



601 Pennsylvania Avenue, NW
South Building, Suite 500
Washington, D.C. 20004

T 202.778.3200
F 202.331.7487
ahip.org

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Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3409-NC
PO Box 8010
Baltimore, MD 21244

Submitted electronically via regulations.gov

Re: [CMS-3409-NC] Request for Information; Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities

Dear Administrator Brooks-LaSure,

On behalf of AHIP¹, thank you for the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS') Request for Information (RFI) on Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities, published in the *Federal Register* on December 3, 2021.

We share the Administration's commitment to improving the quality and safety of care delivered in the transplant ecosystem, while strengthening access to care and upholding principles of competitiveness. Health insurance providers engage in a wide variety of activities and programs designed to improve health care access, quality, and value for the populations they serve. Our member companies implement policies that protect patient safety, emphasize evidence-based care, drive better health outcomes, and support quality reporting.

Based on this experience, AHIP supports CMS' intentions to make impactful, system-wide improvements to diagnosing kidney disease early, promoting early interventions, and overall efforts to improve kidney care and the transplantation health system. Organ donation and transplantation have saved the lives of millions of Americans, and it is imperative that federal rules protect and improve the health of patients in need.

¹AHIP is the national association whose members provide health care coverage, services, and solutions to hundreds of millions of Americans every day. We are committed to market-based solutions and public-private partnerships that make health care better and coverage more affordable and accessible for everyone. Visit www.ahip.org to learn how working together, we are Guiding Greater Health.

Improving Quality of Care

Any efforts to make system-wide improvements must ensure that patients receive high quality care, regardless of the setting, payment, or delivery model. To achieve these results, we encourage CMS to take the following steps:

- **Work with stakeholders to produce better clinical guidance and best practices for clinicians, so that providers of all types, across all care settings can follow this important information.**
- **Support further research that informs evidence-based decision making across all aspects of care**, including medication management; dialysis decisions; care management; evaluation of transplant options; and strategies to address barriers that may impact a patient's care, like social determinants of health.
- **Provide patients with the flexibility to make decisions about their kidney health that best fits their and their family's needs.** This should start with early diagnosis, education, and interventions. Patients must have access to information and tools that enable an informed decision in collaboration with their providers. Patients, caregivers, and their families should be clearly informed about their options, as well as their pros and cons to make a decision that is right for them. CMS should increase the number of covered education courses and start them earlier in the disease progression. Starting earlier and increasing the number of sessions could grant patients, families, and caregivers more time to make informed decisions about care and to do so before options are more limited by the disease in later stages.
- **Create a Renal Failure Navigator Program to support care transitions for patients whose conditions progress and require new management and treatment techniques.** There are many options available for people receiving kidney care, and it is important that all stakeholders are aware of these options to make the best decisions for their needs.
- **Provide further education for primary care providers on kidney health in addition to patients and caregivers.** Primary care is the likely entry point for most patients, and providers must be able to diagnose, educate, and direct their patients to the appropriate next step in disease management, whether that is coordinated through primary care or referral to a specialist.

Early detection and management can help prevent a patient from progressing from reversible earlier stages of kidney disease to more serious stages that require more significant interventions like dialysis or transplantation. Primary care providers can deliver initial diagnosis and management strategies with patients. Additionally, provider shortages that may impact particular regions of the country or that impact particular patient groups increase the importance of equipping primary care clinicians to help manage kidney disease. With some estimates indicating that as many as 90% of patients with impaired kidney function have not been

diagnosed with kidney disease, providers must be able to assess symptoms and test results earlier with the hope of preventing disease progression.²

Care teams may involve stakeholders from multiple disciplines, including those who provide social support, community health workers, and non-physician providers, and patients must know what options are available. To meet these goals CMS should:

- **Allow and encourage all providers to practice at the top of their licenses and training, with respect to oversight regulations, to maximize access to care for patients.**

Enabling Alternative Sites of Care

Health insurance providers are committed to facilitating innovation, expanding access to kidney care at home, and improving patient access to dialysis training and support. By fostering and investing in alternative sites of care, we can bring additional competition to the market for the benefit of patients. Moreover, additional options will facilitate reducing disparities by improving access for harder to reach populations and communities. Patients should be afforded the opportunity to receive care via the most convenient, accessible means possible, so long as care can be furnished in a manner that is of high quality and high value. Insurance providers should have the flexibility to connect patients with those patients' delivery modality of choice.

To accomplish this, CMS should seek ways in which to modernize federal regulations and guidance to keep pace with innovations in self-care, home dialysis, and telehealth for dialysis patients. CMS should also consider ways in which to remove and streamline regulatory barriers for home-focused providers to expand patient access to home dialysis and self-dialysis. Lastly, we encourage CMS to promote access to care through other alternative delivery sites, such as mobile units. Mobile units can offer an alternative for patients who can neither access facility-based care nor home dialysis. Mobile units bring the care to the patient and have proven effective during the COVID-19 pandemic. With the ongoing pandemic, mobile units can help people avoid hospitals that are filled with COVID-19 patients and can help care teams target resources directly to high-need areas.

