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## SUPPLEMENTAL ADMINISTRATIVE COMPLAINT

May 18, 2022

*By Email (ocrmail@hhs.gov and addresses listed below)*

Ms. Lisa Pino, Director  
Office for Civil Rights, HHS  
lisa.pino@hhs.gov

Mr. Michael Leoz, Regional Manager, Region IX  
Office for Civil Rights, HHS  
michael.leoz@hhs.gov

Peggy Lee, Deputy Regional Manager  
Alicia Brown, Supervisor  
Laura Coronado, Equal Opportunity Specialist  
Office for Civil Rights, HHS – Pacific Region  
yun-kyng.lee@hhs.gov  
alicia.brown@hhs.gov  
laura.coronado@hhs.gov

***Re: OCR Transaction Number 22-463083  
High-Speed Hemodialysis Has a Disparate Impact on Latino and Asian  
American Patients***

Complainants the Service Employees International Union-United Healthcare Workers West, the National Health Law Program, Roopa Bajwa, Virginia Robledo, John Does 1 and 2, and Jane Doe 1 (collectively, “Complainants”) submit this Supplemental Complaint against DaVita, Inc., Fresenius Medical Care North America, Inc., and Satellite Healthcare, Inc. (collectively, the “Dialysis Centers”) in the matter of OCR Transaction No. 22-463083. The original complaint, submitted on January 11, 2022, is incorporated by reference as though fully set forth here (hereinafter, “Complaint”).<sup>1</sup> This Supplemental Complaint is provided to follow up on questions from the Office for Civil Rights about who bears the responsibility for the civil rights violations alleged in the original Complaint.

As alleged in the Complaint, the Dialysis Centers have a practice of providing hemodialysis treatments at dangerously high speeds; that is, they use ultrafiltration rates that exceed 10 ml/h/kg. This practice falls disproportionately on Latino and Asian American patients. And as alleged in this Supplemental Complaint, this practice is squarely within the control of the

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<sup>1</sup> For ease of reference, the Complaint is included hereto as Exhibit A.

Dialysis Centers as set forth in the Conditions for Coverage for End-Stage Renal Disease facilities established by the Centers for Medicare & Medicaid Services (“CMS”).

## I. DISCUSSION

### A. The Conditions for Coverage for Participation in Medicare and Medicaid Make the Dialysis Centers Responsible for Patient Safety and Care.

CMS develops Conditions for Coverage (“Conditions”) for facilities providing care to patients with End Stage Renal Disease (“ESRD”), and under these Conditions, the Dialysis Centers are responsible for patient safety, including the speed at which dialysis is delivered. “The purpose of the existing conditions for coverage . . . is to protect dialysis patients’ health and safety and to ensure that quality care is furnished to all patients in Medicare-approved dialysis facilities.” 73 Fed. Reg. 20372 (Apr. 15, 2008). Facilities must meet the Conditions in order to participate in the Medicare and Medicaid programs. CMS also develops interpretive guidance, which it uses when evaluating whether the care and services of each facility meet the Conditions.

The Conditions make the dialysis facilities and the medical directors of the facilities broadly responsible for patient care and safety. The Conditions require facilities to have “a medical director . . . to be responsible for the delivery of patient care and outcomes in the facility.” 42 C.F.R. § 494.150. Further, facilities must have an interdisciplinary team that “consists of, at a minimum, the patient . . . a registered nurse, a physician treating the patient for ESRD, a social worker, and a dietitian.” 42 C.F.R. § 494.80. This team provides “each patient with an individualized and comprehensive assessment of his or her needs. The comprehensive assessment must be used to develop the patient’s treatment plan and expectations for care.” *Id.*

Notably, the patient’s prescription must be “individualized to meet the needs of the patient”<sup>2</sup> as part of the comprehensive assessment. *See* 42 C.F.R. § 494.80(a)(2). This includes reevaluating components of the prescription, such as the ultrafiltration rate, where the patient experiences symptoms, such as a muscle cramping or low blood pressure, that might indicate a need for adjustment.<sup>3</sup> Not only must the facility’s staff ensure that the dialysis prescription is individualized to meet the needs of the patient, but the patient’s record “should show evidence that the patient’s individual dialysis needs have been assessed and the current dialysis prescription evaluated as to whether it is meeting those needs.”<sup>4</sup>

Thus, the facility has the ultimate responsibility for ensuring that the prescription is individualized for the needs and safety of a patient, including the ultrafiltration rate component. Indeed, it is the responsibility of the medical director to “[e]nsure that [a]ll policies and procedures relative to patient admissions, patient care, infection control, and safety are adhered to by all individuals who treat patients in the facility, including attending physicians and

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<sup>2</sup> CMS, Interpretive Guidance, Tag V503 (Oct. 3, 2008), available at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/downloads/esrdpigmguidance.pdf> at 193 (last visited April 11, 2022) (hereinafter, “Interpretive Guidance”).

<sup>3</sup> *Id.*

<sup>4</sup> *Id.*

nonphysician providers.” 42 C.F.R. § 494.150(c)(2)(i). That is, the medical director is responsible for ensuring that the facility’s practices and policies around ultrafiltration rate are also adhered to by prescribing nephrologists. On information and belief, based on the records of the aggrieved Complainants and the analysis of Complainant SEIU-UHW, none of the Dialysis Centers have done so for either the individual complainants, or for any other patients receiving care at their facilities.

**B. The End Stage Renal Disease Network Clinical Standards Recommend a Maximum UFR of 13 ml/h/kg.**

Recommendations by CMS “Networks” also make the Dialysis Centers responsible for delivering dialysis at a safe speed. Networks are regional groups into which ESRD facilities are organized. These Networks are designated by CMS and tasked with “developing criteria and standards relating to the quality and appropriateness of patient care.” 42 C.F.R. § 405.2112. Northern California belongs to ESRD Network 17, while southern California belongs to Network 18.<sup>5</sup> Both Networks 17 and 18 are contracted to Health Services Advisory Group, which promulgates the clinical performance guidelines and standards of care that apply to those regions.<sup>6</sup> These standards “include quality statements that describe the care patients should receive and define requirements to assist all Medicare-certified ESRD facilities in providing high-quality treatment to patients.”<sup>7</sup>

The clinical standards for Network 17 explicitly recommend that “fluid removal during hemodialysis should . . . [have] an average UFR <13 ml/kg/hr per treatment, for all patients.”<sup>8</sup> Jane Doe 1 receives treatment at a facility in northern California that is subject to Network 17’s clinical standards concerning UFR. Nevertheless, Jane Doe 1’s treatments regularly exceed an ultrafiltration rate of 13 ml/h/kg.

