Quality-based ratings in Medicare and trends in kidney transplantation

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Objective: To assess the relationship between the 2007 Medicare regulation enforcing quality standards for transplant centers and trends in kidney transplantation.

Data Sources: Transplant centers' biannual reports and the national registry for kidney transplantation from 2003 to 2010.

Study Design: Non-compliant (low-performing) centers were compared with centers in compliance with quality standards according to: number of transplants, waiting-list registrations, and rates of graft failures, transfers, and deaths. Multivariate regressions were estimated to evaluate the association between the regulation and transplantation outcomes.

Data Extraction Methods: Patient characteristics and outcomes were aggregated to six-month periods and linked to centers' reports.

Principal Findings: Relative to average-performing centers, 12 percent of transplants shifted away from low-performing centers and high-performing centers captured 6 percent of this decline. Low-performing centers experienced a 2-percentage point per period decline in 1-year graft failure rates and a 15-percent decrease in registrations post-regulation, whereas high-performing centers incurred a 5-percent decrease in registrations relative to average-performing centers.

Conclusions: Government oversight in kidney transplantation was associated with a small downward shift in overall kidney transplants. Reductions in graft failure rates at low-performing centers may imply an increase in quality or a decline in transplantation of either marginal organs or riskier patients; whereas reductions in registrations may indicate risk aversion toward high-risk patients. Policy makers should consider making less punitive requirements for programs, which employ new transplantation techniques to expand access.

KEYWORDS

quality rating, regulation, report card, transplantation, volume

1 | INTRODUCTION

Over time, there has been a growing interest in the effect of performance incentives and quality rating systems on health care quality.¹⁻¹² In one notable example in 2007, the Centers for Medicare and Medicaid Services (CMS) began to penalize kidney-transplantation programs with significantly lower quality as measured by 1-year

patient and graft survival rates. Quality performance standards in transplantation have been used since the early 1990s by the Organ Procurement and Transplantation Network (OPTN) and are utilized to govern operations of transplant centers and regulate deceased-donor organ procurement and allocation. Transplant centers' patient and organ graft risk-adjusted survival rates are compared to national averages to determine compliance. Dissemination of

program-specific reports including survival performance measures has increased since October 2002, when they were first published online by the Scientific Registry for Transplant Recipient (SRTR). Although the OPTN used quality standards to identify non-compliant centers, it did not enforce any sanctions for underperformance. This changed with a CMS regulation on March 30, 2007, increasing oversight of transplant centers. In the "Conditions of Participation" (CoP) defined in the regulation effective June 28, 2007, CMS took a regulatory approach by stating that programs failing to comply with the OPTN quality performance standards risk decertification for Medicare coverage, the new enforcement mechanism.¹³ Before getting decertified for Medicare coverage, non-compliant programs are put on probation and are listed on the OPTN's website as "members not in good standing." As Medicare remains the primary insurance for end stage renal disease (ESRD) patients seeking kidney transplantation,¹⁴ decertification and loss of Medicare reimbursement would likely mean program closure.

According to the OPTN quality standards, a center's performance is considered non-compliant if its observed risk-adjusted survival rates are lower than its expected survival rates in addition to having (a) the difference between the number of observed events (ie, patient deaths or graft failures) and expected events larger than 3 ($O-E > 3$); (b) a ratio of observed to expected events larger than 1.5 ($O/E > 1.5$); and (c) a one-sided P -value less than 0.05, based on an exact Poisson test for the difference between observed and expected events.¹³

Historically, Medicare, Medicaid, and commercial insurers implemented quality improvement strategies in surgery (eg, bariatric and cardiac surgery) to divert patients away from "poor-performing" providers to those likely to have superior results for specific procedures.^{1,15,16} Through these access and reimbursement restrictions, payers sought to regionalize care at high-performing providers, and therefore improve average patient population outcomes. Unlike prior quality improvement strategies in surgery, the intent of the kidney transplantation CoP was not to regionalize transplantation care but rather to improve overall quality of care in a corrective manner.