Supporting Access to Care Through Telehealth

Health insurance providers believe strongly in the value of telehealth. If care can be appropriately delivered virtually, where a clinician can gather the information needed for an appropriate evaluation, diagnosis, treatment, or management of a person's condition, then the

²"Kidney Disease: The Basics," National Kidney Foundation, available at: <https://www.kidney.org/news/newsroom/fsindex#:~:text=Approximately%2090%25%20of%20those%20with,at%20risk%20for%20kidney%20disease>

fact that the care is delivered virtually should not be a barrier to accessing care that is convenient and appropriate. Telehealth also helps expand access, especially in rural areas, where a patient can get care from a remote site without traveling long distances for specialized in-person care. Provider reach can be extended significantly, allowing for better triage and flexibility to manage patients effectively – which promotes patient access and convenience, provider efficiency, and potentially contains costs. For all of these reasons, telehealth should play a significant role in helping to manage kidney care and CMS should:

- **Make permanent flexibilities granted during the public health emergency (PHE), including the services and providers eligible to practice via telehealth, the use of audio-only care in some circumstances, and inclusion of remote patient monitoring services.** The PHE flexibilities expanded who could access virtual care and for which services while maintaining patients’ access to high-quality care.
- **Allow the kidney disease education benefit to be delivered via telehealth, including audio-only telehealth, without cost sharing.**

Modernize Conditions for Coverage (CfCs) to Facilitate Alternate Sites

We believe that modernizing the regulatory framework, such as the CfCs, aligns with the Administration’s broader goals to enhance competition. Today’s kidney care market is highly concentrated: two companies provide dialysis to more than 73% of US ESRD patients.³ Consolidated markets drive up prices, reduce patient choice, and discourage innovation. Expanding access to home dialysis and alternative sites of care could benefit consumers by spurring competition in the kidney care space, including in areas where there is poor access to care and remote or underserved areas, leading to lower prices and higher quality.

Currently, dialysis facilities are not defined to reflect differences in the type of facility. This means that a facility primarily intended to support home or self-dialysis is subject to the same rules, regulations and guidance that applies to in-center dialysis facilities. The one-size-fits-all framework creates a challenge for facilities of different capacities to operate within the same regulatory environment; it also stunts innovation. Differentiating by site of service could encourage the growth of alternative site of care and home dialysis training, including novel and hybrid dialysis care models, thereby encouraging greater patient choice to decide which site of care best meets their needs and enabling new entrants into the market to disrupt current consolidation. For example, some patients who ultimately decide not to return home, or be unable to fully return to home, may instead desire to remain in a small care setting and conduct only the aspects of care that they feel comfortable performing themselves while depending on

³ Deidra C. Crews, MD, ScM, Precious McCowan, MS, and Tonya Saffer, MPH; “Bringing Kidney Care Home: Lessons from Covid-19,” NEJM Catalyst (Apr. 9, 2021).

additional support from dialysis clinic staff. It would also encourage investment in home programs for patients who prefer to dialyze at home.

CMS should consider implementing a regulatory framework that differentiates between sites of service for dialysis. **We propose to update the definition of “dialysis facility” to differentiate the types of facilities at 42 CFR § 494.10:** (1) in-center dialysis facility and (2) home dialysis training.

Creating this differentiation would allow greater flexibility for the agency to regulate dialysis care by setting and craft requirements that match the site of care more appropriately while fostering innovation. This will ultimately encourage use of home dialysis and could be tailored as appropriate to ensure patient safety. However, tailored standards should not result in poorer outcomes. When evaluating mobile units, telehealth, and other alternative settings of care, regulators should ensure that quality standards are comparable across settings as we discuss later in this letter.

Increasing Access to Home Dialysis

The COVID-19 pandemic has underscored how home-based care choices are more important than ever and enable patients to receive necessary care in a comfortable, safe setting. Patients should have the option to use home dialysis when clinically appropriate. Studies have shown home dialysis can improve quality of life and independence, improve fluid status and blood pressure control, reduce the burden of dietary restrictions, and increase survival benefits as compared to in-center dialysis.⁴ However, despite the potential benefits of home dialysis, nearly 90% of patients receiving dialysis use in-center hemodialysis, regardless of evidence suggesting that home dialysis has similar patient outcomes, higher patient satisfaction, and reduced costs to the Medicare program.⁵

