than they were currently traveling. In the Findings the analyst stated, "It is therefore not clear from the information presented by the applicant how it anticipates that 30 of its current patients will travel from existing BMA facilities to the proposed Louisburg location, when only 18 patients will actually see a reduction in travel." From this decision, it is clear that the Agency has determined that an analysis of distance differentials, comparing travel distance to the patient's current facility to the distance to the proposed facility, is a reasonable consideration; and clearly BMA was on notice of this consideration when it submitted the current application.

Nevertheless, this Tar River Application still suffers from the same defects with regard to travel distances. In fact, the information available makes it even more clear that once the same analytical approach that was used in the prior application is applied to the current application, many of the patients whom BMA has projected to transfer to the proposed Tar River facility would have to travel a greater distance than they are currently traveling if they transfer.

B. The Patient Letters in the Tar River Application.

In its application, BMA included 35 support letters from patients, each identical in text to all of the others. TRC recognizes that by their nature, the CON Section cannot expect a patient to make an irrevocable commitment to transfer to a proposed facility, but each applicant is under an obligation to present information to demonstrate that its assumptions are reasonable.

Each letter in the Tar River Application states, "A BMA dialysis facility in Louisburg will be much more convenient for me **and is closer to my home.**" It is important to note that each patient signed a letter under the apparent understanding that the proposed facility would be "closer to my home." As the following analysis shows, this is clearly not the case for at least eight of the patients who signed these letters.

The letters go on to say, "Dialyzing at the new FMC Tar River dialysis facility would mean **less time involved in transportation** and more time for me, and my needs." Again, the analysis below shows that for at least two of the patients who would have to take back roads to get to the proposed facility, rather than Highway 64, their transportation time is likely to increase, not decrease.

Each letter also has the patient stating an awareness of the prior BMA application that was denied, and adding the assertion that:

> The State should not decide what is best for me with regard to my transportation and choice of dialysis facilities. I am in a better position to determine if Louisburg is more convenient than my current dialysis facility.

But the fact remains that the only motivating factor offered in any of these letters to support the assumption that a patient may transfer is greater proximity to the patient's home, and a reduction in transportation time. There is no reference to any other factor such as more scheduling flexibility with different shift times, family or work ties in Franklin County, or anything else. So clearly, the only patient motivation offered in the letters as a basis for the assumed transfer is reduced travel time due to having a closer facility. This is not a subjective consideration at all. It is an objective factor that can be easily analyzed with available data, following the same line of reasoning used by the CON Section in denying the previous application.

In commenting on the Agency analysis of the prior application in this current Tar River Application, BMA has stated, "BMA disagrees with this analysis," and then goes on to discuss the difficulty of determining a specific distance from one location defined only by zip code to a second, specific location. However, there is much more precise information available.

C. ***Information in the Tar River Application Shows the projections are flawed.***

The map provided by BMA in Exhibit 27 in the Tar River Application shows the place of residence for BMA's patients. We have added to this map the approximate location of Eastern Wake Dialysis and Zebulon Kidney Center as well as the proposed Tar River facility. To determine which facility would be closest to each patient, we have added intersecting circles of the same size from each existing facility and the Tar River facility. It seems obvious that if a patient's residence falls within one of these circles, that they would reside closest to that facility. **See Exhibit 1**.

With a few exceptions that are discussed below, it seems likely that patients residing in zip codes 27549 and 27525 are fairly likely to transfer their care to the proposed Tar River facility. It also is possible that some patients in zip codes 27508 and 27544, which at least on a map appear actually to reside closer to their existing facilities, still might choose to transfer their care to the proposed Tar River facility.

With all that being said, once they would come to realize that the Tar River facility will be considerably farther from them than their current facility it seems very unlikely that the patients listed below would transfer.

Patient Name	County	Zip Code	Current Facility
Domingo _______	Wake	27587	Zebulon Kidney Center
Mar____ James	Franklin	27587	Eastern Wake
Brooke _______	Franklin	27596	Eastern Wake
Unknown	Franklin	27596	Eastern Wake
Cedric Jones	Franklin	27597	Zebulon Kidney Center
WT Wiggins	Franklin	27597	Zebulon Kidney Center
Kenneth O_______	Nash	27557	Zebulon Kidney Center
S __ Robinson / Leonard Robinson	Nash	27557	Zebulon Kidney Center

Based on the map in the BMA Application, another group of patients who are shown in the chart below, appear to reside about the same distance from the proposed facility as they do from their current facility. But an even more important consideration is that they also appear to live fairly close to Highway 64, which is a major road that goes to Zebulon. To get to the Tar River facility in Louisburg, they would have to take back roads, which would probably be less convenient and would take longer. It seems unlikely that they would choose to do this.

Patient Name	County	Zip Code	Current Facility
Virginia A. Harris	Franklin	27882	Zebulon Kidney Center
J_______	Franklin	27882	Zebulon Kidney Center

Finally, while the remaining patients, who are listed in the chart below, more than likely reside closer to the proposed site of the new facility than to the facility where they currently are dialyzing, (i.e. Wake Dialysis and Raleigh Dialysis) we also note that they more than likely already reside closer to existing facilities such as Eastern Wake and Zebulon. Each of these patients is grouped among that 25 Franklin County in-center patients, so they are receiving in-center dialysis. Rather than choosing to transfer their in-center dialysis to either the Eastern Wake or Zebulon facilities they have been choosing to drive past these facilities to receive in-center dialysis at facilities in the heart of Wake County.

BMA states on page 73 of the application, "BMA begins with the 25 Franklin County in-center dialysis patients currently served." These four patients are included in that figure of 25. Therefore, we can only assume that the four Franklin County patients listed below as dialyzing at Wake Dialysis and Raleigh Dialysis have a reason for choosing to go to drive past closer facilities to receive in-center dialysis and are more likely going to continue to do so.

