Supplemental Appendix to:

“Bundled Payment Reform and Dialysis Facility Closures in End-Stage Kidney Disease”

Supplement Contents:

Exhibit 1: Identifying and Validating Dialysis Facility Closures

Our objective was to identify lasting dialysis facility closures that are most likely to affect the care that patients receive and access to care. Below are three important ways in which a lasting dialysis facility closure can affect dialysis patients:

1) Closures could affect patients through the transfer of dialysis care to a new organization. The care that patients receive may change in various ways as they are subject to a different organization's practices and are cared for by new staff.
2) Closures could affect patients by requiring that they travel to a less convenient location for dialysis. For many patients receiving dialysis, regular travel to and from dialysis can be a challenge. When a dialysis facility closes, patients at the closed facility must arrange travel to a new dialysis facility, which can present challenges.
3) Closures could affect patients by limiting access to dialysis care either temporarily or over the long term. This would happen, for example, if patients have difficulty identifying a new facility where they can receive care.

There are several features of a dialysis facility closure to indicate that it is lasting and that are necessary in order for a patient to experience these potential challenges.

1) Patients must be receiving regular dialysis care at the facility that closes. The "closure" of a dialysis facility that provides intermittent dialysis care for very few patients and that frequently has periods of time where there are no patients is unlikely to have a meaningful effect on patients receiving maintenance dialysis.
2) In the period leading up to- and following – a dialysis facility closure, patients at the closed facility switch to a new facility that is at a different location. As we describe below, occasionally dialysis facility identification numbers change while patients continue to receive care at the same location. A "closure" a dialysis facility where a majority of patients continue to receive dialysis at the same location is better characterized as an acquisition or a paired closure and opening.
3) Closures need to be more than temporary. For instance, a closure that lasts several months while a facility undergoes a brief renovation is less likely to have a lasting effect on patients.

Based upon these aims, we developed the following method to identify patients who were affected by dialysis facility closures:

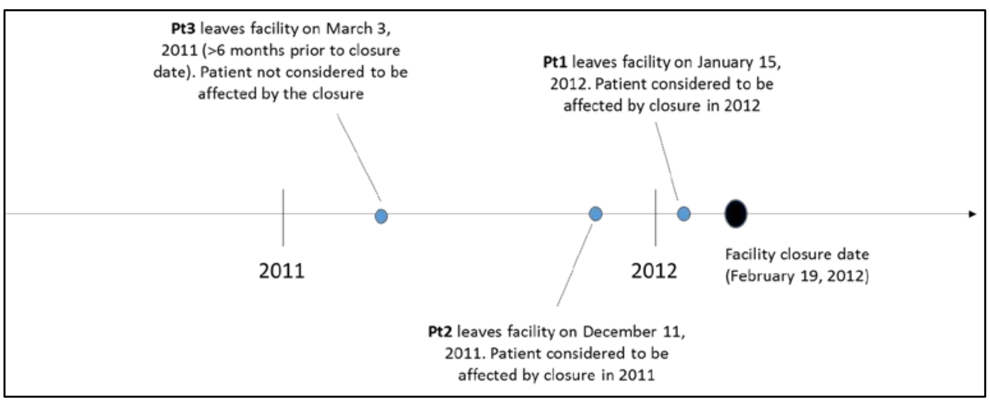
1) During the study period, we identified dialysis facilities that reported caring for at least 5 dialysis patients (in-center or home) at the beginning of each calendar year and that were not listed as "transplant" facilities. We identified facilities based upon the provider identification (ID) number which is included in the United States Renal Data System (USRDS) database and which comes directly from an identifier maintained by the Centers for Medicare and Medicaid Services (CMS). These restrictions eliminated the majority of facilities that had temporary periods with no patients receiving dialysis. In each year, we also excluded facilities that did not have an annual dialysis facility survey.
2) We used dialysis treatment history records reported from Medicare claims and by the end-stage renal disease (ESRD) Networks (RXHIST) to identify "potential" facility closures. Potential closures occurred when facilities cared for 0 patients at any given point in time. One facility could have more than one potential closure throughout the study period.
3) We then categorized "potential" facility closures as actual closures if there were no patients receiving dialysis at the potentially-closed facility for at least 6 months. In many instances, the facility ID at these closed facilities never appeared again in the USRDS database. However, in

some instances (between 10% and 22% throughout the study period) the facility provider ID did appear again within the subsequent calendar year, suggesting that a closed facility reopened. However, we considered 6 months to be long enough in duration for the magnitude of care disruption to be similar when compared to patients at facilities that never re-opened.

