

Mandating Staffing Ratios in Hemodialysis Facilities

California SB 349 and Unintended Consequences

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Maintenance hemodialysis is a life-sustaining treatment that imposes significant clinical challenges and expenses to the health care system, particularly Medicare. The Centers for Medicare and Medicaid Services, which oversees the payment and quality of care for patients receiving dialysis, does not mandate specific staffing ratios for dialysis facilities but has focused instead on tracking and publicly reporting outcomes (*e.g.*, the efficiency of urea removal, hemoglobin concentrations, the proportion of patients with selected forms of vascular access, *etc.*) in an effort to ensure safe and effective care (1,2). However, eight states (Georgia, Maryland, Massachusetts, New Jersey, Oregon, South Carolina, Texas, and Utah) and the District of Columbia have implemented regulations mandating specific staffing ratios in dialysis facilities. More recently, the California Senate and Assembly introduced bills (SB 349 and AB 251) aiming to improve quality of care for patients receiving maintenance hemodialysis by establishing fixed staffing ratios, minimal treatment transition times, more frequent inspections of facilities, and limiting facility medical loss ratios. In the fall of 2017, the bills were withdrawn when there seemed to be insufficient support from the California legislature and an indication from the Governor that he would not sign the final bills. Although well intentioned, there is no evidence that these provisions would improve quality of care, and in fact, serious unintended consequences are likely. The latter include decreasing access to care, decreasing choice of dialysis facilities, and treatment shifts among others. Below is a summary of the two key provisions of SB 349. (1) To establish a minimum of one dialysis nurse per every eight patients and one dialysis technician per every three patients. The current level of staffing in California is an average of one dialysis nurse per every 12 patients and one dialysis technician per every four patients. The ratios in the California bill are higher than in all other states that previously mandated staffing ratios. The proposed ratio will require hiring of approximately 2750 full-time equivalent nurses. On the basis of the most recent United States registered nurse report, a shortage of about 141,000 nurses in California is expected by 2030 (3). Moreover, on the basis of reports from the US Renal Data System (USRDS), the prevalence of treated ESKD is increasing, in part because of modest but consistent improvements in survival over the past decade (4). Combining these data with

challenges in recruiting newly graduated registered nurses to California (most likely due to exceptionally high costs of housing), a sizeable proportion of dialysis facilities will be unable to meet these mandates. The dialysis industry projects that SB 349 could lead to closure of up to 20% of currently active units and delay development of new facilities in areas needing additional capacity. Patients could be displaced from their current facilities and/or endure extended travel to a facility adhering to mandated staffing ratios. In fact, there is no evidence to support the proposed ratios. Although research to determine the optimal staffing mix and staff-to-patient ratios could be fruitful, to date, no adequately designed study has determined the association between staffing and outcomes in outpatient hemodialysis facilities. On the basis of publically available data from Dialysis Facility Compare and the ESKD Quality Incentive Program, outcomes, including survival, rates of hospitalization and infection, and patient satisfaction are not superior in states where mandated staffing ratios are in effect, and in California, where there are presently no mandated staffing ratios, outcomes are among the best in the United States. (2) To establish a minimum transition time of 45 minutes between treatments sessions. The transition between treatment sessions requires multiple actions, including completion of the prescribed session, removal of disposable materials (*i.e.*, dialyzer and tubing), ensuring that the patient is clinically stable (*e.g.*, measuring sitting and standing BP and ensuring hemostasis of the fistula or graft needle sites), disinfecting the equipment, and preparing the next patient for his or her session. This transition can range from 20 to 45 minutes depending on multiple factors. Proponents of the minimum transition time claim that this is necessary for proper infection control. However, guidelines for dialysis facility infection control published by the Centers for Disease Control and Prevention and the American Society of Nephrology make no mention of a minimum transition time (5,6). Disinfection can be completed in as few as 12 minutes. Imposing a fixed 45-minute transition time could lead to two unintended consequences. First, sizeable proportions of dialysis facilities, especially in rural areas, are currently running four treatment shifts per day 3 or 6 days per week (usually starting around 4 a.m. and extending through around 11 p.m.) to accommodate the needs of patients. Imposing a fixed,

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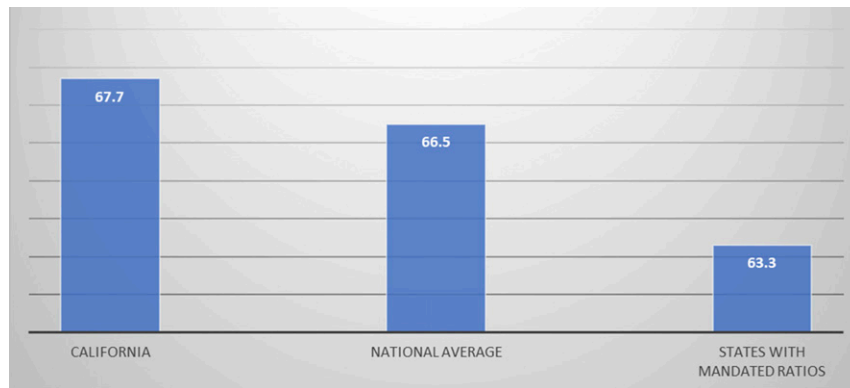


Figure 1. | Percentage of patients who rated their dialysis facility a nine or ten on a one to ten scale, indicating that patient satisfaction with the dialysis units in California was higher than in states with mandated staffing ratios or national averages.

lengthy transition time will essentially eliminate the ability to offer a fourth shift in these facilities, leading to displacement of patients, particularly those who are employed and require a late afternoon or evening shift on which to dialyze. Second, a fixed transition time will eliminate or at least sharply reduce flexibility in providing the scheduled session lengths for patients who arrive late to their appointments, which may be unavoidable (*e.g.*, due to traffic or other unexpected transportation issues). Skipping or shortening of dialysis sessions has been associated with adverse outcomes, including higher rates of mortality and hospitalization (7).

Hemodialysis care differs from other medical treatments in significant ways: several patients are cared for in the same space, with nurses always a few steps away. There is a long-term relationship between the treatment team and patients, and factors other than staffing ratios play an important role in clinical outcomes. In a recent study, physician engagement, interpersonal relationships among patients and the health care team, and more resourceful and knowledgeable dietitians were determined to be factors differentiating facilities with lower than expected mortality from those with higher than expected mortality (8). Although this study did not explore the association between staffing and outcomes, it highlights the importance of the interpersonal, individualized relationships in dialysis care.

On the basis of the most recent data from the USRDS, patients in California have the lowest mortality rates in hemodialysis among the 18 ESKD networks (9). Moreover, patient satisfaction in California is higher than in the rest of the nation, and interestingly enough, it is higher than in states with mandatory staffing (Figure 1) (10).

AB 251 would cap the medical loss ratio for any given dialysis facility, despite the fact that the most recent MedPAC report showed that dialysis facilities on average are losing money on Medicare beneficiaries: up to 4.5% per treatment. In addition to these bills, there is a move to place an initiative on the California ballot that would limit the charges that facilities can make for services and impose fines if these limits are exceeded. If California were to impose financial limits and/or fines on dialysis facilities, it would limit providers' ability to deliver and/or expand dialysis care, particularly in rural and underserved regions (11).

Advocates and lawmakers should heed the principle "*primum non nocere*" (at first do no harm). The proposed legislation and potential ballot initiative seem to be solutions in search of a problem. Strengthening the survey and certification process and monitoring of outcomes through publicly available data are reasonable approaches aimed toward improving outcomes for Californians on dialysis.

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