Patient Name	County	Zip Code	Current Facility
Newell Pender	Franklin	27525	Wake
Deborah Smith	Franklin	27549	Wake Dialysis
Hattie Cannady	Franklin	27596	Wake
Lacy M. Ch	Franklin	27596	Raleigh Dialysis

In summary, there is nothing in any of the patient letters that explains why any of these patients would choose to travel farther or longer to get their dialysis treatments; or why some patients, who are currently traveling past several dialysis facilities to get their treatments in Raleigh would suddenly choose to go to a new facility simply because it is closer, when they haven't done this in the past.

BMA's obligation under Criterion 3 is not only to identify a patient population, but also to demonstrate the need that population has for the service proposed—in this case, the need for a new dialysis facility at the location proposed. Evidently, each of the persons who signed a letter is a patient in need of dialysis because they are receiving in-center treatments now. But whether they need dialysis at the proposed facility is a different, and more involved issue.

Each of these persons states that they are receiving treatment at a BMA facility, so BMA personnel have regular contact with them. Yet the only motivating factors that are mentioned by any of these patients in the text of 35 identical letters is distance and travel times. When this sole consideration offered to justify the assumed transfers is analyzed in light of key objective factors like geography and highway systems, it is unreasonable to assume that anyone besides the 21 patients shown in the chart below are likely to transfer to the proposed Tar River facility. This includes the four expected home dialysis patients (two from Wake and two from Nash) who are currently dialyzing at Raleigh Dialysis. So the more likely starting population for the proposed Tar River facility would be 17 in-center patients, not the 25 patients projected in the application.

	Patient Name	County	Zip Code	Current Facility
1	Lynwood Neal	Franklin	27508	Zebulon Kidney Center
2	Otha Ivey	Franklin	27508	Zebulon Kidney Center
3	Kenneth Stanton	Franklin	27508	Eastern Wake
4	Eddie James Campbell	Franklin	27525	Neuse River Dialysis
5	Dorothy Barwell	Franklin	27525	Oxford Dialysis
6	Shirley Morgan	Franklin	27525	Neuse River Dialysis
7	Harold ________	Franklin	27525	Eastern Wake
8	Kenneth Epp______	Franklin	27525	Eastern Wake
9	R_____________	Franklin	27525	Eastern Wake
10	Johnny Vale	Franklin	27549	Eastern Wake
11	Alma M. Pratt	Franklin	27549	Eastern Wake
12	A____P______	Franklin	27549	Oxford Dialysis
13	Tracy A. Crowleys	Franklin	27549	Eastern Wake
14	D.A. Jones	Franklin	27549	Eastern Wake
15	Melvin Allen	Vance	27544	Neuse River Dialysis
16	Bobby Bridgers	Vance	27544	Neuse River Dialysis
17	Audrey Lowe	Vance	27544	Oxford Dialysis
18	Darrell _______	Wake	27597	Raleigh Dialysis
19	W.C. Wilson	Wake	27597	Raleigh Dialysis
20	Drewery Lane	Nash	27882	Raleigh Dialysis
21	Alana B__________	Nash	27882	Raleigh Dialysis

* Patient numbers 18-21 are projected to begin as home dialysis patients based on information in the FMC Tar River application.

D. The Tar River Facility will be underutilized.

Applying this data to the methodology used by BMA in its application, leads to the following conclusion with regard to BMA's utilization projections, beginning with the 14 Franklin County patients listed in the chart above, and applying BMA's methodology from the application:

Begin with 14 Franklin County in-center dialysis patients currently served, as of March 15, 2013 – the application filing date.	14 in-center patients
Project this patient population forward for 9 months to December 31, 2013 using a growth rate of 7.7%.	[14 X (0.77 / 12 X 9)] + 14 = 14.8
Project this patient population forward for 12 months to December 31, 2014 using the growth rate of 7.7%	(14.8 X .077) + 14.8 = 15.9
Add the three patients from Vance County who can reasonably be expected to transfer to FMC Tar River in Louisburg. This should be the projected beginning census for this project.	15.9 + 3 = 18.9
Project the Franklin County patient population forward for 12 months to December 31, 2015. This is the end of Operating Year 1.	(15.9 X .077) + 15.9 = 17.1
Add the three patients from Vance County who can reasonably be expected to transfer to FMC Tar River in Louisburg.	17.1 + 3 = 20.1

Subtract two Franklin County patients who are projected to change modality to home dialysis during Operating Year 1. This is the projected Operating Year 1 ending census for the in-center program.	20.1 – 2 = 18.1
Project the Franklin County patient population forward for 12 months to December 31, 2016. This is the end of Operating Year 2.	(15.1 X .077) + 15.1 = 16.3
Add the three patients from Vance County who can reasonably be expected to transfer to FMC Tar River in Louisburg.	16.3 + 3 = 19.3
Subtract two Franklin County patients who are expected to change modality to home dialysis during Operating Year 2. This is the projected Operating Year 2 ending census for the in-center program.	19.3 – 2 = 17.3

Based on this methodology BMA's Tar River facility would begin operations with 17 in-center patients and 4 home dialysis patients (21 total patients). At the end of the first operating year it would have a total of 24.1 patients (18.1 in-center patients and 6 home dialysis patients). Due to the projected change of patients to a home modality during the second operating year, at the end of the second operating year it would have only 17 in-center patients, and 8 home dialysis patients for a total of 25 patients. To conform with 10A NCAC 14C .2203(a) BMA must have at least 32 in-center dialysis patients at the end of Operating Year 1. Since it can reasonably project to have only 24 patients, BMA must be found non-conforming with 10A NCAC 14C .2203(a) in addition to Criterion 3 because it failed to demonstrate the need to establish a 10-station facility; and for the same reasons, the application should be deemed non-conforming with Review Criteria 4 and 6.