Though high-quality designation in surgery was found to be associated with an increase in procedure volume, it did not translate into better average patient population outcomes.^{17,18} A propos kidney transplantation, earlier studies indicated that procedures declined at low-performing centers¹⁹⁻²¹ but also suggested ancillary factors that could have attenuated potential benefits from the CoP (eg, higher rates of organ waste).²² Markedly, to comply with regulations, transplant centers may adopt stringent eligibility criteria for waiting-list admission to the detriment of riskier patients who may benefit from transplantation²³ or avoid innovative and high-risk procedures.²⁴ Moreover, it is not clear whether the impact of the regulation on the number of transplants in low-performing centers translates into changes in other health outcomes for wait-listed patients (eg, death, transfers to other centers) and into changes in transplantation trends in high-performing centers. Understanding how the regulation interacts with these health outcomes and potential spillovers to "high-performing" centers could inform on designing

future quality improvement strategies in surgery in general and in transplantation of solid organs in particular. This study offers a more comprehensive approach to assessing the relationship between the quality standards enforcement through CMS regulatory oversight and trends in kidney transplantation, and examines changes in other health outcomes in addition to the number of transplants and changes in practice at high-performing centers.

2 | CONCEPTUAL MODEL

I hypothesize that transplant centers may become risk averse as a result of the CMS CoP¹⁹ and will respond to poor quality rating by curbing behavior, because meeting standards will affect standing of their program with the OPTN, with CMS, and in the transplantation community. Transplant centers incur greater risks due to oversight under the CoP, risks which translate into higher marginal costs of performing transplant procedures for both compliant and non-compliant programs.²¹ Centers' behavioral responses may involve avoiding enrollment and limiting transplantation of high-risk patients; decreasing the use of organs that have a higher risk of failure (ie, expanded-criteria-donor (ECD) organs); and taking initiatives to improve quality. Example of such quality improvement initiatives entail involving multidisciplinary teams of providers (eg, nephrologists, cardiologists, transplant surgeons, dietitians/nutritionists) when selecting and monitoring transplant candidates and when managing patients post-transplantation, designing a robust protocol for patient admission, improving communication across providers and training for staff, and internally evaluating performance for continuous quality improvement.

Risk-averse behavior of transplant centers may result in a decrease in patient enrollment, longer wait times, and higher rates of waiting-list removals for reasons other than transplantation, including death. Patients and their referring nephrologists may also respond to the quality information available on program-specific reports when selecting a transplant program for registration. While on the waiting list, patients have the ability to change transplant programs. I expect low-performance designation to affect the rate of transfers between centers. Such transfers will lead to shifts in volume of patient registrations and possibly transplants to centers with superior performance ratings, *high-performing* centers.

3 | DATA

Two complementary datasets were used: (a) the publicly available program-specific reports published by the SRTR between July 2003 and January 2010, and (b) the United Network for Organ Sharing Standard Transplant Analysis and Research (UNOS STAR) kidney-transplantation waiting lists between January 1, 2003, and June 30, 2010. The SRTR reports were published biannually and provided information on centers' 1-month, 1-year, and 3-year risk-adjusted performance measures. Reports included graft/patient survival rates,

expected graft/patient survival, ratio of observed to expected performance measures, which are independent statistical assessments of centers' performance relative to the national average. Since the CMS only used the 1-year measures for evaluating centers, this analysis exclusively used these performance metrics.

The UNOS, a non-profit contractor operating the OPTN, collected information on transplant candidates including demographics such as gender, race, age at listing, education attainment, and body mass index (BMI) at listing. In addition, information was provided on patients' medical and clinical conditions at listing such as high sensitization—an immune condition increasing the chances of graft rejection—diabetes, chronic obstructive pulmonary disease (COPD), insurance coverage, and dates of registration and removal from the waiting list. Reasons for waiting-list removals included transplantation, death, transfer to another center, and other causes (eg, patient condition improved, center was unable to contact patient, patient refused transplant). Information was also included on the source of the transplanted kidney (eg, ECD, a high-risk donor with multiple comorbidities; standard-criteria donor), and the date of graft failure when applicable. Simultaneous kidney and pancreas transplants were excluded.

3.1 | Study sample

There were 227 centers specializing in adult kidney transplantation with waiting-list registrations for patients (age 18 years or older)—with at least one report card—between 2003 and 2010. The analytic sample followed an unbalanced panel data structure comprising centers with reports over fourteen half-year periods (2003-2010) to reflect the semi-annual program-specific report cards: time was measured semi-annually in the analysis. A total of 193 117 patient registrations with follow-up information were aggregated at the half-year level and linked to centers' report-card information. Also included in the sample were transplants conducted between 2003 and 2010 from enrollments prior to 2003 (50 351 registrations).