4) Among facilities that closed, we identified the "closure date" as the first day when there were no patients at that facility.
5) When we examined the timing of when patients leave facilities prior to a closure, we observed several patterns. In many instances, a majority of patients left the facility within 10-30 days prior to a closure. However, there were also a substantial number of closures where patients began leaving facilities in the months leading up to the closure. When we compared the rates of leaving a facility at facilities that closed *versus* those that did not close, we found that the rates began to diverge approximately 6 months prior to closure. Consequently, we identified patients as affected by a facility closure if they received dialysis at the facility within 6 months of the closure date. We also required that they received "stable" dialysis at the closed facility (i.e. were on a given modality at that facility for at least 60 days based on RXHIST data).

Assigning patients to a calendar year.

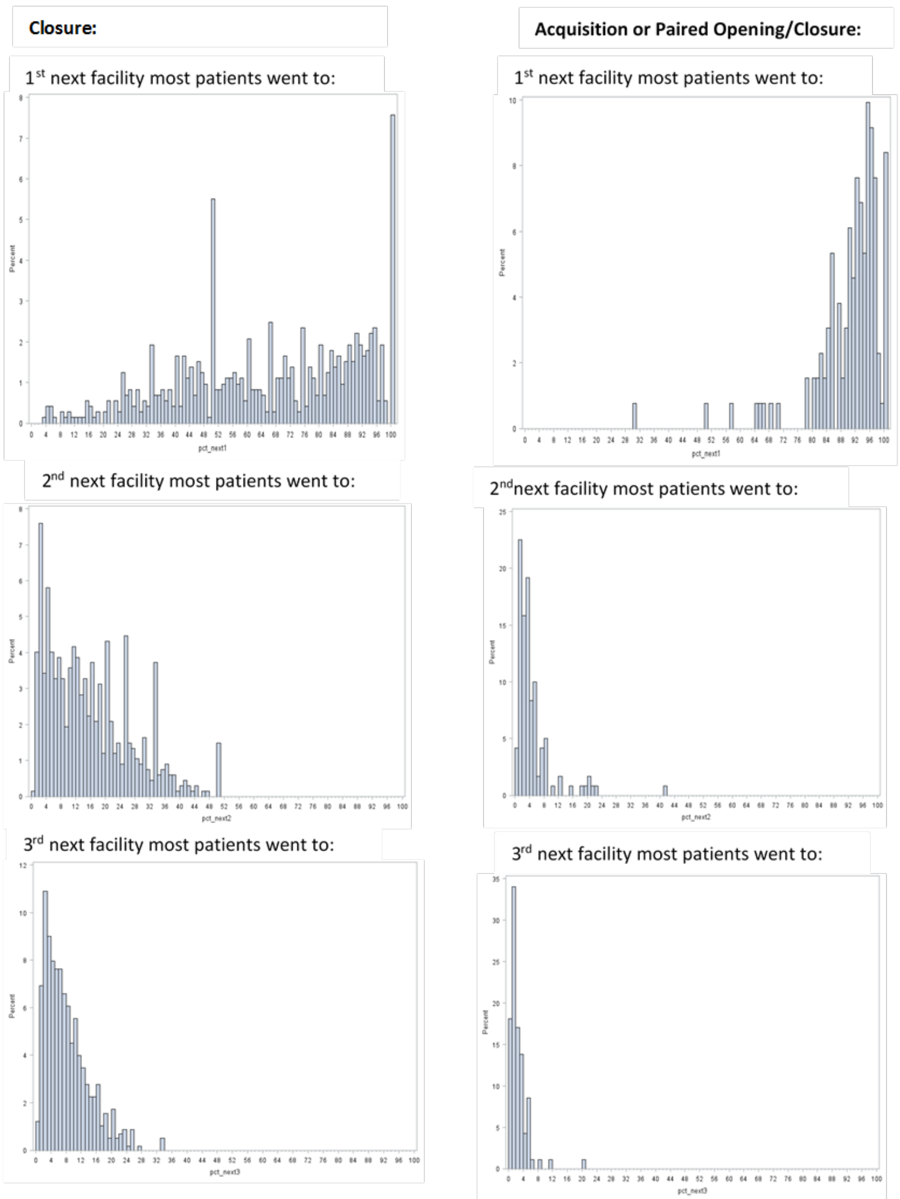
We classified patients as being affected by a facility closure if they received "stable" dialysis at a closed facility within 6 months of the facility closure date. For each patient-year, we classified patients as *affected* or *unaffected* by closures depending upon whether their facility closed and, if so, the date when they left a facility prior to closure. For example, if a facility closed in February 2012 and a patient at that facility stopped dialyzing there in January 2012, the patient would be considered to have been affected by a closure in 2012. If another patient at the same facility left the facility in December 2011, then that patient would be considered to be affected by a closure in 2011. **(See figure below)**