II. THE BMA APPLICATION ALSO FAILS TO CONFORM WITH CRITERION 5.

Among other things, Criterion 5 requires an applicant to, demonstrate the immediate and long-term financial feasibility of a proposal, "based upon reasonable projections of the costs of and charges for providing health services . . . ." Even if one ignores some of the glaring inconsistencies in BMA's patient projections, and assumes that the proposed facility in fact will provide the numbers of in-center and home modality treatments that are forecast, the BMA Application still fails to conform with this critical aspect of Criterion 5 because the net positive margins in its financial projections hinge on unreasonable, and unsupported assumptions about commercial insurance revenues for home treatments, and also depend on unsupported assumptions about Medicare revenues.

A. BMA Projects an Unreasonable Proportion of Commercial Insurance Revenues for Home Dialysis Treatments.

BMA states that its payor source projections for in-center treatments are based on a composite of the payor sources for the BMA Zebulon and FMC Eastern Wake dialysis facilities. Using composite payor source data from those facilities as a basis, BMA presents this payor source data in its Tar River Application for in-center patients:

IC Payor Source	%
Private Pay	0.0%
Commercial Insurance	5.2%
Medicare	85.0%
Medicaid	6.1%
Medicare/Medicaid	0.0%
Medicare/Commercial	0.0%
State Kidney Program	0.0%
VA	3.1%
Other: Self/Indigent	0.6%
Total	100.00%

This proportion of commercial insurance revenues for in-center payments is very close to the actual experience of TRC in Franklin County, as seen in TRC's recent Franklin County Application on page 38, projecting commercial insurance revenues at 6.2 % of total revenues.

BMA states that neither BMA Zebulon nor FMC Eastern Wake dialysis facility offers any form of home dialysis. Since those are the facilities identified as the source of the composite revenue projections in the application, BMA is tacitly admitting that it has provided no basis for its payor source projections for home hemodialysis or home peritoneal dialysis. Yet it projects a far greater percentage of commercial insurance revenues for both of the home dialysis modalities:

Payor Source	In-Center	HH	PD
Private Pay	0.0%	0.0%	0.0%
Commercial Insurance	5.2%	87.0%	24.9%
Medicare	85.0%	10.0%	70.7%
Medicaid	6.1%	0.7%	1.1%
Medicare/Medicaid	0.0%	0.0%	0.0%
Medicare/Commercial	0.0%	0.0%	0.0%
State Kidney Program	0.0%	0.0%	0.0%
VA	3.1%	2.3%	2.2%
Other[Specify] Self/Indigent	0.6%	0.0%	1.1%
Total	100%	100%	100%

BMA acknowledges that a commercial insurance proportion of 5.2% is reasonable to project payor sources for the in-center patient population, and after explaining that the projection of 5.2% commercial insurance is based on patient demographic data from the facilities from which the stations should be transferred, BMA uses a proportion of commercial insurance for PD that is almost five times higher; and for home hemodialysis, it forecasts that commercial insurance will be the overwhelmingly dominant source of payments. It makes these assumptions without offering any basis to support them. The only comment that BMA offers to support these dramatic differences in the proportion of commercial insurance payments for home dialysis modalities is this:

> Projections of future home dialysis reimbursement is a function of BMA historical performance across North Carolina. This is an appropriate representation for new home programs.

There is no statement or data to support the claim that this is "an appropriate representation for new home programs." At most, BMA is asserting that some unidentified aspect of its experience across all of the counties in North Carolina where it provides service should justify using dramatically different payor source projections for home dialysis patients. However, BMA gave no explanation as to why this assertion was reasonable, nor did BMA provide any data to back it up. BMA never identifies which new facilities, in which counties, are the source of this representation; and BMA certainly never tries to relate this commercial insurance projection to the actual demographics of Franklin County in any way whatsoever. In fact, a several recent BMA applications show that these commercial insurance projections are not an "appropriate representation" at all.

In the last few years, BMA has filed CON applications in several counties across the state for new dialysis facilities in which it proposed some home dialysis service. In Section VI of each application, BMA provided their projected payor mix for home services. Attached as **Exhibit 2** is a summary of three of them. In these instances, the Commercial Insurance payors are expected to range from 0.00% to 8.24 %. In no instance are the commercial insurance revenues for home dialysis projected to be anywhere close to the 87% that BMA is projecting for Home Hemo patients in Franklin County, or to the 24.9 % that it is projecting for home PD.

In fact, if you average together just the projections for the three facilities that proposed to provide Home Dialysis, you get an average of 4.12% of home hemodialysis patients and 2.75% of home PD patients who would be Commercial Insurance payors. This certainly makes BMA's 87% home hemodialysis and 24.9 % home peritoneal dialysis projections unreasonable, and completely unsupported.

This has significant implications for the proposed facility's revenues because of the much higher per treatment charges that are projected in Section X on page 105 for the treatments reimbursed by commercial insurance:

	In-Center	Home PD	Home Hemo
Commercial Insurance	$ 1,375.00	$ 550.20	$ 1,375.00
Medicare	$ 234.00	$ 234.00	$ 234.00
Medicaid	$ 137.29	$ 137.29	$ 137.29
VA	$ 146.79	$ 147.85	$ 147.85
Private Pay	$ 1,375.00	$ 550.20	$ 1,375.00

The projected commercial insurance revenues are more than half of net revenues in the second operating year, according to the chart on page 106 of the BMA Application, and so they are critical to the facility's financial feasibility.