AHIP collaborated with Dr. Martin Makary, a professor at the Johns Hopkins University School of Medicine, to focus on Rates of Home Hemodialysis as a key metric in its recent Clinical Appropriateness Measures Collaborative Project.⁶ For this project, AHIP and Dr. Makary sought to use a data-driven approach to promote evidence-based care, which included efforts to

⁴ Ali Ibrahim, Christopher T. Chan, “Managing Kidney Failure with Home Hemodialysis;” *Clin J Am Soc Nephrol*. (Aug. 7, 2019), available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6682817/>; Brent W Miller, Rainer Himmele, et al. “Choosing Home Hemodialysis: A Critical Review of Patient Outcomes;” *Blood Purif.* (Jan. 26, 2018), available at: <https://pubmed.ncbi.nlm.nih.gov/29478056/>.

⁵ Eugene Lin, Paul B. Ginsburg, PhD, et al. “The “Advancing American Kidney Health” Executive Order: Challenges and Opportunities for the Large Dialysis Organizations;” *American Journal of Kidney Diseases* (Aug. 4, 2020), available at: <https://doi.org/10.1053/j.ajkd.2020.07.007>.

⁶ <https://www.ahip.org/clinical-appropriateness-measures-collaborative-project/>

promote adherence to consensus clinical practice standards. The use of home hemodialysis was found to remain low in comparison with clinical standards. Increasing the rates of home hemodialysis can improve patient convenience, reduce costs, and reduce unnecessary use of a hemodialysis suite.

One key barrier that is often overlooked is that ESRD patients who wish to do their dialysis at home require the assistance of a caregiver. It can be a family member, friend, or someone willing to train and assist; a health care professional is not required. Outside of a short training period, there is minimal support or resources provided to the caregiver who is supporting the dialysis care, which can total several hours per day. This can create barriers to patients in accessing dialysis care at home, forcing the patient to elect in-center dialysis. This can be particularly problematic in lower income populations. Thus, CMS should:

- **Provide support and resources to caregivers in addition to the training period to ensure that quality of care is upheld.**
- **Reimburse for dialysis providers for in-home assistance for home dialysis patients** so that all patients can benefit from home dialysis, particularly those who may face more socioeconomic barriers to receiving dialysis at a designated facility.
- **Create “reinforcement” training, beyond the existing mandatory training for caregivers of home dialysis, to ensure that patients continue to follow appropriate protocol in delivering high-quality, safe treatment.** These education and training opportunities should be modernized and standardized to reflect the current means of delivering care, including considerations for interdisciplinary care teams that may be involved in a patient’s care.
- **Offer further training and support for staff in post-acute care settings and residential skilled nursing facilities (SNFs),** among other potential sites of care, to ensure that a patient can receive on-site services without having to travel to in-center care.

Encouraging Patient Choice Through Payment Reform

Reforming the way health care is paid for can effectuate changes in physician and care team behavior that drive clinical improvement for patients. Health insurance providers have embraced value-based care, including in kidney care to improve patient outcomes, enhance care coordination, and reduce unnecessary spending. Furthermore, establishing greater financial accountability for total cost of care through innovative payment arrangements can mitigate concerns regarding overutilization or fraud and abuse, including in regard to services furnished outside of traditional settings such as via telehealth, remote monitoring, or home-based care.

For example, Regence recently partnered with Strive Health to deliver high quality, cost-effective kidney care to Regence Medicare Advantage and commercially insured plan members in several Western states.⁷ The program includes the opening of Strive Health Kidney Care Center in Medford, Oregon, which will accommodate current and future dialysis patients on all modalities, including in-center and at home. The model aims to close gaps in care through coordination between a patient's primary care provider, nephrologist, and other specialists; using AI to identify potential adverse events sooner; delivering home-based and virtual clinical services, education, and training; and establishing teams to support patients through care coordination and disease management activities.

While health insurance providers are endeavoring to make strides toward aligning health care reimbursement with quality outcomes and reductions in total cost of care for members with kidney disease, there are steps CMS can take to encourage greater system transformation and promote alignment across approaches. Medicare is well-positioned to test new frameworks for value-based kidney care that, if successful, can be more broadly adopted by payers and better support innovation on a larger scale.

AHIP and its member plans appreciate the actions CMS has already taken to reform reimbursement and payment incentives to improve the quality of care and reduce costs for patients with kidney disease through Innovation Center demonstrations. For example, the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model aims to test whether greater use of home dialysis and kidney transplantation for Medicare beneficiaries with ESRD will reduce Medicare expenditures, while preserving or enhancing the quality of care furnished to beneficiaries with ESRD. Building off these efforts, CMS should:

- **Seek input from private plans and pursue aligned multi-payer total cost of care kidney care models.** Multi-payer alignment in alternative payment model (APM) implementation aligns with the Innovation Center's goals articulated in its [Strategy Refresh](#) in October 2021. Enabling more payers to participate in Innovation Center demonstrations helps facilitate provider buy-in and can put more patients in accountable care relationships – another one of the Innovation Center's current objectives.