3.2 | Outcome measures

Dependent variables were grouped into two conceptual categories: (a) access to transplantation and (b) quality of transplantation. Measures of access to transplantation included waiting-list registrations, number of transplant, rates of ECD transplants, waiting-list deaths (also including patients removed for being "too sick to transplant"), transfers to other centers, and waiting-list removal for all other causes. Quality of transplantation was measured with graft failure rates within one and three years post-transplantation. The number of graft failures from transplants performed in a period served to calculate 1-year and 3-year graft failure rates. The total number of waiting-list removals in any period, for reasons other than transplantation, was utilized to calculate rates of removal due to death, transfer to other centers, and due to all other reasons. All outcome measures were constructed using the UNOS STAR data.

3.3 | Explanatory variables

Transplant centers' compliance with quality standards was evaluated under the three criteria mentioned above ($O-E > 3$; $O/E > 1.5$; and one-sided P -value < 0.05) separately for 1-year graft survival and patient survival rates resulting in two survival performance ratings per evaluation report. A center-specific report indicated whether its observed survival rates were *statistically higher* than, *statistically lower* than, or *not significantly different* from the expected rates.

Using the three performance evaluation criteria listed above, centers were assigned into performance categories based on graft and patient survival rates. Although performance in consecutive reports was correlated, centers could have different quality ratings from one report to the next. For each transplant program, I defined three dichotomous variables, "low-performing" statuses, indicating whether it was ever flagged for non-compliance with quality standards for its graft survival rates, patient survival rates, separately, or for either of these two measures during the entire analysis period. The last variable, low performance on either graft or patient survival rates was considered because sanctions due to non-compliance would likely affect a kidney transplant program in its entirety. The aggregated patient data for each center were linked to the center's performance report published at the beginning of the period of interest. For example, information from the July 2003 report was linked to aggregated patient data for the second semester of 2003.

I included an indicator variable to represent the post-regulation period, starting in the second semester of 2007. Also included were proportions of registrations by race/ethnicity category, average patient age and BMI for registered patients, proportion of female, patients with Medicare as a primary insurance, private insurance, college education attainment, and with particular medical conditions (eg, high sensitization, diabetes, COPD). I also included annual kidney donations identified by the number of deceased donors in the center's donor service area, collected from the OPTN's website.

4 | EMPIRICAL STRATEGY

I analyzed the relationship between centers' subpar quality performance and trends in kidney transplantation following the CMS CoP implementation. I used a before-and-after design with a panel structure to assess associations. The panel regression model for this design was defined as follows:

$$E(y_{ijt}) = f(\alpha_0 + \alpha_1 \text{Low Performing}_{ijt} \times \text{Post CMS CoP}_t + \alpha_2 \text{Annual Kidney Donations}_{jt} + \gamma X_{ijt,t-1} + \sigma_i + \tau_t + \varepsilon_{ijt}), \text{ where } t = 2, \dots, 15 \quad (1)$$

where y_{ijt} was the outcome variable for center i in donor service area j in period t . The subscript t denoted half-year periods. The coefficient of interest, $\hat{\alpha}_1$, measured variations in the dependent variable specific to low-performing centers relative to centers in

TABLE 1 Characteristics of transplant centers by quality performance measures and performance status before implementation of the CMS CoP regulation—2003 to 2007 (N = 1693)