Projected Revenue	**Year 1**	**Year 2**
Private Pay	$ -	$ -
Commercial Insurance	$ 832,554	$ 1,024,535
Medicare	$ 1,054,887	$ 1,082,080
Medicaid	$ 42,393	$ 42,749
Medicare/Medicaid	$ -	$ -
Medicare/Commercial	$ -	$ -
State Kidney Program	$ -	$ -
VA	$ 25,188	$ 26,142

Other: Self/Indigent	$ 40,156	$ 41,027
Diagnostic Testing		
Drug Administration	$ 192,155	$ 219,234
Gross Patient Service Revenue	**$ 2,187,333**	**$ 2,435,768**
Deductions From Revenue:		
Bad Debt	Line 34 Table X 5	
Other Deductions from Revenue (Total Contractual Allowances)	$ 349,084	$ 426,225
Total Net Revenue	**$ 1,838,249**	**$ 2,009,543**

The BMA Application projects receipt of $352,602 of commercial insurance revenue in the second operating year from the 5.2% of in-center treatments to be reimbursed by commercial insurance, based on the data on page 107 and TRC does not challenge this commercial insurance payor percentage for in-center treatments. However, according to the chart on page 109 of the BMA Application, $602,910 of the commercial insurance revenue in Operating Year Two is projected to be received on account of home hemodialysis treatments:

HOME HEMODIALYSIS	Treatments	Patient Payment % by source of Revenue	Number of treatments by source	$ Reimbursement per treatment by source	Extended Revenue by Source
Revenue Type					
Year 1					
Private Pay	360	0.00%	0		
Commercial Insurance	360	87.00%	313	$ 1,375.00	$ 430,650
Medicare	360	10.00%	36	$ 234.00	$ 8,424
Medicaid	360	0.70%	3	$ 137.29	$ 346
Medicare/Medicaid	360	0.00%	0		
Medicare/Commercial	360	0.00%	0		
State Kidney Program	360	0.00%	0		
VA	360	2.30%	8	$ 146.79	$ 1,215
Other: Self/Indigent	360	0.00%	0		
			Total Year 1 Projected Revenue		$ 440,635
Year 2					
Private Pay	504	0.00%	0		$ -
Commercial Insurance	504	87.00%	438	$ 1,375.00	$ 602,910
Medicare	504	10.00%	50	$ 234.00	$ 11,794
Medicaid	504	0.70%	4	$ 137.29	$ 484
Medicare/Medicaid	504	0.00%	0		$ -
Medicare/Commercial	504	0.00%	0		$ -
State Kidney Program	504	0.00%	0		$ -
VA	504	2.30%	12	$ 146.79	$ 1,702
Other: Self/Indigent	504	0.00%	0		$ -
			Total Year 2 Projected Revenue		$ 616,890

As noted, BMA's Home Hemodialysis assumptions on page 108 provide no explanation for a proportion of commercial insurance revenue that is much higher than for in-center treatments. This is all that BMA offers to explain its Home Hemodialysis revenue projections:

Operating Year 1: The beginning of Operating Year 1 is January 1, 2015. BMA has projected to begin the first year of operations with two transferring HH patients, ending the year with 3 HH patients. BMA projects the average to be 2.5 patients. BMA multiplied 2.5 patients X 144 annual treatments.

Operating Year 2: BMA has projected to begin the second year of operations with 3 HH patients, ending the year with 4 HH patients. BMA calculates the average number of HH patients for the second year of operations to be 3.5 patients. BMA multiplied 3.5 by 144 annual treatments to produce the projected number of treatments for Operating Year 2.

In addition, according to the chart on page 108, $69,023 of the commercial insurance revenue in year two comes from peritoneal home dialysis treatments:

HOME PERITONEAL DIALYSIS	Treatments	Patient Payment % by source of Revenue	Number of treatments by source	$ Reimbursement per treatment by source	Extended Revenue by Source
Revenue Type					
Year 1					
Private Pay	360	0.00%	0		
Commercial Insurance	360	24.90%	90	$ 550.00	$ 49,302
Medicare	360	70.70%	255	$ 234.00	$ 59,558
Medicaid	360	1.10%	4	$ 137.29	$ 544
Medicare/Medicaid	360	0.00%	0		
Medicare/Commercial	360	0.00%	0		
State Kidney Program	360	0.00%	0		
VA	360	2.20%	8	$ 147.85	$ 1,171
Other: Self/Indigent	360	1.10%	4	$ 550.00	$ 2,178
				Total Year 1 Projected Revenue	$ 112,752
Year 2					
Private Pay	504	0.00%	0		
Commercial Insurance	504	24.90%	125	$ 550.00	$ 69,023
Medicare	504	70.70%	356	$ 234.00	$ 83,381
Medicaid	504	1.10%	6	$ 137.29	$ 761
Medicare/Medicaid	504	0.00%	0		
Medicare/Commercial	504	0.00%	0		
State Kidney Program	504	0.00%	0		
VA	504	2.20%	11	$ 147.85	$ 1,639
Other: Self/Indigent	504	1.10%	6	$ 550.00	$ 3,049
				Total Year 2 Projected Revenue	$ 157,853

BMA's Home PD assumptions on pages 107-108 provide no explanation for a proportion of commercial insurance payments that is almost five times as high as the in-center proportion. This is all that BMA offers with the chart to explain its PD revenue projections:

Operating Year 1: The beginning of Operating Year 1 is January 1, 2015. BMA has projected to begin the first year of operations with two transferring PD patients, ending the year with 3 PD patients. BMA projects the average to be 2.5 patients. BMA multiplied 2.5 patients X 144 annual treatments.