Ensuring Stability of MA

Beginning January 1, 2021, Medicare-eligible beneficiaries with ESRD were allowed to enroll in MA plans. This extension of access to MA enables more ESRD beneficiaries to have lower out-of-pocket costs as well as new supplemental benefits and other services not found in traditional

⁷ "Regence and Strive Health Partner To Deliver Comprehensive Kidney Care Program," Regence (Jan. 4, 2022), available at: <https://news.regence.com/releases/regence-and-strive-health-partner-to-deliver-comprehensive-kidney-care-program>.

Medicare. It also provides ESRD beneficiaries the ability to benefit from the comprehensive care management services offered by MA plans as these patients are often living with multiple chronic conditions. We continue to support CMS policies that allow for network flexibility to promote innovation, increase access, and reduce costs for MA beneficiaries with ESRD.

In addition to broadening access to innovative kidney care models piloted through CMS' Innovation Center, we encourage CMS to:

- **Ensure MA funding levels are stable and continue to support high-quality care and comprehensive benefits.** Specifically, CMS should modify the way ESRD growth rates are calculated to ensure sufficient and stable payments to MA organizations for the costs of providing care and services to ESRD enrollees. In addition, CMS should reexamine the appropriateness of existing methods for calculating ESRD benchmarks at the state level and identify more appropriate geographic units for such benchmarks with the goal of reducing variation in ESRD costs within units. CMS should also fully account for the difference in costs between non-ESRD and ESRD beneficiaries in setting maximum out-of-pocket limits to better reflect expected MA enrollment, and account for beneficiary cost sharing amounts when calculating ESRD benchmarks, in recognition of the limited cost sharing liability of MA enrollees.
- **Modify the definition of Chronic Condition Special Needs Plans (C-SNPs) in MA to allow for the development of a chronic kidney disease (CKD) SNP for CKD stages 3, 4, and 5.** Research has shown better health outcomes for patients enrolled in C-SNPs.⁸ A C-SNP focused on enrollees with CKD would allow plans to develop benefits and services specifically targeted to the care and supports needed to manage CKD.

Improving Quality Measurement

Underpinning any efforts to reform payment must be a strong tie to quality and patient outcomes. Accurate and reliable performance measures that drive improvements in what matters most to patients and their families are critical to transitioning to value-based care. Developing and implementing better measures of kidney care across public and private payers could play a critical role in advancing access and quality by:

- Improving patient outcomes and encouraging patient-centered care,
- Promoting prevention and slower disease progression,

⁸ Bryan N. Becker, MD; Jiacong Luo, MD, MS; Kathryn S. Gray, MS; et al. "Association of Chronic Condition Special Needs Plan With Hospitalization and Mortality Among Patients With End-Stage Kidney Disease," JAMA (Nov. 2, 2020); Brian W. Powers, Jiali Yan, Jingsan Zhu, et al. "The Beneficial Effects of Medicare Advantage Special Needs Plans for Patients with End-Stage Renal Disease," Health Affairs (Sept. 2020).

- Addressing disparities in care and promote health equity, and
- Ensuring access to preferred sites of care and treatments and allowing patients to make informed decisions about which site may be best for them.

As CMS considers increasing access to home dialysis, a key consideration for measurement will be ensuring measures can be used across settings of care. Measures that work across settings would help patients choose the site of care that best meets their needs while also helping CMS and health insurance providers in their efforts to ensure beneficiaries are receiving high-quality care, regardless of location. Measures should be agnostic to the site of care to foster innovation and ensure quality. We encourage CMS to explore ways to encourage quality reporting from home dialysis and make results publicly available so that consumers and payers can understand how quality and outcomes compare across care settings.

Improving Patient Outcomes

Currently, there is a significant measurement gap around health and health care outcomes for patients with CKD and ESRD. Currently the clinical care domain of the ESRD Quality Incentive Program (QIP) is dominated by process and intermediate outcome measures. Additionally, there are only a handful of measures directly related to nephrology in the Merit-Based Incentive Payment System (MIPS) measure set. Implementing more outcome measures related to CKD and ESRD could improve patient care and allow consumers to understand provider performance on the aspects of care most meaningful to them. To ensure high-quality care, we urge CMS to:

- **Develop measures that address key patient outcomes like mortality and morbidity, such as rates of peritonitis, sepsis, functioning peritoneal dialysis catheter and hemodialysis access care.**
- **Report additional infection measures on Dialysis Facility Compare to help patients choose a provider.** We appreciate the use of the Standardized Readmission Ratio (SRR) and Standardized Hospitalization Ratio (SHR) measures in the ESRD QIP and would encourage CMS to expand these measures to other sites of care where dialysis is offered to further support consumer decision making.