While the clinical standards for Network 18, where the remaining individual complainants receive or did receive treatment, are not yet available, the standards for other networks overseen by the Health Services Advisory Group make similar recommendations. For

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<sup>5</sup> ESRD National Coordinating Center, ESRD Network Map, available at <https://www.esrdncc.org/en/ESRD-network-map/> (last visited April 12, 2022).

<sup>6</sup> See Health Services Advisory Group, Clinical Standards of Care and Guidelines, <https://www.hsag.com/en/esrd-networks/about-us/clinical-standards-of-care-and-guidelines/> (last visited April 12, 2022).

<sup>7</sup> Health Services Advisory Group, *Clinical Standards of Care for Network 17 Dialysis Facilities* (2019), available at <https://www.hsag.com/globalassets/esrd/clinical-standards/nw17clinicalstandardsofcare508.pdf> (last visited April 12, 2022).

<sup>8</sup> *Id.*

example, Network 7 (Florida) also recommends an average UFR less than 13 ml/h/kg,<sup>9</sup> as does Network 15 (Arizona, Colorado, Nevada, New Mexico, Utah, and Wyoming).<sup>10</sup>

## II. CONCLUSION

The Conditions for Coverage for participation in the Medicare and Medicaid programs make facilities and medical directors responsible for patient care and safety, including a responsibility to individualize patient prescriptions and treatment. The Dialysis Centers have failed to do so, instead routinely delivering hemodialysis at dangerously high ultrafiltration rates that exceed 13 ml/h/kg. This practice has a disparate impact on Latino and Asian American patients, who also disproportionately bear the risk of suffering adverse health consequences as a result.

Complainants respectfully request that the Office for Civil Rights require the Dialysis Centers to: (1) cease delivering hemodialysis treatment at ultrafiltration rates above 10 ml/h/kg, or at most 13 ml/h/kg; (2) conduct regular audits to ensure ultrafiltration rates do not exceed 10 ml/h/kg, or at most 13 ml/h/kg; and (3) undertake such other relief as may be needed to ensure that ultrafiltration rates do not exceed 10 ml/h/kg, or at most 13 ml/h/kg.

Should you have any questions, or if you would like to discuss any of the allegations raised by this Supplemental Complaint or the original complaint, please contact us at the telephone numbers and email addresses provided below.

Respectfully Submitted,

FEINBERG, JACKSON, WORTHMAN &  
WASOW LLP

By: /s/ Andrea Obando

Andrea Obando  
Catha Worthman  
2030 Addison Street, Suite 500  
Berkeley, CA 94704  
(510) 269-7998  
[andrea@feinbergjackson.com](mailto:andrea@feinbergjackson.com)  
[catha@feinbergjackson.com](mailto:catha@feinbergjackson.com)

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<sup>9</sup> Health Services Advisory Group, *Clinical Performance Guidelines and Standards of Care for Florida Dialysis Facilities* (2018), available at <https://www.hsag.com/globalassets/esrd/clinical-standards/nw7perfguidelinesstandardscare.pdf> (last visited April 12, 2022).

<sup>10</sup> Health Services Advisory Group, *Clinical Performance Guidelines and Standards of Care for Dialysis Facilities in Arizona, Colorado, Nevada, New Mexico, Utah, and Wyoming* (2019), available at <https://www.hsag.com/globalassets/esrd/clinical-standards/standardsofcafinal508.pdf> (last visited April 12, 2022).

NATIONAL HEALTH LAW PROGRAM

By: /s/ Jane Perkins

Jane Perkins  
1415 East Franklin St., Suite 110  
Chapel Hill, NC 27514  
[perkins@healthlaw.org](mailto:perkins@healthlaw.org)

Abbi Coursolle  
3701 Wilshire Blvd, Suite #750  
Los Angeles, CA 90010  
[coursolle@healthlaw.org](mailto:coursolle@healthlaw.org)

# EXHIBIT A



## ADMINISTRATIVE COMPLAINT

*By U.S. Mail and Email (ocrmail@hhs.gov and lisa.pino@hhs.gov)*

Ms. Lisa Pino, Director  
Office for Civil Rights, U.S. Department of Health & Human Services  
200 Independence Avenue SW, Room 509F  
Washington, D.C. 20201

Mr. Michael Leoz, Regional Manager, Region IX  
Office for Civil Rights, U.S. Department of Health & Human Services  
90-7th Street, Suite 4-100  
San Francisco, CA 94103

***Re: High-Speed Hemodialysis Has a Disparate Impact on Latino and Asian American Patients***

### I. INTRODUCTION

This administrative complaint challenges ongoing civil rights violations in the delivery of hemodialysis treatments at dialysis centers in California operated by DaVita, Inc. (“DaVita”) and Fresenius Medical Care North America, Inc. (“Fresenius”). Data, cited below, also implicates Satellite Healthcare Inc. (“Satellite”). These centers are collectively referred to as “the Dialysis Centers,” and they are responsible for the majority of hemodialysis services in California.

Hemodialysis is a life-sustaining treatment for patients suffering from End Stage Renal Disease. The only alternative to hemodialysis is a kidney transplant. The speed at which hemodialysis is provided is known as the ultrafiltration rate.

The Dialysis Centers have a practice of providing hemodialysis treatments at dangerously high speeds, or ultrafiltration rates that exceed 10 ml/h/kg, as described further below. Medical research has shown that ultrafiltration rates that exceed 10 ml/h/kg are associated with a higher mortality risk. Use of ultrafiltration rates that exceed 13 ml/h/kg are particularly dangerous, with a higher likelihood of death and other adverse consequences, such as permanent damage of the heart and loss of cognitive function. As described here, the adverse health consequences of this high-speed hemodialysis treatment are being disproportionately borne by Latino and Asian American patients, who in California are exposed to dangerously high hemodialysis treatments at a rate approximately 50% higher than White patients.

The Dialysis Centers are federal fund recipients. The disproportionately high likelihood that their Latino and Asian American patients face of receiving hemodialysis at ultrafiltration rates that exceed 10-13 ml/h/kg violates Title VI of the Civil Rights Act and the Department of

Health and Human Services's ("HHS") implementing regulations, as well as Section 1557 of the Affordable Care Act ("Section 1557").<sup>1</sup>

## **II. COMPLAINANTS AND RECIPIENTS**

This administrative complaint is filed against the Dialysis Centers by complainants, the Service Employees International Union-United Healthcare Workers West, the National Health Law Program, Roopa Bajwa, Virginia Robledo, John Does 1 and 2, and Jane Doe 1 (collectively, "Complainants"), on behalf of themselves and Latino and Asian American hemodialysis patients pursuant to Title VI, HHS regulations, and Section 1557.