Characteristics	Quality performance measure						Either graft or patient survival			
	1-year (Total) graft survival only			1-year (Total) patient survival only			Met performance standards		Low performing	
	Met performance standards	Low performing	P-value ^a	Met performance standards	Low performing	P-value ^a	Met performance standards	P-value ^a	Met performance standards	P-value ^a
Registration, mean (SD), count	78.2 (99.1)	48.4 (41.0)	0.0000	71.9 (97.9)	60.0 (48.0)	0.0073	78.6 (106.0)	0.0073	55.2 (45.3)	0.0000
Transplant, mean (SD), count	35.1 (29.5)	25.4 (20.7)	0.0000	32.6 (29.2)	30.2 (22.4)	0.0897	35.2 (30.5)	0.0897	27.5 (21.8)	0.0000
Transplant from ECD, %	11.1	10.4	0.2763	11.1	10.4	0.1926	11.3	0.1926	10.4	0.1349
Other waiting list removal reasons, %										
Death	21.2	21.2	0.9473	20.7	22.1	0.0302	20.3	0.0302	22.3	0.0007
Transfer	5.2	4.8	0.4606	5.5	4.0	0.0027	5.3	0.0027	4.7	0.2510
Other cause	15.4	15.1	0.5509	15.2	15.6	0.4527	15.2	0.4527	15.5	0.5145
Graft failure rate-1 year, %	4.3	6.8	0.0000	4.8	6.0	0.0004	4.3	0.0004	6.3	0.0000
Graft failure rate-3 years, %	8.3	12.2	0.0000	8.8	11.2	0.0000	8.1	0.0000	11.5	0.0000
Patient demographics										
Age, mean, (SD), Years	49.2 (6.5)	49.1 (5.7)	0.7222	49.0 (7.1)	49.5 (3.9)	0.0736	49.1 (7.0)	0.0736	49.2 (5.2)	0.5787
Race/Ethnicity, %										
White	51.6	53.7	0.0701	52.7	51.5	0.3137	52.2	0.3137	52.4	0.9131
Black	26.0	26.6	0.5420	22.9	32.9	0.0000	23.2	0.0000	29.8	0.0000
Hispanic	14.1	13.2	0.3416	15.2	11.1	0.0000	15.3	0.0000	12.0	0.0002
Asian	5.0	4.2	0.0232	5.5	3.2	0.0000	5.4	0.0000	3.9	0.0000
Other ethnicity	2.7	1.8	0.0026	2.9	1.3	0.0000	3.1	0.0000	1.6	0.0000
Female, %	38.3	38.8	0.3760	37.9	39.8	0.0008	37.8	0.0008	39.4	0.0029
Body mass index (BMI), mean, (SD), Index	27.2 (3.4)	27.4 (2.9)	0.2837	27.0 (3.7)	27.7 (1.8)	0.0003	27.1 (3.6)	0.0003	27.6 (2.6)	0.0011
College Education, %	39.9	37.5	0.0077	40.2	36.7	0.0001	40.8	0.0001	37.0	0.0000
Insurance, %										
Medicare	45.7	51.5	0.0000	45.0	53.2	0.0000	44.5	0.0000	51.6	0.0000

(Continues)

TABLE 1 (Continued)

Characteristics	Quality performance measure					
	1-year (Total) graft survival only			1-year (Total) patient survival only		
	Met performance standards	Low performing	P-value ^a	Met performance standards	Low performing	P-value ^a
Private insurance	40.2	38.9	0.1754	40.1	39.0	0.2906
Other insurance	14.1	9.6	0.0000	14.9	7.7	0.0000
Patient clinical and medical conditions, %						
Diabetes	37.9	38.7	0.2030	37.9	38.7	0.1887
COPD	1.1	1.5	0.0025	1.2	1.5	0.3761
High sensitization	4.0	3.4	0.0338	3.7	3.9	0.3075
Observations	1117	576		1145	548	
					933	760

Notes: Center-period represents the unit of observation (N). All numbers are means per 6-month period. Percent may not sum exactly to one hundred due to rounding error.

^aDifferences between transplant center performance groups were tested by t-tests. Low-performing centers are centers ever flagged for non-compliance with quality standards. The comparison group includes all centers performing at or above expectations.

compliance with quality standards in periods following the CMS CoP implementation.

Annual kidney donations in the center's donor service area adjusted for the supply of deceased-donor organs available for transplantation in a particular year. The vector X comprised lagged patient characteristics in a center, as defined above. The model adjusted for these covariates to capture potential differences in pre-regulation trends. Since transplant volume may increase attractiveness of a center, lagged number of transplants was included when modeling changes in enrollments. Moreover, the rate of ECD transplants was included in regressions modeling graft failure rates. The parameter σ_i represented the transplant center's time-invariant characteristics, τ_t indicated period fixed-effects—controlling for events or other potential (simultaneous) policies that were period specific and did not vary across centers—and ε_{ijt} identified an idiosyncratic error term.

Equation (1) was estimated using a fixed-effect approach and standard errors were clustered at the center level. Negative binomial regressions were estimated for count variables and least-squares regressions were estimated for rate variables. Incidence rate ratios were reported for negative binomial regressions, whereas estimated coefficients were reported for least-squares regressions.