Among patients not affected by closures in a given calendar year, we assigned them to the facility where they received dialysis at the start of each calendar year. When patients initiated dialysis mid-year, we assigned them to the facility where they first received dialysis in their incident dialysis year and we assigned them to the facility where they received dialysis at the start of subsequent calendar years. Patients who received dialysis over multiple calendar years appear in our dataset more than once. Patients could only be affected by a closure once in a given year. This was represented in our regression models as an indicator variable equal to 1 in the year of a closure. In the absence of multiple facility closures in difference calendar years, patients who were affected by a facility closure in one year would not be considered as affected by closures in other calendar years.

Validation and refinement of identification of facility closures.

<u>Validation Approach 1:</u>



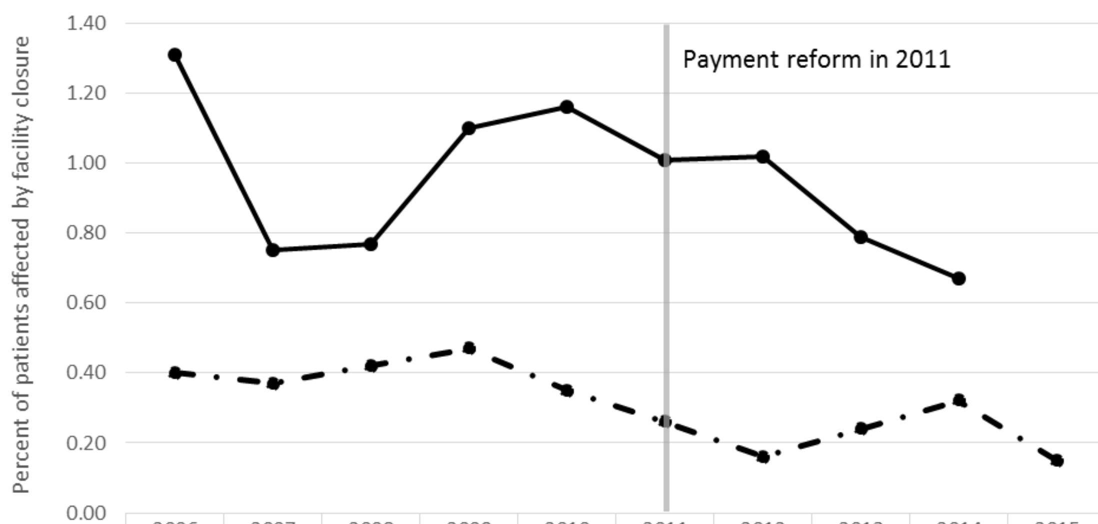
In markets where there are more than one alternative dialysis facility for patients to receive care, we expected for patients affected by any given closure to transition to several nearby dialysis facilities. We used our data to examine whether this was true. For each potentially closed facility, we identified the 3 facilities where the most patients went after leaving the potentially closed facility. As expected, we observed that in many instances patients went to one of several other nearby facilities.