### **A. Complainants**

#### **1. Service Employees International Union-United Healthcare Workers West**

Service Employees International Union-United Healthcare Workers West ("SEIU-UHW") is California's largest healthcare workers' union. It includes more than 93,000 members who are frontline caregivers and who work in hospitals, clinics, and other healthcare facilities, including hemodialysis clinics. Its members also include many hemodialysis patients. SEIU-UHW regularly engages in advocacy related to patient care, as part of which it conducted an extensive data analysis of hemodialysis facility reports and patient-level data that is summarized in this complaint. This analysis shows that Latino and Asian American patients are disproportionately exposed to high-speed hemodialysis.

#### **2. National Health Law Program**

The National Health Law Program ("NHeLP") is a non-profit legal organization that engages in policy, litigation, and education advocacy to improve access to quality health care for low-income and underserved people. For more than 50 years, NHeLP's work has centered on addressing discrimination by recipients of federal funds against individuals based on race, color, or national origin. NHeLP's California office engages in ongoing advocacy to ensure that enrollees in Medi-Cal, CHIP, and Medicare have access to quality, affordable health care.

#### **3. Individual Complainants**

The individual complainants have suffered symptoms, including low blood pressure, dizziness, headaches, and cramping, that are associated with high-speed hemodialysis and high ultrafiltration rates above 10-13 ml/h/kg.

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<sup>1</sup> Complainants urge the Office for Civil Rights to investigate ultrafiltration rates that exceed 10 ml/h/kg, as research that Complainants cite below shows associations between these high ultrafiltration rates and negative health consequences, such as cardiac events and death. However, because there is no publicly available data such as would support an analysis of ultrafiltration rates above 10 ml/h/kg and patient outcomes, Complainants also refer to ultrafiltration rates above 13 ml/h/kg, for which data is publicly available for analysis.



**a. Roopa Bajwa**

Roopa Bajwa brings this complaint on behalf of her late husband, Amar Bajwa. Mr. Bajwa was Asian American and a Medicare Part A and B beneficiary. He received hemodialysis treatment from a Fresenius facility in southern California from approximately 2014 until he tragically died while receiving hemodialysis in September 2021. The morning of his death, Mr. Bajwa appeared to his wife and children to be in perfect health: he prepared his breakfast, he went about his morning routine, and he drove himself to treatment. Neither Ms. Bajwa nor her children can comprehend how he could have passed so suddenly during treatment, but prior to his untimely death, Mr. Bajwa routinely suffered low blood pressure during almost every one of his hemodialysis sessions—a hallmark symptom of high ultrafiltration rates. He also experienced cramping in his hands and feet after his dialysis sessions, and in the past, he had been hospitalized after suffering a cardiac event during dialysis treatment.

**b. Virginia Robledo**

Virginia Robledo received hemodialysis treatment at a DaVita facility in Lemoore, California until approximately October 2020, when she received a kidney transplant. She is Latina, and her hemodialysis treatments were paid for through DaVita’s acceptance of her Medi-Cal coverage. Ms. Robledo frequently experienced dizziness and headaches during dialysis treatment, and she often requested medication from clinic staff because the headaches were unbearable. Ms. Robledo’s blood pressure often dropped during and after receiving hemodialysis treatment, and on one occasion, she was hospitalized for low blood pressure. When her blood pressure would drop, Ms. Robledo would call for assistance from staff members, but clinic staff frequently could not assist her because they were busy with other patients. Her treatments frequently left her feeling so poor that she would cry. Ms. Robledo’s sister also received hemodialysis treatments before she passed away. Ms. Robledo dreaded going in for hemodialysis treatment because she feared the same would happen to her.

**4. Doe Complainants**

The following complainants are current Latino patients at Medicare and Medi-Cal participating Dialysis Center facilities in California. All Doe complainants are Medicare or Medi-Cal beneficiaries. All Doe complainants have suffered symptoms associated with high ultrafiltration rates. All Doe complainants proceed anonymously because they fear retaliation—if the Dialysis Centers were to “involuntarily discharge” them from their facilities, their only alternative would be to seek treatment at a hospital emergency room.<sup>2</sup>

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<sup>2</sup> Involuntary discharges occur when a hemodialysis facility refuses to treat a patient. The End Stage Renal Disease networks, contracted by the Centers for Medicare & Medicaid Services to oversee the hemodialysis facilities in a given geographical region, *see* 42 C.F.R. §§ 405.2102, 405.2110, receive enough calls concerning involuntary discharges to have established guidelines for the prevention and reduction of these discharges, including checklists and procedures for conducting them. *See* End State Renal Disease Alliance Network 18,

The Doe complainants described below are willing to speak to OCR investigators provided sufficient assurances of confidentiality can be provided, such that they will not be placed at risk of losing access to life-sustaining treatment.

**a. John Doe 1**

John Doe 1 has been receiving hemodialysis treatment for three years. He currently receives treatment at a Medicare-Medi-Cal participating facility in southern California, where his hemodialysis sessions occur three times per week for approximately three hours each day. Mr. Doe 1 started experiencing frequent headaches after beginning hemodialysis treatment. In 2018, he suffered a fall after losing consciousness and was treated at a hospital immediately after the fall. The physician who treated Mr. Doe 1 opined that the cause of his loss of consciousness and headaches was the excessive removal of fluid from his body.<sup>3</sup> Mr. Doe 1's headaches became less frequent after DaVita staff were instructed to remove less fluid and reduce the speed of fluid removal. However, since March 2021, Mr. Doe 1 has been experiencing low blood pressure during many of his hemodialysis sessions. The low blood pressure is often accompanied by severe cramping and headaches. According to analyses conducted by Complainant SEIU-UHW, Mr. Doe 1's treatments regularly exceed an ultrafiltration rate of 13 ml/h/kg.

**b. John Doe 2**

John Doe 2 has been receiving hemodialysis treatment for nine years. He currently receives treatment at a facility in southern California three times per week for approximately three hours and thirty minutes each day. Mr. Doe experiences dizziness after most of his hemodialysis treatment sessions. This dizziness lasts for approximately three to four hours each day. He has been hospitalized for low blood pressure. He has witnessed a fellow patient die during hemodialysis treatment, and he fears the same may happen to him. According to analyses conducted by Complainant SEIU-UHW, Mr. Doe 2's treatments regularly exceed an ultrafiltration rate of 10 ml/h/kg.