When considering trends at high-performing centers, the group of compliant centers was further divided into two mutually exclusive subgroups. There was the group of high-performing centers representing programs that were never flagged for non-compliance with quality standards and which had observed 1-year survival rates larger than the corresponding expected rates ($O > E$), in addition to having a one-sided P -value less than 0.05 (P -value < 0.05). The second group comprised *standard-performing* centers, which were programs performing at par with quality standards but which did not qualify as high performing under the criteria defined above. Standard-performing centers included programs that had met at most two of the three non-compliance thresholds. When using these additional classifications, transplant centers were therefore grouped into three performance categories: (a) low-performing (centers ever flagged on either graft or patient survival rates), (b) standard-performing, and (c) high-performing programs.

Hence, Equation (1) was augmented to include another interaction term between Post CMS CoP_{*t*} and High Performing_{*ijt*} status.

$$\begin{aligned}
 E(y_{ijt}) = & f(\beta_0 + \beta_1 \text{Low Performing}_{ijt} \times \text{Post CMS Final Rule}_t \\
 & + \beta_2 \text{High Performing}_{ijt} \times \text{Post CMS Final Rule}_t \\
 & + \beta_3 \text{Annual Kidney Donations}_{jt} + \delta X_{ijt-1} \\
 & + \sigma_i + \tau_t + \mu_{ijt}), \text{ where } t = 2, \dots, 15
 \end{aligned}
 \quad (2)$$

The coefficients of interest in Equation (2) were $\hat{\beta}_1$ and $\hat{\beta}_2$, representing the changes in the dependent variables associated with classification into low-performing and high-performing category post-regulation, respectively, relative to standard-performing centers.

5 | RESULTS

5.1 | Descriptive characteristics

The sample included 2959 center-period observations with 1693 observations pre-CMS CoP. Seventy-three centers were assigned to low-performance status for graft survival rates as opposed to sixty-nine centers for patient survival rates. A total of forty-six centers were low-performing on both metrics at the same time, indicating considerable overlap between the two performance measures. Ninety-six centers were low-performing on *either* graft or patient survival rates.

Compared with centers meeting quality standards pre-CMS CoP, low-performing centers enrolled significantly less patients (55 vs 79 for performance in both settings, Table 1) and conducted less transplants (28 vs

35), on average. Other differences were noted in higher rates of waiting-list deaths (22.3 vs 20.3 percent in both settings, Table 1) and slightly lower rates of transfer (4.7 vs 5.3 percent) out from low-performing centers. Consistent with low-quality designation in both settings, average graft failure rates in the first three years post-transplantation were 2 to 3.4 percentage points higher at low-performing centers (Table 1).

Low-performing centers had lower proportion of minorities at the exception of black patients (29.8 vs 23.2 percent in both settings, Table 1), more female (39.4 vs 37.8 percent), less-than-college-educated (37 vs 40.8 percent), higher BMI (27.6 vs 27.1), Medicare patients (51.6 vs 44.5 percent), and patients with COPD (1.3 vs 1.2 percent), relative to centers meeting quality standards. However, low-performing centers had slightly less patients with high sensitization (3.6 vs 3.9 percent in both settings, Table 1).

FIGURE 1 Covariate-Adjusted Number of Transplants from 2003 to 2010—Performance on Either Graft or Patient Survival Rates. Panel (B): Centers meeting quality standards in Panel (A) are split to single out high-performing centers (green) from other “standard” performing centers (blue) [Color figure can be viewed at wileyonlinelibrary.com]

FIGURE 2 Covariate-Adjusted 1-Year Graft Failure Rate from 2003 to 2010—Performance on Either Graft or Patient Survival Rates. Panel (B): Centers meeting quality standards in Panel (A) are split to single out high-performing centers (green) from other “standard” performing centers (blue) [Color figure can be viewed at wileyonlinelibrary.com]

TABLE 2 Changes in kidney transplantation associated with low-performance post-CMS CoP regulation by performance measure