In some cases, however, a majority of patients at a closed facility went to one new facility. We examined these facility closures in more detail by comparing the facility addresses and chain names (reported to CMS in Annual Dialysis Facility Surveys and reported to ESRD Networks and published in CMS Dialysis Facility Compare). For each closure where more than ½ of patients at a facility transferred to 1 different facility, we compared addresses (and chain names) of the closed facilities to the addresses (and chain names) of the facility where the most patients went to after the closure. In some instances a majority of patients at a closed facility went to only one new facility which had the same address as the potentially closed facility. In the majority of these occurrences, the chain name changed, suggesting that these facilities were acquired rather than closed, In several instances, both the address and the chain name remained unchanged. This could represent either an acquisition of one independent facility by another independent facility or a paired closure/opening involving the same owner. Based upon these findings, we re-classified 19% of closure events as acquisitions or paired closure/opening, and did not consider patients at these facilities to be affected by closures. The histograms above illustrate the percent of patients at each facility switching to the 1st, 2nd, and 3rd most common "next" facility among facilities classified as closures and those which were re-classified.

Validation Approach 2:

In an additional validation analysis we compared closures identified using our method to closures identified from annual dialysis facility surveys submitted to CMS. We considered a facility to have closed based on dialysis facility surveys if the facility stopped completing a survey for at least 2 years. Among facilities that we identified as closing using our treatment-based method, 91% stopped submitting facility surveys within the 2 years following the closure. The figure below illustrates overall trends in closures over time using the 2 methods. While the facility survey method identified more patients affected by closures, the overall trends over time were similar.

Percentage of Patients Affected by Dialysis Facility Closures.



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
From FS	1.31	0.75	0.77	1.10	1.16	1.01	1.02	0.79	0.67	
from RXHIST	0.40	0.37	0.42	0.47	0.35	0.26	0.16	0.24	0.32	0.15

Validation Approach 3:

Finally, we compared the number of patients and dialysis facilities that we identified as having been affected by closures in 2009 through 2014 to the numbers of patients and facilities in annual dialysis reports published by the Medicare Payment Advisory Commission (MEDPAC). 2009 was when MEDPAC began consistently reporting these data. The table below illustrates how the numbers of patients and facilities reported to be affected by closures are similar, as is the general trend over time towards decreasing impact of closures:

Patients Affected by Closures						
	2009	2010	2011	2012	2013	2014
Our analysis	1967	1552	1202	760	1158	1611
MedPAC	3600	3950	3300	2600	2300	2100
Facilities that Closed						
	2009	2010	2011	2012	2013	2014
Our analysis	69	54	36	18	33	49
MedPAC	90	90	65	40	40	60

In summary, we developed a method of identifying dialysis facility closures that are most likely to influence patients and the care that they receive. We developed this method following a process that involved several refinement steps. We validated the method in several ways, including assessment of the facilities where patients went to following closures and comparing the number of patients affected by closures from our method to patients affected by closures based on an alternative methods.

Exhibit 2: Calculating a Comorbidity Score.

We ascertained comorbidities from information included in the CMS Medical Evidence (2728) Report. This form is completed for every patient at the time of dialysis onset, regardless of health insurance. We incorporated co-morbidities in our regression model using a Charlson Comorbidity Index that was adapted for patients with ESKD. We had to further modify this index to address co-morbidities available on the 2728 form.

Our comorbidity index assigns 1 point for each condition among patients with: 1) peripheral vascular disease, 2) chronic obstructive pulmonary disease, and 3) diabetes mellitus. It assigns 2 points for each condition among patients with: 1) congestive heart failure, 2) cerebrovascular disease, 3) atherosclerotic heart disease, and 4) malignancy.