**c. Jane Doe 1**

Jane Doe 1 has been receiving hemodialysis treatment for two and a half years at a Medicare/Medi-Cal participating facility in northern California. Ms. Doe 1 regularly experiences low blood pressure after hemodialysis treatment. It takes Ms. Doe a full day to recover from low blood pressure. According to analyses conducted by Complainant SEIU-UHW, Ms. Doe 1's treatments regularly exceed an ultrafiltration rate of 13 ml/h/kg.

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<https://esrdnetwork18.org/providers/patient-services/> (last visited Dec. 10, 2021); *see also* End State Renal Disease Alliance Network 18, *Involuntary Discharge Checklist for Dialysis Facilities*, [https://www.esrdnetwork18.org/wp-content/uploads/20191022-NW18-IVD\\_Checklist.pdf](https://www.esrdnetwork18.org/wp-content/uploads/20191022-NW18-IVD_Checklist.pdf) (last visited Dec. 10, 2021).

<sup>3</sup> Excessive fluid removal frequently goes hand-in-hand with a high ultrafiltration rate.

## **B. RECIPIENTS**

DaVita is a for-profit provider of dialysis services. DaVita operates dialysis facilities around the world, including approximately 2,910 clinics throughout the United States and approximately 352 clinics in California.<sup>4</sup> DaVita receives federal financial assistance through its provision of services to Medicare Advantage and Medicaid patients.<sup>5</sup>

Fresenius is a for-profit provider of dialysis services. Fresenius operates dialysis facilities around the world, including approximately 2,674 clinics in the United States and approximately 141 clinics in California.<sup>6</sup> Fresenius receives federal financial assistance through its provision of services to Medicare Advantage and Medicaid patients.

Satellite is a provider of dialysis services. Satellite operates primarily in California, with 66 facilities in California and only thirteen locations in the rest of the United States. Satellite receives federal financial assistance through its provision of services to Medicare Advantage and Medicaid patients.

The Dialysis Centers are the top three providers of hemodialysis in California, and they are responsible for approximately 73% of dialysis facilities in the United States and approximately 77% in California.<sup>7</sup>

## **III. LEGAL FRAMEWORK**

### **A. Title VI**

Title VI of the Civil Rights Act of 1964 provides a clear and comprehensive prohibition of discrimination in the use of federal funds: “No person . . . shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance.” 42 U.S.C. § 2000d. This prohibits utilizing methods of administration that have the effect of subjecting individuals to discrimination, or that have the effect of defeating or substantially impairing the objectives of the Medicare and Medicaid programs. *See* 45 C.F.R. § 80.3(b)(2) (rejecting the notion that a defendant’s challenged practice is acceptable if the disparate impact results from some facially non-discriminatory factor).

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<sup>4</sup> Facility counts derived from analysis of dialysis facilities registered with the Centers for Medicare and Medicaid Services, available at <https://data.cms.gov/provider-data/dataset/23ew-n7w9> (last visited Dec. 10, 2021).

<sup>5</sup> *See* Civil Rights Restoration Act, Pub. L. No. 100–259, § 382, 102 Stat. 28, 28–29 (1988) (overturning the United States Supreme Court’s decision in *Grove City Coll. v. Bell*, 465 U.S. 555, 556 (1984), to clarify that the civil rights laws reached an institution, as a whole, even if only part of the institution received federal funding).

<sup>6</sup> Facility counts derived from analysis of dialysis facilities registered with the Centers for Medicare & Medicaid Services, <https://data.cms.gov/provider-data/dataset/23ew-n7w9> (last visited Dec. 10, 2021).

<sup>7</sup> Facility count percentages derived from analysis of dialysis facilities registered with the Centers for Medicare & Medicaid Services, <https://data.cms.gov/provider-data/dataset/23ew-n7w9> (last visited Dec. 10, 2021).

**B. ACA Section 1557**

Specifically targeted to health programs and activities, Section 1557 of the ACA prohibits a similarly broad range of discrimination:

An individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance, including credits, subsidies, or contracts of insurance, or under any program or activity that is administered by an Executive Agency or any entity established under this title (or amendments).

42 U.S.C. § 18116(a). Section 1557 requires that “[t]he enforcement mechanisms provided for and available under [ ] title VI” also apply to violation of Section 1557. *Id.* Evidence sufficient to make out a Title VI violation also establishes a Section 1557 violation. Accordingly, Section 1557 must be interpreted to provide for disparate impact claims brought on behalf of a class or by a third party, and Respondents cannot, consistent with Section 1557, discriminate on the basis of race or national origin.

As recipients of Medicare and Medicaid payments, the Dialysis Centers are subject to the requirements of Title VI and implementing regulations and Section 1557.

**IV. DISCUSSION**

**A. Hemodialysis Is a Vital, Life-Sustaining Treatment for Patients Suffering from End Stage Renal Disease.**

Hemodialysis<sup>8</sup> is a life-sustaining treatment for people who have End Stage Renal Disease (“ESRD”), the last stage of chronic kidney disease, or kidney failure.<sup>9</sup> Hemodialysis serves two primary functions: (1) it filters toxins from blood, and (2) it removes excess fluid (water) from the body. During a dialysis treatment, blood and fluid are removed from the body, filtered by the hemodialysis machine, and returned to the body.<sup>10</sup> Patients with ESRD must receive hemodialysis treatments to replace the filtering functions of their failing kidneys. The only alternative to hemodialysis is a kidney transplant.<sup>11</sup> Most patients receive in-center hemodialysis treatment approximately three times a week.

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<sup>8</sup> Hemodialysis is performed at dialysis clinics and is commonly referred to simply as “dialysis.”

<sup>9</sup> See National Kidney Foundation, *Hemodialysis: What You Need to Know*, at 5, [https://www.kidney.org/sites/default/files/11-50-0214\\_hemodialysis.pdf](https://www.kidney.org/sites/default/files/11-50-0214_hemodialysis.pdf) (last visited Dec. 10, 2021).

<sup>10</sup> *Id.* at 6.

<sup>11</sup> See *id.* at 4 (treatment for kidney failure includes dialysis and kidney transplant).