Performance measurement could also help make kidney care more patient-centered. While we appreciate the use of the Consumer Assessment of Healthcare Providers and Systems (CAHPS) In-Center Hemodialysis Survey in the ESRD QIP, we encourage CMS to explore ways to include more patient-reported outcomes-based performance measures (PRO-PM) in both the ESRD QIP and the Merit-Based Payment System (MIPS). PRO could explore whether symptoms – including pain, fatigue, and spiritual distress - are adequately controlled. Measurement could also be used to assess if facilities are providing patients with the supports, resources, and education they need to manage their current condition and prepare for a transplant. Thus, we urge CMS to:

- **Build on the In-center Hemodialysis CAHPS (ICH CAHPS) survey or develop a new PRO-PM** to assess if patients feel supported in their care and satisfied with the quality of the education and training, they are receiving from their providers. If CMS creates a future quality reporting program for home dialysis, we encourage the agency to add a survey like CAHPS to ensure patient-centered outcomes and health-related quality of life are considered.
- **Explore implementing measures that assess concepts such as advanced care planning in the ESRD QIP** to ensure dialysis facilities are working with patients to meet their needs holistically.

Promoting Prevention and Early Detection

Quality measurement could also be leveraged to promote prevention and early detection of CKD as well as to encourage clinicians to work with patients to slow progression of the disease. CMS could work with health insurance providers to promote the implementation of aligned measures across payers that promote prevention and early detection. Some key measure concepts to explore include early diagnosis via eGFR, Urine ACR testing, and Staging CKD Diagnoses, as well as adding nephrology interventions to slow or halt progression.

AHIP supports efforts to align measures across public and private payers with the goal of enabling upstream interventions to address control of diabetes and hypertension, two leading causes of CKD.⁹ To promote measure alignment across public and private payers, AHIP has partnered with CMS to convene the Core Quality Measures Collaborative (CQMC), a multi-stakeholder coalition working to facilitate cross-payer measure alignment through the development of core sets of measures to assess the quality of healthcare in the United States. The CQMC has developed a [core set](#) addressing accountable care organizations, primary care, and person-centered medical homes that includes measures of blood pressure and HbA1C control.

Addressing Disparities and Promoting Health Equity

Significant disparities exist in CKD with Black Americans and other minority populations disproportionately affected by kidney disease. For example, in 2014, Black Americans comprised 13% of the US population but accounted for more than 30% of patients with ESRD. Social determinants of health have been shown to influence a person's risk of both developing CKD and of the disease progressing to ESRD. Quality measurement could be used to both identify and address disparities. CMS should:

- **Prioritize developing measures that assess if dialysis providers are screening for social risk factors and measures that assess relief of barriers to care influenced by**

⁹ <https://www.niddk.nih.gov/health-information/kidney-disease/chronic-kidney-disease-ckd/causes>

social determinants of health. Measures assessing relief of barriers should be targeted to those that are within the measured entities' control.

- **Prioritize implementing measures in the ESRD QIP that address aspects of care where disparities are prevalent.**
- **Require dialysis facilities to collect demographic data (such as race and ethnicity) on clients to monitor inequities in who is accepted for dialysis and the setting (facility, home, mobile) in which dialysis is delivered.** Codes on sociodemographic data (whether LOINC codes, SNOMED codes, ICD-10 Z codes) could be reported in the CMS-2728 and CMS-2744 forms submitted by dialysis facilities.¹⁰ However, CMS should work with facilities and patients to ensure data is collected in a patient-centered way and that patient privacy is protected. CMS should also monitor for unintended consequences to ensure the collection and use of demographic and social risk data does not exacerbate disparities or biases but instead is used to improve the health of ESRD patients and all Medicare beneficiaries, regardless of payer.
- **Stratify measures in the ESRD QIP by race and ethnicity to identify potential disparities in care.** CMS should provide reports to reports to help facilities, patients and payers understand the disparities in their patient population.

Ensuring Access to Care and Allow Consumers to Make Informed Decisions

Performance measurement can help payers understand if providers are connecting patients who have CKD and ESRD with the additional care they need. First, we need measures to better understand if patients are being referred to transplantation and if they are being appropriately supported while they are on the waiting list for an organ. Specifically, CMS should:

- **Build on the use of the Percentage of Prevalent Patients Waitlisted (PPPW) in the ESRD QIP by developing measures that assess how facilities are supporting patients to help them access transplant waitlists and if facilities are proactively reaching out to patients on the waitlist.**
- Promote shared accountability for encouraging transplantation by aligning the Organ Procurement and Transplantation Network (OPTN) metrics with measures used in the ESRD QIP.
- Stratify these measures by social risk factors such as race and ethnicity, rurality, dual eligible status, and socioeconomic status to monitor for potential disparities.