Comorbidities listed on the 2728 Report may be less reflective of the burden of disease among patients who have been on dialysis for a longer period of time, and are less accurate than comorbidities obtained from Medicare claims. However, because we wanted to include all patients who were potentially affected by facility closures, regardless of insurance type, we could not use Medicare claims to ascertain comorbidities in our population. Instead, we adjust for the time since initiation of dialysis ("vintage") in an effort to capture potential effects of growing disease burden over time on patient health and facility closures. Additionally, we conducted a sensitivity analysis were we restrict our population to patients with Medicare Parts A&B and use Medicare claims to update co-morbidities annually. **(see sensitivity analyses below)**.

Exhibit 3: Interrupted time series regression.

We used an interrupted time series regression model at the level of the individual patient to examine the relationship between enactment of the expanded ESKD payment bundle and the likelihood of patients being affected by dialysis facility closures. This model examines the effect of a policy in two ways. First, it estimates an immediate effect of the policy on closures. Second, it estimates changes in the long term trend in closures over time that result from the policy. The schematic below illustrates the ways in which this model can capture potential policy effects:

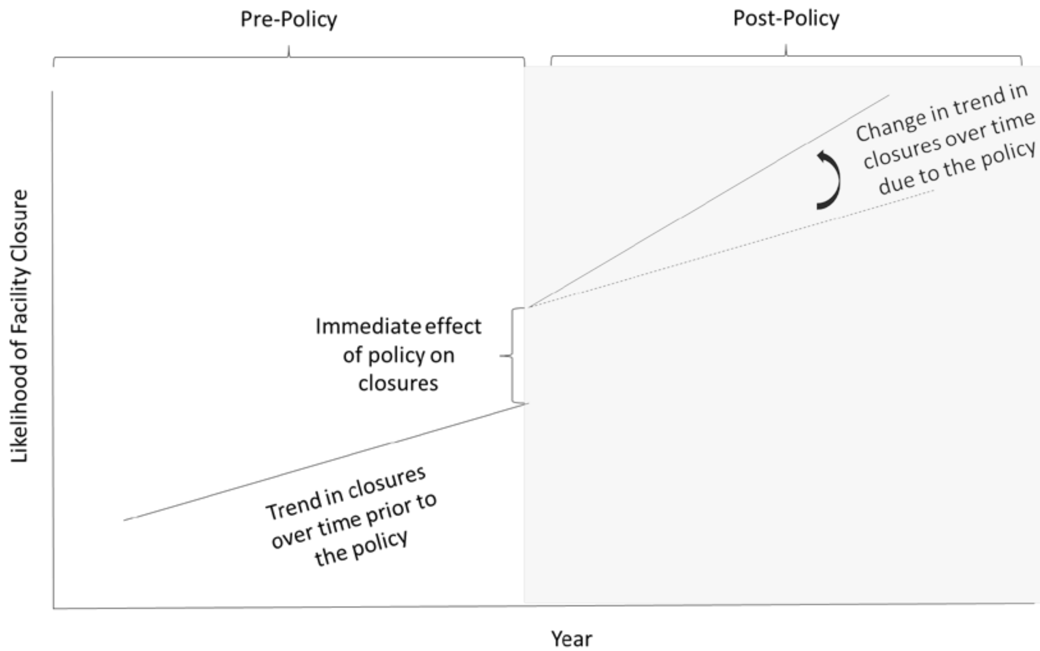


Exhibit 4: Estimating Changes in Facility Closures among High-Risk and Vulnerable Groups after Payment Reform.

We used a series of separate regression models to examine whether observed effects of payment reform on facility closures varied among selected high-risk and vulnerable populations. Each regression model used the same set of covariates that were included in the fully-adjusted interrupted time-series regression with the following exceptions: 1) Rather than modeling calendar year as linear variables representing each year before and after the expanded ESRD Payment Bundle, we use dummy variables for each calendar year. Similar to the primary regression model, we also created an indicator variable representing exposure time on or after 2011. We interact this "post-PPS" indicator variable with each high-risk characteristic of interest (e.g. race, ethnicity, facility type) and include this interaction term in the regression model. Because the post-PPS indicator variable representing time after 2011 is collinear with the calendar year dummy variables, this indicator variable is not included explicitly in the model, but is only incorporated in the model in the form of (Post Policy)*(High Risk) interaction terms.

