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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 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

diagnosed with kidney disease, providers must be able to assess symptoms and test results earlier with the hope of preventing disease progression.[3]

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

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 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 alter (ul) Tw 7.25 0 Td [bs ules(-)Tj 0.022 Tc -.2 0 Td 1; it t2 (dac 0 T.05 -17 (s)-11

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 effectuat S-17

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 facili more at Celplplplentilo

Medicare.

- 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 account

and the possibility of leveraging preemptive 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, individ

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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 at2 (t)-216 Tc -0.0 ectTd [(cy)2 (o)6 y-16 (l)iTd [(cy)m-6 (xa22

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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),

incentive payments for providing education to diverse communities on organ donation and options for transplant surgery and care.

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,

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