Operating Year 2: BMA projects beginning the second year of operations with 3 PD patients, ending the year with 4 PD patients. BMA calculates the average number of PD patients for the second year of operations to be 3.5 patients. BMA multiplied 3.5 by 144 annual treatments to produce the projected number of treatments for Operating Year 2.

B. Adjusting BMA Projection to Adopt a Reasonable Proportion of Commercial Insurance Revenues for Home Dialysis Treatments.

When BMA's projected revenues are adjusted to reflect the only data presented in the application about payor mix, the results for home hemo dialysis are dramatically different:

ADJUSTED HOME HEMODIALYSIS	Treatments	Patient Payment % by source of Revenue	Number of treatments by source	$ Reimbursement per treatment by source	Extended Revenue by Source
Revenue Type					
Year 1					
Private Pay	360	0.00%	0		
Commercial Insurance	360	5.20%	19	$ 1,375.00	$ 26,125
Medicare	360	85.00%	306	$ 234.00	$ 71,604
Medicaid	360	6.10%	22	$ 137.29	$ 3,020
Medicare/Medicaid	360	0.00%	0		
Medicare/Commercial	360	0.00%	0		
State Kidney Program	360	0.00%	0		
VA	360	3.10%	11	$ 146.79	$ 1,615
Other: Self/Indigent	360	0.60%	2	$ 1,375.00	$ 2,750
			Total Year 1 Projected Revenue		$ 131,239
Year 2					
Private Pay	504	0.00%	0		$ -
Commercial Insurance	504	5.20%	26	$ 1,375.00	$ 35,750
Medicare	504	85.00%	428	$ 234.00	$ 100,152
Medicaid	504	6.10%	31	$ 137.29	$ 4,256
Medicare/Medicaid	504	0.00%	0		$ -
Medicare/Commercial	504	0.00%	0		$ -
State Kidney Program	504	0.00%	0		$ -
VA	504	3.10%	16	$ 146.79	$ 2,349
Other: Self/Indigent	504	0.60%	3	$ 1,375.00	$ 4,125
			Total Year 2 Projected Revenue		$ 146,632

The result is a net reduction of home hemodialysis revenues in Year Two of $470,258, about 23 per cent of the total revenues for the entire facility from all treatment modalities. When this large chunk of revenue disappears, the facility is financially infeasible; but there also is an additional, smaller effect on the Home PD revenues from applying the 5.2 % assumption.

ADJUSTED HOME PERITONEAL DIALYSIS	Treatments	Patient Payment % by source of Revenue	Number of treatments by source	$ Reimbursement per treatment by source	Extended Revenue by Source
Revenue Type					
Year 1					
Private Pay	360	0.00%	0		
Commercial Insurance	360	5.20%	19	$ 550.00	$ 10,450
Medicare	360	85.00%	306	$ 234.00	$ 71,604
Medicaid	360	6.10%	22	$ 137.29	$ 3,020
Medicare/Medicaid	360	0.00%	0		
Medicare/Commercial	360	0.00%	0		
State Kidney Program	360	0.00%	0		
VA	360	3.10%	11	$ 147.85	$ 1,626
Other: Self/Indigent	360	0.60%	2	$ 550.00	$ 1,100
	Total Year 1 Projected Revenue				$ 87,800
Year 2					
Private Pay	504	0.00%	0		
Commercial Insurance	504	5.20%	26	$ 550.00	$ 14,300
Medicare	504	85.00%	428	$ 234.00	$ 100,152
Medicaid	504	6.10%	31	$ 137.29	$ 4,256
Medicare/Medicaid	504	0.00%	0		
Medicare/Commercial	504	0.00%	0		
State Kidney Program	504	0.00%	0		
VA	504	3.10%	16	$ 147.85	$ 2,366
Other: Self/Indigent	504	0.60%	3	$ 550.00	$ 1,650
	Total Year 2 Projected Revenue				$ 122,724

The resulting Home PD revenue figure for Year Two is $35,129 less in home PD revenues. When combined with the reduction in Home Hemodialysis revenues the net effect is a reduction of $505,387 in Operating Year Two, more than a quarter of all the revenue projected.

The chart below reflects what BMA's Year 2 revenues might look like if the percentage of home dialysis patients who have Commercial Insurance was adjusted to the same percentage (5.2%) as the in-center population. For purposes of argument, we have used the Drug Administration Revenues and Other Deductions from Revenue that BMA used in the chart on page 106 of the BMA application, but realize that the Drug Administration Revenues would decrease in proportion to the decrease in the number of Commercial Insurance Treatments.

Projected Year 2 Revenue Adjusted for Payor Mix	Year 2 In-Center Revenues	Year 2 Home PD Revenues	Year 2 Home Hemo Revenues	Total All Modalities
Private Pay	$ -	$ -	$ -	$ -
Commercial Insurance	$ 352,602	$ 14,300	$ 35,750	$ 402,652
Medicare	$ 986,906	$ 100,152	$ 100,152	$1,187,210
Medicaid	$ 41,503	$ 4,256	$ 4,256	$ 50,015
Medicare/Medicaid	$ -	$ -	$ -	$ -
Medicare/Commercial	$ -	$ -	$ -	$ -
State Kidney Program	$ -	$ -	$ -	$ -
VA	$ 22,801	$ 2,366	$ 2,349	$ 27,516
Other: Self/Indigent	$ 37,978	$ 1,650	$ 4,125	$ 43,753
Diagnostic Testing				
Drug Administration	$	$ -	$ -	$ 219,234
Gross Patient Service Revenue	**$ 1,441,790**	**$ 122,724**	**$ 146,632**	**$ 1,930,380**
Deductions From Revenue:				
Bad Debt	Line 34 Table X 5			
Other Deductions from Revenue (Total Contractual Allowances)	$	$	$	$ 426,225
Total Net Revenue	**$**	**$**	**$**	**$ 1,504,155**