Outcome variables	Quality performance measures		
	1-year graft survival only	1-year patient survival only	Either graft or patient survival
Impact of low performance post CMS CoP			
No. of registrations ^d			
Low-performing center mean (2003 to 2007)	48.4	60.0	55.2
Incidence rate ratio	0.851 ^c	0.905 ^c	0.873 ^c
SE	0.023	0.024	0.022
No. of transplants			
Low-performing center mean (2003-2007)	25.4	30.2	27.5
Incidence rate ratio	0.802 ^c	0.864 ^c	0.864 ^c
SE	0.020	0.021	0.020
Transplant from ECD rate			
Low-performing center mean (2003-2007)	10.4%	10.4%	10.4%
Coefficient	-0.004	-0.005	-0.003
SE	0.010	0.009	0.008
Waiting-list removal rate: Death ^d			
Low-performing center mean (2003-2007)	21.2%	22.1%	22.3%
Coefficient	0.007	0.008	0.001
SE	0.011	0.010	0.010
Waiting-list removal rate: Transfer ^d			
Low-performing center mean (2003-2007)	15.1%	15.6%	15.5%
Coefficient	0.027 ^b	0.008	0.018 ^a
SE	0.012	0.011	0.010
Waiting-list removal rate: Other cause ^d			
Low-performing center Mean (2003-2007)	4.8%	4.0%	4.7%
Coefficient	0.001	0.014	0.001
SE	0.012	0.012	0.011
Graft failure rate (1 year) ^e			
Low-performing center mean (2003-2007)	6.8%	6.0%	6.3%
Coefficient	-0.019 ^c	-0.013 ^c	-0.016 ^c
SE	0.005	0.005	0.004
Graft failure rate (3 years) ^e			
Low-performing center mean (2003-2007)	12.2%	11.2%	11.5%
Coefficient	-0.030 ^c	-0.020 ^c	-0.026 ^c
SE	0.006	0.006	0.006

Notes: N = 2959. Negative Binomial regressions were estimated for the count variables and Least Squares (LS) regressions were estimated for proportion and rate outcome variables. Covariates used in all regressions include first lagged values for proportion of patient registrations by race/ethnicity (Black, Hispanic, Asian, and other; white is the reference category), average patient age, average patient BMI at listing, proportion of female, Medicare patients, patients with private insurance, highly sensitized patients, patients with college education, and patients with chronic diseases (diabetes, chronic obstructive pulmonary disease (COPD)), the number of annual kidney donations from deceased donors in the center's donor service area, and time period fixed effects. Coefficients on covariates are available upon request. Heteroskedasticity-robust SEs, in parentheses, are clustered at the center level.

^aIndicates significance at the 90% level. ^bIndicates significance at the 95% level. ^cIndicates significance at the 99% level. ^dAdditional covariates include first lagged values for the number of transplants. ^eAdditional covariates include proportion of ECD transplants.

5.2 | Regression-adjusted results

Figure 1 graphically presents results from modeling trends in the number of kidney transplants comparing centers with

low-performance rating on either 1-year graft or patient survival with centers meeting quality standards, considering the regulation publication and implementation as separate events. It shows a decline in the number of transplants at low-performing centers right

TABLE 3 Changes in kidney transplantation associated with low/high-performance post-CMS CoP regulation

Outcome variables																
Variables	No. of registrations		No. of transplants		Transplant from ECD rate		Waiting-list Removal rate: Death		Waiting-list removal rate: Transfer		Waiting-list removal Rate: Other cause		Graft failure rate (1 year)		Graft failure rate (3 years)	
	IRR		IRR		Coeff		Coeff		Coeff		Coeff		Coeff		Coeff	
Impact of low performing post-CMS CoP	0.854 ^b	(0.024)	0.884 ^b	(0.023)	-0.002	(0.010)	0.004	(0.011)	0.016	(0.012)	0.001	(0.013)	-0.017 ^b	(0.005)	-0.026 ^b	(0.007)
Impact of high performing post-CMS CoP	0.946 ^a	(0.031)	1.057 ^a	(0.031)	0.002	(0.009)	0.010	(0.012)	-0.007	(0.009)	0.0002	(0.014)	-0.003	(0.005)	-0.0004	(0.006)

Notes: See notes in Table 2. Coeff, coefficient; IRR, incidence rate ratio. Low-performing centers are defined as centers ever flagged for non-compliance with quality standards on either graft or patient survival rates.