Approximately 785,883 people in the United States have ESRD.<sup>12</sup> Due primarily to population changes, as well as the prevalence of obesity and diabetes (which can lead to kidney failure), the number of patients with ESRD is expected to grow by up to 68 percent by 2030.<sup>13</sup> Today in California, over 65,000 patients receive dialysis, the vast majority of them at one of over 600 outpatient hemodialysis facilities.<sup>14</sup> Approximately 43% of all California dialysis patients are Latino and approximately 18% of all California dialysis patients are Asian American.<sup>15</sup>

Despite the prevalence of ESRD and hemodialysis, the survival rates are grim. In the United States, one in four hemodialysis patients die within a year of initiating treatment.<sup>16</sup> Six in ten die within five years.<sup>17</sup> These mortality rates are far bleaker than much of the rest of the world. For example, patients receiving hemodialysis in the United States are more likely to die following the first year of treatment than hemodialysis patients receiving treatment in Australia, New Zealand, Belgium, Canada, France, Germany, Italy, Sweden, and the UK.<sup>18</sup>

The dangers of hemodialysis increase when treatment is delivered at higher speeds.<sup>19</sup> Notably, the countries with the lowest mortality rates are more likely to deliver hemodialysis with longer session times that equate to lower speeds.<sup>20</sup> For example, in Europe, the average treatment time is approximately 10% longer than it is in the United States.<sup>21</sup>

**B. The Ultrafiltration Rate, or the Speed at Which Hemodialysis Is Conducted, Is a Function of the Amount of Fluid to Be Removed, Session Length, and the Patient's Weight.**

Most people on maintenance hemodialysis have little or no residual kidney function. To prevent fluid overload, all fluid consumed between hemodialysis treatments must be removed at the next treatment. The goal of ultrafiltration is to return the hemodialysis patient to their base,

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<sup>12</sup> United States Renal Data System, *End Stage Renal Disease, Chapter 1: Incidence, Prevalence, Patient Characteristics, and Treatment Modalities*, <https://adr.usrds.org/2020/end-stage-renal-disease/1-incidence-prevalence-patient-characteristics-and-treatment-modalities> (last visited Dec. 10, 2021)

<sup>13</sup> See Keith P. McCullough et al., *Projecting ESRD Incidence and Prevalence in the United States Through 2020*, 30(1) *J. Am. Soc. Nephrology* 127 (2019), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6317596/>.

<sup>14</sup> Calculation derived from analysis of 2020 Dialysis Facility Reports, <https://data.cms.gov/dialysis-facility-reports>.

<sup>15</sup> *Id.*

<sup>16</sup> United States Renal Data System, Reference Table I: Patient Survival, <https://adr.usrds.org/2020/reference-tables> (click "I. Patient Survival") (last visited Dec. 10, 2021).

<sup>17</sup> *Id.*

<sup>18</sup> Bruce M. Robinson et al., *Worldwide, Mortality Risk is High Soon After Initiation of Hemodialysis*, 85 *Kidney Int'l* 158, 160 (2014).

<sup>19</sup> See Jennifer Flythe et al., *Rapid Fluid Removal During Dialysis is Associated with Cardiovascular Morbidity and Mortality*, 79 *Kidney Int'l* 250 (2011) (finding that dialysis performed at higher speeds is associated with a greater risk of cardiovascular death).

<sup>20</sup> See R. Saran et al., *Longer Treatment Time and Slower Ultrafiltration in Hemodialysis: Associations with Reduced Mortality in the DOPPS*, 69 *Kidney Int'l* 1222, 1223 (2006).

<sup>21</sup> *Id.*

target weight.<sup>22</sup> The volume of fluid that must be removed during the hemodialysis session is calculated by subtracting the patient's base, target weight from their weight at the start of a dialysis session.<sup>23</sup> The speed at which the fluid is removed is the ultrafiltration rate ("UFR").

UFR is a function of the amount of fluid to be removed (in milliliters), the treatment time or hemodialysis session duration (in hours), and body weight (in kilograms). As such, the session length or treatment time is a significant factor in determining the UFR or fluid removal rate, with longer treatment sessions resulting in a lower UFR and shorter treatment sessions resulting in a higher UFR.

For example, in a patient weighing 100 kilograms (220 pounds) that needs 5 liters of fluid removed:

- With a treatment time of 3 hours of hemodialysis has a UFR of 16.7 ml/h/kg
- With a treatment time of 4 hours of hemodialysis has a UFR of 12.5 ml/h/kg
- With a treatment time of 5 hours of hemodialysis has a UFR of 10.0 ml/h/kg
- With a treatment time of 6 hours of hemodialysis has a UFR of 8.3 ml/h/kg.<sup>24</sup>

Ultrafiltration has a disproportionate impact on patients with relatively low body weight. Holding the amount of fluid to be removed and treatment time constant, as body weight decreases, UFR increases. That is because the same amount of fluid is a larger proportion of body weight for a lighter person as compared to a heavier person. With a treatment time of 4 hours and 5 liters of fluid to be removed:

- A person weighing 125 kg (276 pounds) has a UFR of 10.0 ml/h/kg
- A person weighing 100 kg (220 pounds) has a UFR of 12.5 ml/h/kg
- A person weighing 75 kg (165 pounds) has a UFR of 16.7 ml/h/kg
- A person weighing 50 kg (110 pounds) has a UFR of 25.0 ml/h/kg.<sup>25</sup>

### **C. Hemodialysis Conducted at a High Ultrafiltration Rate Is Associated with Higher Mortality, Cardiac Events, and Negative Health Consequences.**

Ultrafiltration rates are a critical component in hemodialysis safety, and since the mid-2000s, medical literature has increasingly recognized high ultrafiltration rates as a risk factor for mortality and other grave complications.<sup>26</sup> In particular, research has found a significant

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<sup>22</sup> See National Kidney Foundation, *Ultrafiltration*, <https://www.kidney.org/atoz/content/ultrafiltration> (last visited Dec. 10, 2021).

<sup>23</sup> See *id.*

<sup>24</sup> Calculated using the Home Dialysis Central Ultrafiltration Rate Calculator, <https://homedialysis.org/home-dialysis-basics/ufr-calculator> (last visited Dec. 10, 2021).