Exhibit 5: Sensitivity Analyses

1) We examined the sensitivity of our findings to the ascertainment of comorbidities listed in the CMS 2728 Form. We did this by restricting the study population to patients with Medicare Parts A&B at the onset of ESRD or at the beginning of each calendar year, and then ascertaining a more comprehensive and up-to-date comorbidity score using Medicare claims. Findings from this model were not substantially different from findings in the fully-adjusted primary regression model. The OR for the after Prospective Payment System (PPS) variable changed from 0.63 in the primary model to 0.64 (95% CI 0.59 to 0.69), while the OR associated with each year after the PPS changed from 0.94 in the primary model to 0.95 (95% CI 0.92 to 0.99).
2) We examined the sensitivity of our findings to the requirement that facilities close for at least 6 months in order to be categorized as a closure. We did this by extending the requirement to 12

months. In a sensitivity analysis where we require that dialysis facilities close for at least 12 months in order to identify facility closures, findings from the fully-adjusted interrupted time-series model did not change substantially. In particular, the estimated OR for time spent receiving care after the expanded ESRD PPS was 0.70 (95% CI 0.65 to 0.75) and the estimated OR for each year after payment reform was 0.95 (95% CI 0.92 to 0.98), compared to 0.63 (95% CI 0.59 to 0.67) and 0.94 (95% CI 0.91 to 0.97) in the primary analysis, respectively.

3) We examined the sensitivity of our findings to potential differences in patient follow-up time among different patients. For each patient, we measured follow-up time in each year and developed four distinct categories of follow-up: 1) ≤3 months, 2) 3 to ≤6 months, 3) 6 to ≤9 months, 4) >9 months. In instances where patients were at a facility that closed, we assumed that they were followed after closure until death or transplantation. This variable was assigned to each patient-year record, depending on follow-up duration in that year. Our findings were not sensitive to inclusion of this additional adjustment. The estimated OR for time spent receiving care after the expanded ESRD PPS was 0.63 (95% CI 0.59 to 0.68) and the estimated OR for each year after payment reform was 0.91 (95% CI 0.89 to 0.94), compared to 0.63 (95% CI 0.59 to 0.67) and 0.94 (95% CI 0.91 to 0.97) in the primary analysis, respectively.

Exhibit 6: Examining the Estimated Effects of Black Race and Facility Closures.

In the nested multivariable logistic regression models, Black race was associated with a decreased likelihood of being affected by facility closure relative to White race in models that adjusted for patient demographic and socioeconomic characteristics (Odds Ratio (OR) 0.93; 95% CI 0.90 to 0.97) and patient health characteristics (OR 0.89; 95% CI 0.85 to 0.93). However, in the fully-adjusted regression model which also accounted for facility and geographic characteristics, the independent effect of Black race became *positively* associated with facility closures (OR 1.11; 95% 1.07 to 1.16).