^aIndicates significance at the 90% level. ^bIndicates significance at the 99% level.

around implementation of the CMS CoP, whereas centers meeting quality standards remained on an increasing trajectory (Figure 1 panel a). Patterns were similar among standard-performing and high-performing centers (Figure 1 panel b). Similarly, Figure 2 presents results from modeling trends in the 1-year graft failure rates post-transplantation. It indicates that following implementation of the CMS regulation, graft failure rates dropped significantly at low-performing centers, while they increased temporarily at centers meeting performance standards until about one-year post-regulation and then dropped (Figure 2 panels a and b). As the number of transplants and subsequent graft failure rates are outcomes readily used in evaluating quality of transplant centers, graphical representation was presented for both analyses for these two outcomes. Figure S1 presents results from modeling trends in the remaining outcome variables (registrations, rates of ECD transplants, 3-year graft failures, deaths, transfers and removals for other cause), when distinguishing between high performers and other standard performers. Low-performing centers experienced a slight drop in registrations post-regulation but high-performing centers experienced a more important decline in registrations between the regulation publication and implementation periods (Figure S1 panel a). ECD transplant rates declined across all performance groups between publication and implementation of the CMS CoP with a more pronounced decline at low-performing centers (Figure S1 panel b). Figure S1 panel c shows an important reduction in 3-year graft failure rates at low-performing centers while centers in compliance with the CMS CoP experienced a temporary increase in the first semester of 2007, and 3-year graft failure rates consistently dropped post-regulation implementation. Death rates slightly declined during the publication period at low-performing centers but increased in all centers in periods following implementation of the regulation (Figure S1 panel d). Transfer rates increased during the publication phase to remain stagnant at low-performing centers post-implementation, whereas they slightly declined at centers in compliance (Figure S1 panel e). Finally, Figure S1 panel f shows a jump in rates of removal for other cause in the second semester of 2007 across all transplant centers, followed by stagnation in trends.

Table 2 lists the coefficients on changes in the outcome variables at low-performing centers compared with centers meeting quality standards when the regulation change is measured as a one-time shift for the implementation period, controlling for patient demographics, comorbidities, organ supply, time trends, and centers' time-invariant characteristics. Low-performance designation post-regulation was associated with a 9 to 15 percent (or 5 to 7 patient registrations) decrease in patient enrollments when considering performance on graft survival (IRR = 0.85; 95 percent CI, 0.81-0.90; $P < 0.001$, Table 2), patient survival (IRR = 0.91; 95 percent CI, 0.86-0.95; $P < 0.001$), separately but also in both settings (IRR = 0.87; 95 percent CI, 0.83-0.92; $P < 0.001$). The drop in patient registrations was driven by reductions in registrations of older patients and severely and morbidly obese patients (Table S1). In periods following the CMS CoP, the number of transplant procedures also dropped with low performance by 14 to 20 percent (or 4 to 5 transplants)

(graft survival rating IRR = 0.80; 95 percent CI, 0.76-0.84; $P < 0.001$; patient survival rating IRR = 0.86; 95 percent CI, 0.82-0.91; $P < 0.001$; and in both settings IRR = 0.86; 95 percent CI, 0.83-0.90; $P < 0.001$; Table 2).

The regulation was also associated with a notable increase in the rate of waiting-list transfers out from low-quality centers by about 2 to 3 percentage points (or 2 to 3 per 100 patients), all else constant (Table 2). Statistically significant associations were also estimated with graft failure rates, which decreased at low-performing centers following the regulation implementation by up to 2 percentage points (or 2 per 100 failures) within one year of transplantation and 3 percentage points within three years (Table 2). These associations were substantial given the average graft failure rates ranging from 6.0 to 6.8 percent within one year and 11.2 to 12.2 percent at the 3-year mark at low-quality centers (Table 2). Additional analyses, not reported, showed significant changes in these outcomes as early as the first designation as low-performing in periods following the CMS CoP. The observed changes in the outcome variables were not driven by centers not observed in all time periods due to insufficient data to generate report cards (eg, new centers, those which had terminated their transplant program, centers which were temporarily not enrolling patients) (not shown). Significant changes were not observed for rates of ECD transplants, waiting-list deaths, and waiting-list removals for all other causes, following the regulation at low-performing centers.

When further distinguishing high-performing centers (a total of 37 centers) from others centers meeting performance standards, a marginally significant decrease of 5 percent was observed in registrations (IRR = 0.95; 95 percent CI, 0.89-1.01; $P = 0.087$, Table 3) at high-performing programs. This reduction was not driven by a decrease in admission of any single patient category (Table S2). Relative to average-performing programs and considering both quality ratings, about 12 percent of transplantations (IRR = 0.88; 95 percent CI, 0.84-0.93; $P < 0.001$) shifted away from low-performing centers and high-performing centers captured an estimated 6 percent (IRR = 1.06; 95 percent CI, 1.00-1.12; $P = 0.059$) of this decline. Additional analyses, not shown, indicated that the estimated changes in trends at low- and high-performing centers were robust to dropping data for the regulation publication period and were even higher in magnitude.