<sup>25</sup> *Id.*

<sup>26</sup> See, e.g., Charles Chazot et al., *Even a Moderate Fluid Removal Rate During Individualised Haemodialysis Session Times is Associated with Decreased Patient Survival*, 44 *Blood Purification* 89 (2017) (finding that

association between UFRs that are equal to or exceed 10 ml/h/kg and higher mortality risk. The association is even stronger when the UFR is equal to or exceeds 13 ml/h/kg.<sup>27</sup> The Kidney Care Quality Alliance (an organization dedicated to developing quality care measures for use in dialysis care) has developed measures using a UFR of less than 13 ml/h/kg as a quality measure.<sup>28</sup> The National Quality Forum has endorsed the KCQA measure.<sup>29</sup> Further, the Centers for Medicare & Medicaid Services (“CMS”) has proposed using a UFR of 13 ml/h/kg as a data collection measure,<sup>30</sup> and the National Kidney Foundation has acknowledged that the 13 ml/h/kg target “has the most consensus among experts.”<sup>31</sup>

Higher UFRs are also associated with higher rates of hospitalizations and longer post-hemodialysis recovery times.<sup>32</sup> Patients who receive hemodialysis at a higher UFR are also more likely to suffer cardiac events,<sup>33</sup> nausea, vomiting, severe leg cramps, dizziness,<sup>34</sup> and low blood

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ultrafiltration rates above 7.8 ml/h/kg are associated with increased mortality risk); Magdalene Assimon et al., *Ultrafiltration Rate and Mortality in Maintenance Hemodialysis Patients*, 68(6) *Am. J. of Kidney Disease* 911 (2016) (high ultrafiltration rates associated with greater mortality in study examining 118,394 patients); Jennifer Flythe et al., *Rapid Fluid Removal During Dialysis is Associated with Cardiovascular Morbidity and Mortality*, 79 *Kidney Int'l* 250 (2011) (finding that dialysis performed at higher speeds is associated with a greater risk of cardiovascular death); R. Saran et al., *Longer Treatment Time and Slower Ultrafiltration in Hemodialysis: Associations with Reduced Mortality in the DOPPS*, 69 *Kidney Int'l* 1222, 1223 (2006).

<sup>27</sup> See *id.*34.

<sup>28</sup> See National Quality Forum, *NQF-Endorsed Measures for Renal Conditions, 2015, Technical Report* at 65-66, available at [https://www.qualityforum.org/Publications/2015/12/Renal\\_Measures\\_Final\\_Report.aspx](https://www.qualityforum.org/Publications/2015/12/Renal_Measures_Final_Report.aspx) (2015) (last visited Dec. 10, 2021).

<sup>29</sup> *Id.*

<sup>30</sup> National Quality Forum (2015) Renal: Draft Report for Comment at 98. Retrieved from: [http://www.qualityforum.org/Projects/n-r/Renal\\_Measures/Draft\\_Report\\_for\\_Comment.aspx](http://www.qualityforum.org/Projects/n-r/Renal_Measures/Draft_Report_for_Comment.aspx).

<sup>31</sup> The CMS standard was proposed as part of the proposed rule for the ESRD Quality Incentive Program for Payment Year 2020. See 81 Fed. Reg. 42839 (proposed June 30, 2016) (to be codified at 42 C.F.R. pt. 414). While quality care advocates have been advocating for the adoption of this standard, it has not yet been codified. See, e.g., Letter from National Kidney Foundation to Andrew Slavitt, Acting Administrator for the Centers for Medicare and Medicaid Services (Aug. 19, 2016), <https://www.kidney.org/sites/default/files/20160817%20NKF%20Comments%20on%20ESRD%20PPS%20AKI%20and%20QIP.PDF>.

<sup>32</sup> Jennifer Flythe et al., *Effect of Ultrafiltration Profiling on Outcomes Among Maintenance Hemodialysis Patients: A Pilot Randomized Crossover Trial*, 34 *J. of Nephrology* 113 (2020).

<sup>33</sup> Mehmet Kanbay et al., *An Update Review of Intradialytic Hypotension: Concept, Risk Factors, Clinical Implications and Management*, 13(6) *Clinical Kidney J.* 981 (2020); James O. Burton et al., *Hemodialysis-Induced Cardiac Injury: Determinants and Associated Outcomes*, 4 *Clinical J. Am. Soc’y of Nephrology* 914 (2009).

<sup>34</sup> See National Kidney Foundation, *KDOQI Clinical Practice Guidelines for Cardiovascular Disease in Dialysis Patients*, [https://kidneyfoundation.cachefly.net/professionals/KDOQI/guidelines\\_cvd/intradialytic.htm](https://kidneyfoundation.cachefly.net/professionals/KDOQI/guidelines_cvd/intradialytic.htm) (last visited Dec. 10, 2021) (nausea, vomiting, muscle cramps, and dizziness are associated with low blood pressure during hemodialysis sessions).

pressure that leaves them at risk of losing consciousness.<sup>35</sup> High UFRs can also lead to permanent damage of the heart and loss of cognitive function.<sup>36</sup>

Fresenius has known for *at least ten years* that high UFRs pose health risks: in a 2011 memo addressed to clinicians, Fresenius acknowledged that data indicated that a UFR greater than 10 ml/h/kg was associated with higher mortality risk.<sup>37</sup> Fresenius wrote that “Medical Directors and Attendings are strongly encouraged to implement this clinical practice recommendation to initiate . . . with a minimum dialysis treatment time of 4 hours, while aiming for UFR at  $\leq 10$  ml/kg/hr.”<sup>38</sup> On information and belief, DaVita has a similar policy of not allowing UFR to exceed 13 ml/h/kg. Nevertheless, both DaVita and Fresenius have continued to provide treatments at levels that exceed their own internal recommendations, and according to an analysis conducted by Complainant SEIU-UHW, Satellite also has a practice of exceeding UFRs of 13 ml/h/kg.<sup>39</sup>

#### **D. Limiting High Ultrafiltration Rates Results in Identifiable Differences in Patient Outcomes.**

UFR and treatment time are modifiable hemodialysis practices. UFR is under the direct control of hemodialysis providers: it can be monitored throughout the hemodialysis session, and it can be lowered by extending treatment time. Facilities also have access to their UFR in real time, yet the Dialysis Centers continue to exceed UFRs of 13 ml/h/kg.

Research is clear that facilities can successfully modify their treatment practices. When facilities implement practices to limit ultrafiltration rates, as Wake Forest University and Northwest Kidney Centers have done, they achieve dramatic, positive results: the percent of patient months with treatments that exceed 13 ml/h/kg falls as low as 1.9%—California’s average is closer to 12%.