Additionally, measures could be developed that assess access to care that can help patients avoid the disruption and effects of dialysis that patients with late-stage CKD receiving specialty care

¹⁰ <https://jasn.asnjournals.org/content/jnephrol/32/2/265.full.pdf?with-ds=yes>

and the possibility of leveraging pre-emptive transplant. Measures could also be developed to understand patients' ease of access to a preferred site of care for dialysis treatments. To ensure the right measures are available, CMS should:

- Develop and promote the implementation of quality measures that assess what matters most to patients and can be readily implemented.
- Focus on priority measure gaps such as patient outcomes, and especially patient-reported outcomes, as well as measures that could promote access and equity.
- Partner with providers to improve demographic data collection to support the stratification of quality measures to address disparities.

Promoting Health Equity

As discussed in the RFI, there are barriers to equity in dialysis, transplant access, and post-transplant care. Communities of color have much higher rates of risk factors for kidney disease-- Black Americans are almost four times more likely and Latinos are 1.3 times more likely to have kidney failure compared to White Americans.¹¹ Despite the higher risk, data shows that Black and Latino patients on dialysis are less likely to be placed on the transplant waitlist and have a lower likelihood of transplantation.¹²

To reduce or prohibit discrimination and inequities in access to kidney care and transplants, CMS should:

- **Prohibit discrimination for organ transplant based on disability status.** Currently, individuals with disabilities (whether intellectual, development, or physical) are discriminated against in the process of determining eligibility for organ transplants, even though many of these disabilities would not preclude successful transplant or high quality of life post-transplant.
- **Implement regulations that require any provider or practice who provides dialysis treatments to accept any client into their service unless there is a valid medical reason why they cannot provide them with services.** This would help ensure that providers or practices do not deny services to individuals based on race, ethnicity, gender, sexual orientation, gender identity, socioeconomic status, or another demographic factor.
- **Reduce disparities in access to organ transplants among Black and African American populations by enacting policies that allow registration on the waitlist at higher levels of eGFR (estimated glomerular filtration rate or kidney filtration rate) for Black and African American populations.** There is considerable evidence that

¹¹ <https://www.kidney.org/atoz/content/minorities-KD>. Race, Ethnicity, & Kidney Disease.

¹² Social Determinants of Health: Going Beyond the Basics to Explore Racial Disparities in Kidney Transplantation. https://journals.lww.com/transplantjournal/Fulltext/2020/07000/Social_Determinants_of_Health_Going_Beyond_the.9.aspx

Black and African American populations have higher kidney filtration rates. Under current eGFR threshold standards, they are not eligible to be placed on organ transplant waitlists until the eGFR reaches a low filtration rate. As a result, kidney disease progresses to kidney failure faster in Black and African American populations than in other races (sometimes as much as nine months faster).¹³ We encourage CMS to work with professional societies and organ procurement organizations to transition away from the eGFR as new tests become available given the disparities that exist when using eGFR. For example, cystatin C or measurement of kidney clearance could provide a more complete picture of kidney health across populations.^{14,15}

- **Conduct regular audits to ensure ultrafiltration rates do not exceed safe levels** and to ensure certain communities do not disproportionately experience poorer outcomes by undergoing ultrafiltration rates.^{16,17}
- **Issue the proposed rule on CfCs for ESRD.**¹⁸ Health plans in the individual health insurance market have been directly impacted by specific practices of kidney dialysis providers and the charities they fund--steering Medicare- and Medicaid-eligible patients to individual market plans. These providers have made clear, including in public statements, that they benefit financially from enrolling these patients in individual market plans. Patients receiving dialysis who remain in the individual market run the risk of losing their premium payment support at the end of the year after they receive a transplant, putting them at jeopardy of losing post-transplant health care services and prescription drug coverage.

Another key area of inequity relates to coverage and access to care. **CMS should engage with stakeholders to consider ways in which it could extend coverage for more services that are critical to kidney care and organ transplantation.** Suggested areas to promote access to care and coverage include:

- **Provide 100% coverage for organ transplant evaluations** to increase the rates of referrals, evaluations, and transplants—particularly for historically marginalized populations.

¹³ <https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/reassess-inclusion-of-race-in-estimated-glomerular-filtration-rate-egfr-equation/>

¹⁴ <https://health.ucdavis.edu/blog/lab-best-practice/race-and-egfr-addressing-health-disparities-in-chronic-kidney-disease/2021/04>

¹⁵ <https://jasn.asnjournals.org/content/32/3/523>

¹⁶ 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)

¹⁷ 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).