In order to provide the number of in-center and home treatments that are projected, BMA projects it will incur expenses totaling $1,746,081 in its first operating year and $1,862,150 in its second operating year. If you disregard the income taxes projected on Line 33, the result is a total pre-tax expense of $1,684,635 in its first operating year and $1,763,889 in its second operating year. (See Total Pre-Tax Expense Line in Chart Below). Focusing on the second year, which has been used in the past as the key period for analysis of financial feasibility, to demonstrate conformity with Criterion 5, BMA must show that it can reasonably project that its pre-tax revenues exceed its expenses of $1,763,889 in that critical second operating year, which based on the chart above, they clearly do not.

These are the operating costs projected by BMA on page 110 of its application:

ESTIMATED ANNUAL OPERATING COSTS	**Year 1**	**Year 2**
Routine Services	Annual	Annual
1. Salary - RN	$ 145,600	$ 149,968
2. Salary - LPN	$ -	$ -
3. Salary - Patient Care Techs.	$ 119,340	$ 122,920
4. Medical Records	$ 13,520	$ 13,926
5. Payroll Taxes & Benefits	$ 98,728	$ 101,690
6. Medical Director	$ 50,000	$ 51,500
7. Training/Travel/Tuition		
8. Medical Supplies	$ 110,404	$ 121,254
9. Non-Legend Drugs	$ 136,529	$ 147,749
10. Quality Assurance	$ -	$ -
11. Other: Ancillaries & Labs	$ 101,090	$ 109,439
12. Subtotal Routine	**$ 775,212**	**$ 818,446**
13. Dietary Consultant	$ 13,000	$ 13,390
14. Social Services	$ 11,960	$ 12,319
15. Housekeeping Service	$ 55,884	$ 59,255
16. Plant Operation & Maintenance	$ 148,626	$ 157,416
17. Salary - Admin.	$ 106,912	$ 110,119
18. Salary -- Other	$ 59,800	$ 61,594
19. Transportation		
20. Interest - operations		
21. Amortization of Start-Up		
22. Subtotal Gen./Administrative	**$ 396,181**	**$ 414,093**
23. Depreciation Land improvements		
24. Depreciation Bldg/Bldg Improvements		
25. Depreciation Equip & Cars		
26. Depreciation Leasehold Improvements	$ 142,382	$ 142,382
27. Rent or Lease	$ 172,032	$ 177,193
28. Equipment Rental	$ 57,642	$ 57,642
29. Mortgage Interest		
30. Real Estate Taxes		
31. Other (Specify)		
32. Subtotal Property, Ownership & Use	**$ 372,056**	**$ 377,217**
33. Income Taxes	$ 61,446	$ 98,261
34. Bad Debts/Charity	$ 141,186	$ 154,134
35. Depreciation Direct Cap. Exp		
36. Contributions Made		
37. Other		
Total Pre-Tax Expenses	1,684,635	1,763,889
38. Total Operating Costs	**$ 1,746,081**	**$ 1,862,150**

Thus, once more reasonable payor projections are applied, and Operating Year Two Revenues are adjusted to disregard the projected income taxes, it is clear that projected Pre-Tax Expenses of $1,763,889 in Year Two will exceed the adjusted revenues of $ 1,504,155.

C. Adjusting BMA Projections to Reflect a Reasonable Medicare Reimbursement Level.

Finally, as TRC pointed out in the Harnett County appeal last year, Medicare only reimburses 80% of the total reimbursement rate. The remaining 20% is either paid by a secondary payor, such as Medicaid or Commercial Insurance, or it is not paid. (See **Exhibit 3**, page 50005 from the September 29, 2009 Federal Register.) This is true regardless of the modality of the dialysis treatment. However, BMA has not identified any secondary payor sources for the treatments reimbursed by Medicare, so it has no basis to assume that it will receive more than 80 percent of the Medicare charge on account of those treatments. In the statement on page 105 of the application, under the chart showing the charges by payment source, BMA does acknowledge that there will be contractual adjustment for commercial insurance, but BMA has failed to document or explain how it has accounted for this 20 % reduction in Medicare payments anywhere in Section X of its application. Therefore, BMA's Medicare revenues should be adjusted downward by 20% to reflect this as shown in the chart below:

Projected Year 2 Revenue Adjusted for Payor Mix and 80% Medicare Reimbursement	**Year 2 In-Center Revenues**	**Year 2 Home PD Revenues**	**Year 2 Home Hemo Revenues**	**Total All Modalities**	**Total All Modalities Medicare at 80%**
Private Pay	$ -	$ -	$ -	$ -	$
Commercial Insurance	$ 352,602	$ 14,300	$ 35,750	$ 402,652	$ 402,652
Medicare	$ 986,906	$ 100,152	$ 100,152	$1,187,210	$ 949,768
Medicaid	$ 41,503	$ 4,256	$ 4,256	$ 50,015	$ 50,015
Medicare/Medicaid	$ -	$ -	$ -	$ -	$ -
Medicare/Commercial	$ -	$ -	$ -	$ -	$ -
State Kidney Program	$ -	$ -	$ -	$ -	$ -
VA	$ 22,801	$ 2,366	$ 2,349	$ 27,516	$ 27,516
Other: Self/Indigent	$ 37,978	$ 1,650	$ 4,125	$ 43,753	$ 43,753
Diagnostic Testing					
Drug Administration	$	$ -	$ -	$ -	$ 219,234
Gross Patient Service Revenue	**$ 1,441,790**	**$ 122,724**	**$ 146,632**	**$1,711,146**	**$ 1,692,938**
Deductions From Revenue:					
Bad Debt	Line 34 Table X 5				
Other Deductions from Revenue (Total Contractual Allowances)	$	$	$	$	$ 426,225
Total Net Revenue	**$**	**$**	**$**	**$**	**$ 1,266,713**

Based on this discussion of factors relating to Criterion 5, and even if you ignore the problems with its patient projections and assume that BMA can somehow manage to attract the numbers of patients it has projected, the Tar River facility would still suffer a loss in Year Two of over $250,000 if its percentage of home dialysis patients was adjusted to more reasonable levels, and would experience a loss of almost $500,000 if its Medicare revenues were adjusted to 80%. Therefore, the application fails to demonstrate conformity with Criterion 5.