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<sup>35</sup> Chitrada Thongdee et al., *Ultrafiltration Rates and Intradialytic Hypotension: A Case-control Sampling of Pooled Haemodialysis Data*, *J. of Renal Care* 1 (2020); Jason A. Chou et al., *Intradialytic Hypotension, Blood Pressure Changes and Mortality Risk in Incident Hemodialysis Patients*, 33(1) *Nephrology Dialysis Transplantation* 149 (2018).

<sup>36</sup> See Hemodialysis Central, *Organ Stunning on Hemodialysis: What Is It and What Can You Do?*, <https://homedialysis.org/life-at-home/articles/organ-stunning-on-hemodialysis-what-is-it-and-what-can-you-do> (last visited Dec. 10, 2021) (citations omitted) (noting that fast fluid removal, or high ultrafiltration, during hemodialysis can lead to organ “stunning,” tissue damage leading to permanent heart damage, and loss of cognitive function).

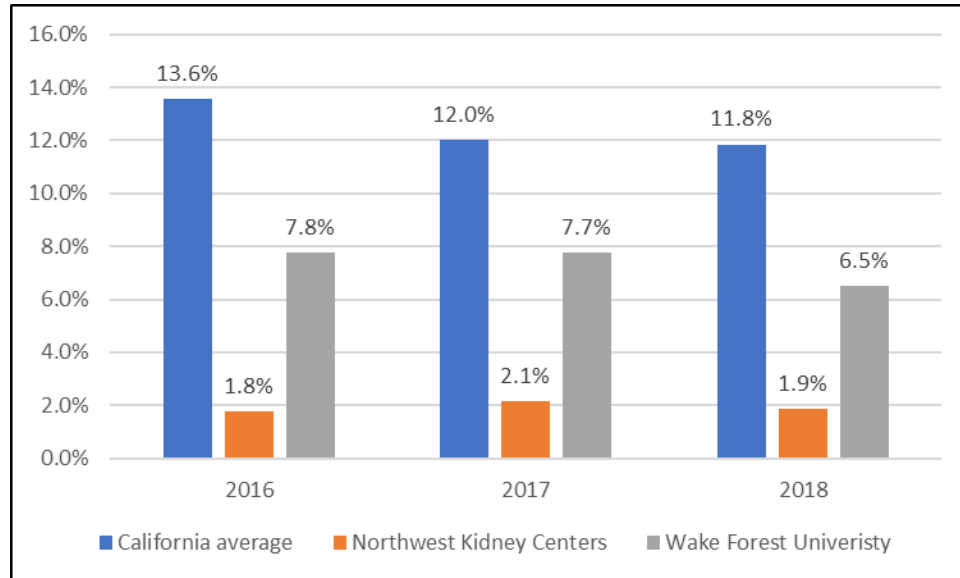
<sup>37</sup> Document available upon request. As far as Complainants are aware, this guidance remains in place today.

<sup>38</sup> *Id.*

<sup>39</sup> Based on Complainant SEIU-UHW’s analysis of available data, available upon request: C. Kirkman and A. Logemann, *Disparities in High Ultrafiltration Rate Hemodialysis in the United States* (2021).



**Figure 1: Percent of Patient Months with UFR Exceeding 13 ml/h/kg**



**E. High Ultrafiltration Rates Are Pervasive in California Hemodialysis Centers and Disproportionately Affect Latino and Asian American Patients.**

The Dialysis Centers’ practices of routinely providing treatment at ultrafiltration rates known to be associated with increased risk of death and other adverse health events disproportionately subject Latino and Asian American patients to poor health outcomes and risk of fatality. Dialysis Centers submit a monthly sample of data to the Centers for Medicare & Medicaid Services; and according to Complainant SEIU-UHW’s analysis of California data,<sup>40</sup> which was reviewed by an independent nephrologist, more than one million hemodialysis treatments a year are delivered at a UFR greater than 13 ml/h/kg, including at facilities operated by the Dialysis Centers. During the three-year period of 2016-2018, Complainants estimate that approximately 3.5 million treatments in California exceeded a UFR of 13 ml/h/kg.<sup>41</sup> Put another way, that is approximately 3.5 million times a year that the risk of death is increased by the unnecessary and unsafe practice of high UFR.

Collectively, Latino and Asian American patients are exposed to these high speed treatments at a rate approximately 50% higher than White patients. Approximately one in five treatments delivered to Asian American patients is delivered at dangerously high speeds above 13 ml/h/kg, and the picture is only marginally better for Latino patients, who receive

<sup>40</sup> In the interest of brevity, Complainants do not include with this Complaint their complete analyses or methodology. The full reports are available upon request, and due to lags in the release of the underlying data, includes analysis of the period from 2016-18. Patient-level analysis includes analysis of long-term patients who have already completed one year of dialysis.

<sup>41</sup> Estimate based on an extrapolation of monthly reporting by dialysis facilities to CMS.

approximately one in seven treatments at speeds above 13 ml/h/kg. From over 800,000 monthly treatments submitted to CMS in the three-year period from 2016 to 2018, Latino and Asian American patients received over 134,000 treatments at UFRs above 13 ml/h/kg.<sup>42</sup> Given that hemodialysis patients receive approximately 13 treatments in an average month, Complainants believe that the true number of treatments delivered to long-term Latino and Asian American patients at UFRs greater than 13 ml/h/kg from 2016-2018 is closer to 1.75 million. Collectively, Latino and Asian American patients accounted for 65% of all treatments delivered at UFRs above 13 ml/h/kg. This is so despite Latino and Asian American patients accounting for only 56% of all treatments and only 54% of the entire patient population analyzed. By way of comparison, during the same period, White patients received treatments that exceeded 13 ml/h/kg approximately 11% of the time, or only approximately 40,000 of 370,000 recorded treatments over the same period. White patients also accounted for only 20% of all treatments above 13 ml/h/kg. This is so despite accounting for 25% of all treatments and 27% of the patient population analyzed.

These disparities widen at 10 ml/h/kg, i.e., the level that Fresenius's internal guidance recommends that clinics aim to stay below. Approximately 42% of all treatments delivered to Asian American patients from 2016-2018 exceeded a UFR of 10 ml/h/kg, while 37% of all treatments delivered to Latino patients exceeded 10 ml/h/kg. Collectively, Latino and Asian American patients accounted for 63% of all treatments delivered at UFRs above 10 ml/h/kg. During the same time period, White patients received treatments at a UFR greater than 10 ml/h/kg only 29% of the time, and they accounted for only 21% of all treatments above 10 ml/h/kg.