¹⁸ 81 FR 90,211

- **Extend coverage for medical expenses for post-transplant surgery care** so that coverage is not just for pre-donation services and the organ transplant surgery itself but also for post-transplant-surgery care.
- **Extend coverage for travel costs for organ transplant surgery** since many people have to move for a couple of months to the city where the transplant center is located due to high probability of rejection.
- **Create wraparound services to assist the family with care navigation** as soon as someone needs a transplant and/or dialysis to assist in navigating the process to increase access to care. Navigator support could include: providing education about dialysis and transplantation modality options, appointment reminders, weight loss interventions, interpretative services, or arranging transportation.¹⁹ Many health plans have navigator programs for kidney care already in place that support members with education, care coordination, and other assistance, which has led to increased member satisfaction, increased patient choice with treatments, and reduced hospitalizations.^{20, 21}
- **Consider engagement with stakeholders about potential coverage for other types of services, such as nutritional consultations and mental health support for individuals beginning dialysis treatment.**

To promote greater access and equity to kidney care and organ transplants in the Medicaid program, we recommend that CMS engage with stakeholders to:

- **Consider whether variation in Medicaid coverage policy is a potential partial driver of inequities in access to organ transplants.** This speaks to the importance of stratifying quality measures by demographic factors (such as dual status) to better identify and address disparities.
- **Incentivize Medicaid programs to cover transplants in nearby states** for beneficiaries who live in the state but who need to travel to another state for their transplant surgery given lack of convenient transplant facilities in their own state. Currently, many Medicaid programs only cover transplants performed in their state, which hinders patient choice and accessibility. For many beneficiaries, the closest and most convenient transplant facilities may be across state lines.
- **Evaluate state Medicaid policies more closely in the domain of organ transplantation and consider alternative paths that incentivize states toward more transparent and equitable coverage policies,** including but not limited to the following:
(1) evaluate the accessibility, costs, and outcomes of organ transplantation in the

¹⁹ <https://cjasn.asnjournals.org/content/13/4/529.full>

²⁰ <https://news.blueshieldca.com/2021/10/21/how-blue-shield-of-california-and-cricket-health-are-reimagining-kidney-care>

²¹ <https://newsroom.cigna.com/improving-patient-engagement-clinical-outcomes-people-with-kidney-disease>

Medicaid population by state and make this available to the public; (2) request that states make coverage policies transparent to the public; and (3) encourage states to adopt CMS National Coverage Determination (NCDs), or some alternative national clinical standard like OPTN, to support Medicaid coverage guidelines for Medicaid beneficiaries.

To monitor and address disparities and inequities in kidney care and organ transplant, it is important to have accurate data on sociodemographics. We recommend that CMS engage with stakeholders to determine how best to:

- **Require dialysis facilities to collect sociodemographic data (such as race and ethnicity) from patients to monitor disparities in who is accepted for dialysis as well as to track equitable uptake in home therapies.** Codes on sociodemographic data (whether LOINC codes, SNOMED codes, ICD-10 Z codes) could be reported in the CMS-2728 and CMS-2744 forms submitted by dialysis facilities.²²
- **Require dialysis facilities to report additional access, quality, experience, and outcome measures and to stratify these measures (such as the ESRD QIP measures) by race/ethnicity, dual status, and potentially other demographics to monitor disparities for access to dialysis and waitlist times.**
- **Require organ transplant facilities to collect sociodemographic data (such as race and ethnicity) on clients to monitor disparities in acceptance for organ transplants. CMS should also require organ transplant facilities to report access, quality, experience, and outcome measures and to stratify these measures by race/ethnicity and potentially other demographics to monitor disparities for access to transplants, transplant evaluations, referrals, waitlist times, and post-transplant outreach to monitor outcomes.** This will provide greater insight into roadblocks to organ transplant that may disproportionately affect communities of color.²³
- **Consider setting a minimum number of outreaches by transplant centers to patients/families who are on the transplant waitlist and audit medical records to ensure equity in access while informing future work in these areas.** Ideally, audits on program outcomes should reflect reduced disparities and improved equity.
- **Adjust the ESRD Treatment choices payment model based on socioeconomic risk** that are associated with decreased use of home dialysis or transplant (such as income, housing instability, social support, etc.) so that organizations who serve populations with more socioeconomic needs are not disqualified from receiving payment adjustments. For example, housing instability essentially precludes the use of home dialysis, which limits patient choice. Without appropriate risk adjustment, participants who care for patients with housing instability are at risk for financial penalties under the Performance Payment