III. CONCLUSION

Based on all of the information in these comments, it is clear that the BMA Application fails to demonstrate conformity with Review Criteria 3, 4, 5, 6, and the Performance Standard Rule. Its nonconformity on each of these grounds is a sufficient basis to deny the application.

FMC Franklin County
Exhibit 27, Map 1

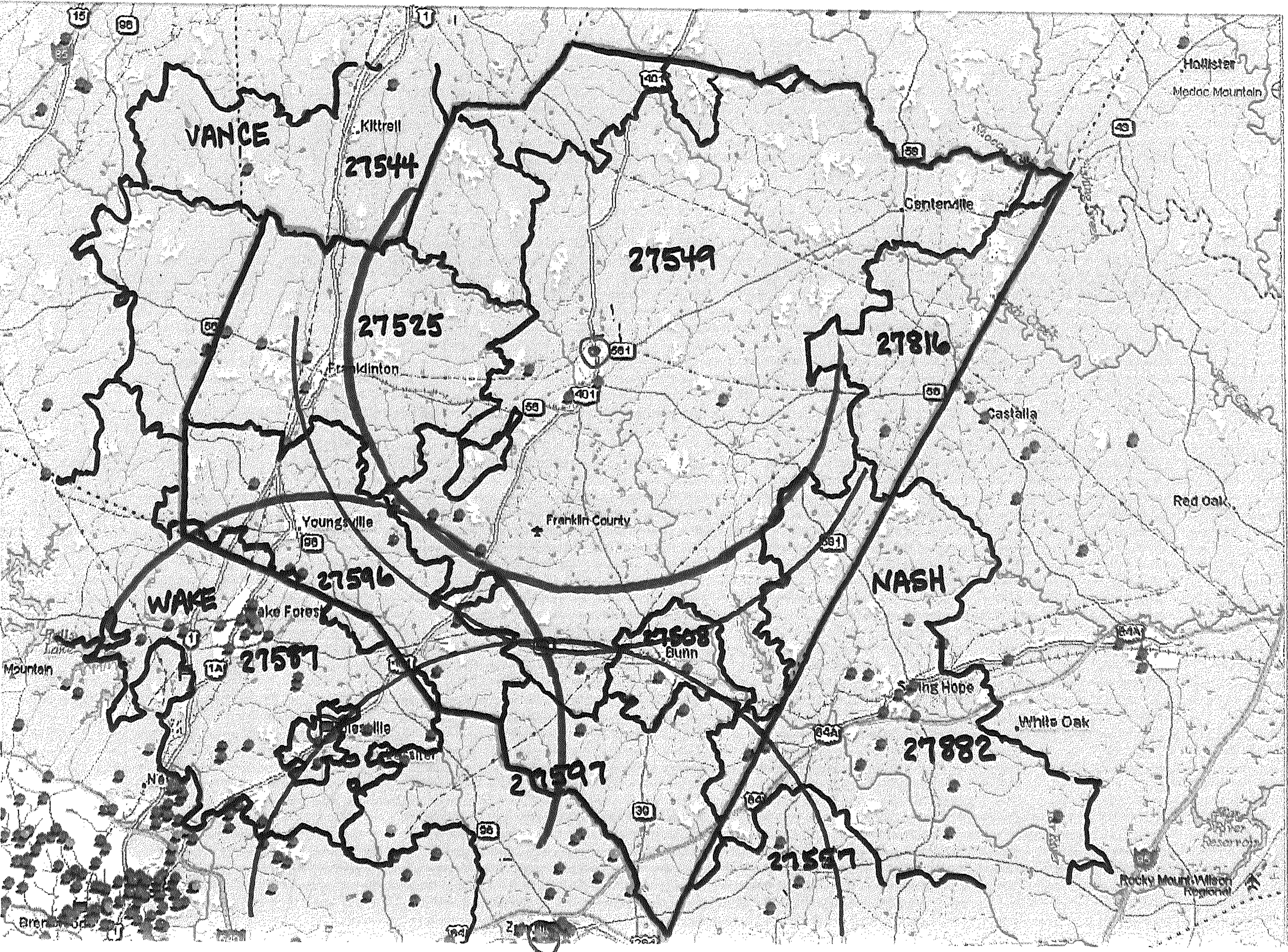

EXHIBIT 1

EXHIBIT 2

SUMMARY OF PAYOR MIX FROM SEVERAL RECENT BMA APPLICATIONS THAT INCLUDED HOME DIALYSIS SERVICES

Revenue Type	FMC Anderson Creek M-8752-11		FMC of Roseboro M-8258-08		FMC Cleveland County C-8756-11	
	Home Hemo	Home PD	Home Hemo	Home PD	Home Hemo	Home PD
Private Pay	0.00%	0.00%		0.00%	0.00%	0.00%
Commercial Insurance	8.24%	8.24%		0.00%	0.00%	0.00%
Medicare	74.50%	74.50%		50.00%	33.00%	33.00%
Medicaid	8.83%	8.83%		50.00%	64.00%	64.00%
Medicare/Medicaid	0.00%	0.00%		0.00%	0.00%	0.00%
Medicare/Commercial	0.00%	0.00%		0.00%	0.00%	0.00%
State Kidney Program	0.00%	0.00%		0.00%	0.00%	0.00%
VA	8.43%	8.43%		0.00%	0.00%	0.00%
Other / Self/Indigent	0.00%	0.00%		0.00%	3.00%	3.00%