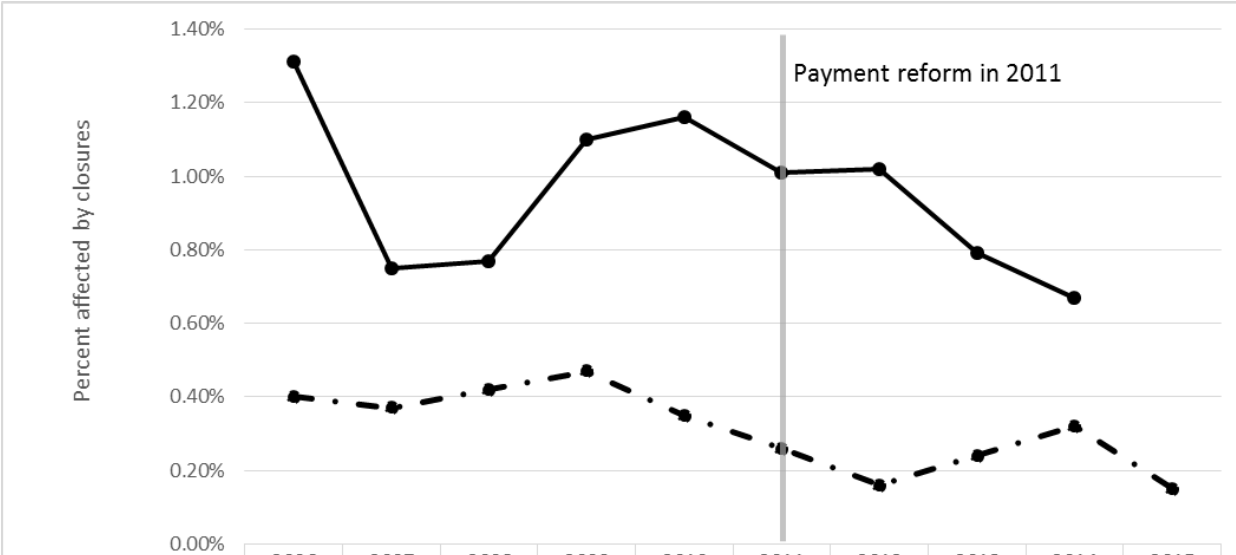
To investigate this finding in more detail, we ran a series of regression analyses where we added each facility and geographic characteristic separately. We found that the addition of dialysis facility size as a model covariate had the most profound influence on the observed association between Black race and facility closure. In a fully adjusted model without facility size, the estimated coefficient for Black race was 0.95 (95% CI 0.91 to 0.99). This increased to 1.11 after inclusion of facility size in the model. When we examined the proportion of Black patients in each facility size category, we found that Black patients are more likely to dialyze in larger facilities (21%, 28%. 35% and 37% in facilities with <25, 25-50, 50-100, and >100 patients, respectively. Because smaller size facilities are more likely to close, these findings suggest that the lower likelihood of being affected by closures among Black patients observed prior to adjustment can be explained be an increased likelihood of dialyzing at larger facilities.

Table S1. Results from logistic regression analyses of effect modification.

	Before 2011			After 2011			p-value testing difference
	OR	LCI	UCI	OR	LCI	UCI	
Black race	1.07	1.02	1.13	1.18	1.11	1.25	0.009
Hispanic ethnicity	0.97	0.90	1.05	0.73	0.66	0.80	<0.001
Dual eligibility	1.25	1.19	1.31	1.12	1.06	1.18	0.003
Private group health insurance	0.82	0.74	0.91	0.77	0.68	0.89	0.46
Hospital-based	1.40	1.28	1.53	2.71	2.46	2.99	<0.001
Size < 25*	6.66	6.21	7.15	8.16	7.59	8.78	<0.001
Size 25-49*	3.45	3.27	3.64	2.22	2.08	2.38	<0.001
Rural & small town	0.71	0.65	0.77	0.74	0.67	0.81	0.53

Note: OR is odds ratio; LCI is lower 95% confidence interval and UCI is upper 95% confidence interval. Odds ratios for time exposure on or after 2011 were obtained from a linear combination of the estimated coefficients for the characteristic of interest (e.g. Black race) and the coefficient for time after 2010. *When assessing facility size, both size categories were included as separate interaction terms in one regression model. Otherwise, each row includes results from a separate regression model. All regression models adjust for all characteristics included in our fully-adjusted primary regression model illustrated in tables 1 and 2 of the main text. However, in models of effect modification, calendar year is included as dummy variables rather than a linear trend.

Figure S1: Compare two identification methods, facility survey (FS) or RXHIST, on percent of patients affected by facility closure



	2006	2007	2008	2009	2010	2011	2012	2013	2014	2015
From FS	1.31%	0.75%	0.77%	1.10%	1.16%	1.01%	1.02%	0.79%	0.67%	
From RXHIST	0.40%	0.37%	0.42%	0.47%	0.35%	0.26%	0.16%	0.24%	0.32%	0.15%

Figure S2 Logistic Regression Estimates with and without the Expanded ESRD Prospective Payment System.