6 | DISCUSSION

Concurrent with previous studies,¹⁹⁻²¹ Medicare-based quality ratings were associated with important reductions in trends in kidney transplantation with substantial declines in transplant procedures at low-quality centers in periods following the regulation. Nonetheless, this shift was only partially captured by high-quality programs. Additionally, geographic dispersion of transplant centers could limit the extent to which transplants lost to low-performing programs would be absorbed by centers meeting quality standards. Although the estimated decrease in transplant procedures may not represent

all feasible procedures because of variations in quality of donated organs, patients' health conditions, and matching with donors, the modest but steady increase in supply of organs²⁵ may hint on a decrease in organ utilization rates across centers.^{22,26} Anecdotal evidence further pointed to fewer transplants in general and to centers becoming more conservative as a result of CMS scrutiny.²⁶

Registrations decreased at both low- and high-performing centers, possibly indicating risk averse behavior in the transplantation community.^{19,26} Nonetheless, there are a number of competing factors that could contribute to these results. First, the distance between centers may have limited the transfer of enrollments out from low to high performers because distance is an important factor in selection of health care providers.²⁷⁻²⁹ Second, findings suggested that the estimated reductions in registrations may be due to avoidance of high-risk patients such as older and (extremely) obese patients, two growing subpopulations.^{30,31} In contrast, patients (and referring physicians) may have become more cognizant of centers' performance, therefore altering sorting behavior. The existing literature on patients and physicians' use of quality information, investigating settings other than kidney transplantation, but pointing to mixed results, found that this type of information is rarely used effectively.³²⁻⁴² Nonetheless, it may be that in the case of kidney transplantation, there is greater patient engagement to compare quality ratings across centers. In all, the extent to which patients use provider quality information in kidney transplantation remains an empirical question for future studies. Though findings may not suffice to conclude that access has declined, the increasing prevalence of ESRD over the years¹⁴ coupled with the consistently increasing number of donors and the growing gap between waiting-list additions and (deceased- and living-donor) transplant volume over time²⁵ raise concerns.

The estimated reduction in graft failure rates at low-performing centers may imply an increase in quality of transplantation or a decline in transplantation of either marginal organs or riskier patients.^{12,26,43} The potential welfare effects of avoiding high-risk patients for enrollment and transplantation, or those associated with a decrease in the use of marginal kidneys for transplantation, were not clear and would require comparison of patients' benefits from transplantation to costs for patients remaining on dialysis, costs to which would be added the estimated costs to all other patients enrolled in the same programs if the centers were to close for low performance.

This analysis used rich data combining centers' report cards and several patient outcomes, to evaluate the relationship between the CMS CoP and trends in measures of access and quality of transplantation care. In addition to utilizing long time periods before the regulation, the use of various center-specific characteristics as confounders offered additional robustness to the analyses and contribution.

A limitation to this analysis is that although the conditions of participation apply to all liver and kidney transplant centers, the study only emphasized kidney transplantation. Because transplant facilities have multiple organ transplant programs (eg, kidney, liver, heart, pancreas, and kidney-pancreas) within their centers, low-quality designation on kidney (or liver) transplant outcomes may have some

spillover effects on other programs. Nonetheless, investigating kidney transplant programs independently is salient because kidney remains the most transplanted solid organ in the United States.²⁵ Future research should investigate the case of liver transplantation to inform on whether the relationship between the regulation and trends in transplantation varies across organ types.

Consistent with earlier findings of volume increase at high-quality programs following Medicare-based accreditation in bariatric surgery,^{17,18} results in this study showed that policy change enforcing quality standards in kidney transplantation was associated with a modest increase in transplants at high-performing centers. In light of findings on enrollments and transplants, an evaluation of the regulation's potential welfare effects is warranted. The CMS may therefore consider making the regulation less punitive for programs that expand access by employing new strategies and techniques in transplantation, so as to maximize the use of donated organs. This would alleviate risk-averse behavior that may lead to deleterious impacts on overall access to transplantation in the long run. Results, indicating the partial shift in procedures from low- to high-performing centers, also have implications for public policies increasing regionalization of specialty care to "Centers of Excellence." In sum, CMS should be aware of changes in provision of care associated with this regulation, when designing future quality improvement strategies.

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CONFLICT OF INTEREST

The authors have no conflicts of interest to report.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of the article.

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