EXHIBIT 3

transition or under the ESRD PPS. We further note that the transition period provided for under section 1881(b)(14)(E)(i) of the Act is intended to provide existing ESRD facilities time to adjust from payments based on the current basic case-mix adjusted composite payment methodology to bundled payments under the ESRD PPS. New ESRD facilities that begin providing renal dialysis services and home dialysis to Medicare beneficiaries on or after January 1, 2011, would not have received payment under the current basic case-mix adjusted composite payment system; therefore, we do not believe new ESRD facilities require a transition period in order to make adjustments to their operating procedures. Accordingly, we propose that ESRD facilities that are certified for Medicare participation and begin providing renal dialysis services and home dialysis on or after January 1, 2011, not have the option to choose whether to be paid a blended rate under the transition or the payment amount under the ESRD PPS. Rather, we propose that new ESRD facilities be paid based on 100 percent of the payment amount under the ESRD PPS.

As set forth in § 413.171 of this proposed rule, we are proposing to define a new ESRD facility as an ESRD facility that is certified for Medicare participation on or after January 1, 2011.

2. Limitation on Beneficiary Charges Under the Proposed ESRD PPS and Beneficiary Deductible and Coinsurance Obligations

Section 1833 of the Act governs payments of benefits for Part B services and the cost sharing amounts for services that are considered medical and other health services. In general, many Part B services are subject to a payment structure that requires beneficiaries to be responsible for a 20 percent coinsurance after the deductible (and Medicare pays 80 percent). With respect to dialysis services furnished by ESRD facilities to individuals with ESRD, under section 1881(b)(2)(a) of the Act, payment amounts are 80 percent (and 20 percent by the individual).

In this rule, we have proposed the items and services that would be considered renal dialysis services included in the ESRD PPS payment such as the composite rate related services, certain separately billable drugs, former Part D drugs used in the treatment of ESRD, laboratory testing, etc. We understand that certain items and services such as laboratory tests and Part D drugs have different beneficiary coinsurance structures. However, these items and services would be considered renal dialysis services after the ESRD PPS is implemented when furnished by an ESRD dialysis facility to an ESRD beneficiary. Therefore, a 20 percent beneficiary coinsurance would be applicable to the ESRD PPS payment for these services including any adjustments to the ESRD PPS payment such as adjustments for case-mix, geographic wage index, outlier, etc.

Thus, we are proposing that an ESRD facility receiving an ESRD PPS payment may charge the Medicare beneficiary or other person only for the applicable deductible and coinsurance amounts as specified in § 413.176. The beneficiary coinsurance amount for the ESRD PPS base rate is 20 percent of the total ESRD PPS payment (including payments made under the transition). We note that the amount of coinsurance is based on the proposed ESRD PPS payment for renal dialysis services and home dialysis in 42 CFR part 413. In general, facilities are paid monthly by Medicare for the ESRD services they furnished to a beneficiary even though payment is on a per treatment basis. We are proposing to continue this practice to pay ESRD facilities monthly for services furnished to a beneficiary beginning January 1, 2011. During the transition period before January 1, 2014, ESRD facilities that do not elect to go 100 percent into the ESRD PPS in 2011 would receive a blended payment amount of the prospective payment system in effect prior to January 1, 2011, and the ESRD PPS payment amount for services furnished to a beneficiary. ESRD Facilities would receive a monthly payment that is a blended payment amount for services furnished to a beneficiary. The services included in this blended monthly payment amount would be subject to a 20 percent beneficiary coinsurance.

Additionally, in accordance with section 1881(b)(1) of the Act and consistent with other established prospective payment systems policies, we are proposing in § 413.172(b) that an ESRD facility may not charge a beneficiary for any service for which payment is made by Medicare. This policy would apply, even if the ESRD facility's costs of furnishing services to that beneficiary are greater than the amount the ESRD facility would be paid under the proposed ESRD PPS.

B. Claims Processing

As indicated above, section 1881(b)(14)(A)(i) of the Act requires the Secretary to implement a payment system under which a single payment is made for renal dialysis services and other items and services related to home dialysis. For example, those services would include supplies and equipment used to administer dialysis in the ESRD facility or at a patient's home, drugs, biologicals, laboratory tests, and support services.

Implementation of the proposed ESRD PPS will require a significant amount of changes to the way we process claims. Some of the changes could entail consolidated billing rules and edits and the data elements reported on claims, as discussed below.

1. Consolidated Billing

Since the ESRD PPS payment model represents an all-inclusive payment for renal dialysis services and home dialysis items and services, the ESRD facility itself is responsible for virtually all of the services mentioned above that its patients receive. It is important that billing and payment for these services, which could be provided by other entities, such as laboratories, is made only to the ESRD facility so that duplicate payment is not made by Medicare. Therefore, as stated previously in section XIII.B, suppliers, laboratories, and Part D plans would not be permitted to bill Medicare for renal dialysis services and home dialysis items and services that they furnish to ESRD beneficiaries. The consolidated billing approach essentially confers to the ESRD facility itself the Medicare billing responsibility for all of the renal dialysis services that its patients receive.

a. Laboratory Tests

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.