²² <https://jasn.asnjournals.org/content/jnephrol/32/2/265.full.pdf?with-ds=yes>

²³ <https://jasn.asnjournals.org/content/jnephrol/32/2/265.full.pdf?with-ds=yes>

Adjustment, leading to disincentives to provide equitable care for disadvantaged patient populations. These disincentives could worsen disparities and discrimination against populations with socioeconomic needs. However, adjusting payments based on socioeconomic need would help dedicate resources to help address socioeconomic barriers to health and improve access to kidney care and organ transplants. For example, dialysis facilities located a greater distance from transplant evaluation centers could receive add-on payments for travel and care coordination. Or, dialysis facilities could use enhanced payments to work with local governments and other partners to implement permanent supportive housing programs or housing vouchers for patients with kidney failure and housing instability to encourage equitable inclusion of these patients into kidney care and organ transplant programs.²⁴

There are also challenges associated with the social determinants of health that should be addressed to reduce inequities in kidney care and organ transplant. Health insurance providers are pursuing numerous concurrent strategies to address these barriers, including through expanded case management programs to increase collaboration with primary care and other clinicians to coordinate earlier referrals to specialists. However, we recommend CMS engage with stakeholders to determine how best to address other socioeconomic barriers to kidney care and organ transplant. Suggested areas to consider include:

- **Develop culturally-sensitive education programs in partnership with community- and faith-based organizations to inform individuals about diabetes, hypertension, and the signs and symptoms of early renal failure**, which could lead to improved health literacy, earlier detection, and improved outcomes. These education programs could also inform patients about the different types of dialysis modalities and alternative sites of service. Facilities and providers should receive additional incentive payments for providing education to diverse communities to promote equity in modality choice.
- **Increase culturally-sensitive awareness and education programs in partnership with community- and faith-based organizations around organ donation and Paired Kidney Exchange programs to encourage more people to become organ donors and to reduce fear around the organ donation process, with consideration given to varying health literacy levels.** This is particularly important to increase the number of living donors who could participate in Paired Kidney Exchange programs. Currently, living donors are mostly White (75%) as opposed to people of color. While racial concordance is not required for organ transplants, it is significant in living donation, with 95% of living donations being racially congruent. It is also important to increase the number of organ donors who are Blood Type B (70% of whom are non-White) to ensure that Type B patients do not face inequities with longer wait times and lower transplant rates.²⁵ Dialysis facilities, providers, and transplant centers should receive additional

²⁴ <https://jasn.asnjournals.org/content/jnephrol/32/2/265.full.pdf?with-ds=yes>

²⁵ <https://www.kidneymedicinejournal.org/action/showPdf?pii=S2590-0595%2821%2900181-3>

incentive payments for providing education to diverse communities on organ donation and options for transplant surgery and care. CMS could also consider requiring OPOs to have a stronger focus on public education including organizations serving underserved communities.

- **Increase equity in prescription and availability of novel medications (e.g., SGLT2 inhibitors) for higher-risk or minority populations.** This is imperative in light of increasing awareness of potential treatment disparities in race, gender, income, and socioeconomics.
- **Provide universally available and covered transportation for dialysis and organ transplant patients** to ensure that anyone, regardless of where they live or if they have access to transportation options, can access needed kidney care and organ transplants.
- **Consider a limited home modification benefit for eligible home dialysis beneficiaries related to water/plumbing, shelving for supplies, and general assistance to prepare for home therapy.**
- **Consider how mobile health interventions could help patients with post-transplant-operative care to ensure that individuals with lower social support are not excluded or deemed “ineligible” for organ transplants.** Mobile health interventions could help with medication adherence, appointment reminders, remote monitoring of symptoms, care management, assessments and data monitoring, diet, education, and emotional connection, among other supports. These alternative ways to provide support post-transplant can help achieve greater equity in organ transplant waitlists.²⁶

Establishing Greater Transparency

AHIP appreciates that CMS is seeking input to address concerns that joint ventures between dialysis organizations and physicians may create financial incentives for participating physicians to inappropriately influence decisions about patient care. To increase transparency, **we recommend that CMS collect information on joint venture arrangements between dialysis facilities and treating nephrologists to examine if incentives influence behavior.**

Furthermore, we support additional rulemaking that increases transparency around all types of third-party payments to address improper steering by dialysis providers into commercial plans. In particular, AHIP encourages CMS to issue new proposed rules requiring dialysis providers to educate patients on coverage options and notify health insurance providers before making third-party payments.²⁷

²⁶ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6818754/>

²⁷ 81 FR 90,211.

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Conclusion

We appreciate the opportunity to provide these comments on such an important issue. We look forward to continuing to work with the Administration on the most effective approaches to providing beneficiaries with access to needed care and services. Please do not hesitate to contact me with any questions.

Sincerely,

A handwritten signature in black ink, appearing to read "Elizabeth Cahn Goodman". The signature is fluid and cursive, with a long horizontal flourish at the end.

Elizabeth Cahn Goodman, DrPH, JD, MSW
Executive Vice President, Government Affairs and Innovation