As discussed in Section IV.C, *supra*, patients treated with higher ultrafiltration rates are more likely to have heart failure compared with patients treated with lower ultrafiltration rates. The same is true for other negative health consequences, including low blood pressure and loss of cognitive function. Thus, the adverse health outcomes of these high UFR treatments are also disproportionately borne by Latino and Asian American patients. In an average month with thirteen dialysis treatments, Asian American patients should expect to receive six treatments at UFRs above 10 ml/h/kg, while Latino patients should expect to receive five treatments a month at this dangerously high level. That is, five to six times a month that their risk of dying, like Mr. Bajwa, is increased by the unnecessary and unsafe practice of high UFR.

According to Complainant SEIU-UHW's analysis of publicly available data aggregated at the facility level,<sup>43</sup> 60% of the facilities with the highest proportion of treatments that exceed 13 ml/h/kg had more deaths than expected, as compared to only 40% at facilities with the lowest proportion of UFR treatments over 13 ml/h/kg.<sup>44</sup> The facilities with the most treatments over 13

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<sup>42</sup> Because this analysis is based on monthly reports by dialysis facilities to CMS, Complainants believe that the true number of treatments delivered at UFRs greater than 13 ml/h/kg is much higher.

<sup>43</sup> There is no publicly available data that would allow for an analysis of patient outcomes at the patient and demographic level. The only data available is at the aggregate and facility level.

<sup>44</sup> There is no publicly available data that would allow for an analysis of patient outcomes at UFRs greater than 10 ml/h/kg. The only data available is at 13 ml/h/kg.

ml/h/kg also had greater hospital readmissions (62% versus 42%); greater emergency department visits that result in hospital admissions (48% versus 44%); and more patients with at least one emergency department visit (63% versus 57%).

Notably, the facilities with the highest proportion of treatments that exceed 13 ml/h/kg (and also with the worst patient outcomes) disproportionately serve Latino patients: despite accounting for only 43% of the total population of dialysis patients in California, Latino patients make up 53% of the patient population at the facilities that are the worst offenders when it comes to providing hemodialysis at rates that exceed 13 ml/h/kg. This relationship between race and dangerously high ultrafiltration rates has also been independently noted by the Centers for Medicare & Medicaid Services, which found there to be a statistically significant difference in ultrafiltration rate between the facilities with the highest Latino population and the lowest, with more treatments delivered at UFRs that exceed 13 ml/h/kg at those facilities with larger Latino populations.<sup>45</sup>

The Dialysis Centers' practice of delivering hemodialysis at UFRs above 10-13 ml/h/kg falls disproportionately on Latino and Asian American patients and therefore violates Title VI, the HHS implementing regulations, and Section 1557.

**F. There Is No Justification for the Disparate Impact Caused by the High Ultrafiltration Rates.**

Under Title VI, the HHS Title VI regulations, and Section 1557, a showing of disparate impact shifts the burden to the Dialysis Centers to justify the adverse disparate impact on Latino and Asian American patients as necessary or legitimate under the Medicare or Medicaid statutes.

Complainants respectfully submit that the Dialysis Centers are unable to justify the disparate impact of high-speed hemodialysis treatment. A central objective of the Medicare and Medi-Cal programs is to provide quality care, which the Dialysis Centers fail to uphold by providing hemodialysis with dangerously high ultrafiltration rates that make Latino and Asian American patients disproportionately susceptible to negative health outcomes associated with high ultrafiltration rates.

Indeed, the Dialysis Centers could provide hemodialysis treatment in ways that have a less discriminatory effect on Latino and Asian American patients by, for example, instituting and enforcing a policy prohibiting ultrafiltration rates above 10 ml/h/kg or, at most, 13 ml/h/kg. This would be an exceptionally easy change for them to make, as evidenced by the Fresenius internal memo, described above.

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<sup>45</sup> See National Quality Forum, *Measure #2700 Ultrafiltration rate >13 ml/kg/hour*, retrieved from <http://www.qualityforum.org/ProjectTemplateDownload.aspx?SubmissionID=2700> (last accessed Feb. 2, 2021).

## V. CONCLUSION

By providing hemodialysis at dangerously high UFRs, which clinical studies have correlated to poor health outcomes and fatalities, the Dialysis Centers are failing to ensure quality health care through the Medicare and Medi-Cal programs. The Dialysis Centers' practices of providing hemodialysis at high UFRs—and the harms associated with those practices—fall disproportionately on Latino and Asian American patients, who are each exposed to dangerously high UFRs at nearly double the rates of White patients. Accordingly, the Dialysis Centers are subjecting Latino and Asian American patients to discrimination on the basis of race.

Under 45 C.F.R. § 80.7(c), the Office for Civil Rights must undertake a prompt investigation of this Complaint. Based on the evidence discussed in this complaint, the Office for Civil Rights should find that the Dialysis Centers have violated Title VI, the HHS Title VI implementing regulations, and Section 1557. The Office for Civil Rights should require the Dialysis Centers to: (1) cease delivering hemodialysis treatment at an ultrafiltration rate above 10 ml/h/kg, or at most 13 ml/h/kg; (2) conduct regular audits to ensure ultrafiltration rates do not exceed 10 ml/h/kg, or at most 13 ml/h/kg; and (3) undertake such other relief as may be needed to ensure ultrafiltration rates do not exceed 10 ml/h/kg, or at most 13 ml/h/kg.

Given the health risks described above, Complainants urge the Office for Civil Rights to initiate investigation of this Complaint as soon as possible. Should you have any questions, or if you would like to discuss any of the allegations raised by Complainants, please contact us at the telephone numbers and email addresses provided below.

Respectfully Submitted,

FEINBERG, JACKSON, WORTHMAN &  
WASOW LLP

By: /s/ Andrea Obando

Andrea Obando  
Catha Worthman  
2030 Addison Street, Suite 500  
Berkeley, CA 94704  
(510) 269-7998  
[andrea@feinbergjackson.com](mailto:andrea@feinbergjackson.com)  
[catha@feinbergjackson.com](mailto:catha@feinbergjackson.com)

NATIONAL HEALTH LAW PROGRAM

By: /s/ Jane Perkins

Jane Perkins  
1415 East Franklin St., Suite 110  
Chapel Hill, NC 27514  
[perkins@healthlaw.org](mailto:perkins@healthlaw.org)

Abbi Coursolle  
3701 Wilshire Blvd, Suite #750  
Los Angeles, CA 90010  
[coursolle@healthlaw.org](mailto:coursolle@healthlaw.org)