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January 11, 2021

Congressional Research Service
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R46655

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SUMMARY

R46655

January 11, 2021

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Medicare Advantage (MA) Coverage of End Stage Renal Disease (ESRD) and Network Requirement Changes

Starting in calendar year (CY) 2021, all Medicare beneficiaries with end stage renal disease (ESRD) are allowed to enroll in Medicare Advantage (MA) plans. MA plans are an alternative to original Medicare under which beneficiaries receive all required Medicare benefits (except hospice) through private insurers. Prior to CY2021, beneficiaries with ESRD, in general, were not allowed to enroll in MA plans but could be *enrolled* in MA plans in limited circumstances. For example, Medicare beneficiaries with ESRD could remain in MA plans if they were diagnosed with ESRD while already enrolled in an MA plan. In 2019, there were 534,000 Medicare beneficiaries with ESRD, of whom approximately 25% (131,000) were in MA plans. The CY2021 policy change, which Congress required in the 21st Century Cures Act (Cures Act; P.L. 114-255), is expected to increase the number of MA enrollees with ESRD by 83,000 (more than 60%) over six years, with half the increase in CY2021.

Congress enacted the Cures Act change for several reasons. Most ESRD patients undergo thrice-weekly dialysis treatments to stay alive, and many have other chronic health conditions that require medical care, such as diabetes, heart disease, or hypertension. Patient advocates and lawmakers have said that ESRD patients, because of their complex medical conditions, could benefit from joining MA plans, which are required to ensure continuity of care and integration of services. In addition, MA plans include a cap on annual enrollee out-of-pocket spending, which is not a feature of original, or *fee-for-service* (FFS), Medicare. Because ESRD patients have high medical bills, they may realize savings by enrolling in an MA plan.

Private insurers that sponsor MA plans have expressed concern about expanded ESRD enrollment due, in part, to the higher cost of covering such enrollees. Congress and the Centers for Medicare & Medicaid Services (CMS) attempted to address the cost issue by requiring organ acquisition costs associated with kidney transplants for ESRD patients to be paid by FFS Medicare rather than by MA plans. Still, MA plan sponsors told CMS the proposed changes in payment to comply with the Cures Act would not adequately account for the increased costs.

On June 2, 2020, CMS issued a final rule to govern MA plan operations for CY2021 that implemented the Cures Act provisions. One portion of the rule has drawn scrutiny and a lawsuit from ESRD patient advocates. As part of the regulation, CMS codified existing, less-formal network guidance that limits the length of time and the geographic distance MA plans can require enrollees to travel to obtain services from network providers and medical facilities. However, the rule waived the time and distance limits for one set of providers, outpatient dialysis facilities (*dialysis clinics*), which had long been subject to such limits. CMS justified the change on the grounds that relaxing the standards would help MA plans offer their enrollees a broader array of dialysis services, including home-based dialysis. CMS also pointed to the statutory and regulatory requirement that plans must provide access to Medicare required dialysis services with reasonable promptness and in a manner that ensures continuity of benefits, consistent with "the prevailing community pattern of health care delivery in the area." Commercial insurers, which favor the rule, said it would encourage market competition. By contrast, dialysis providers and patient groups said the rule could allow MA plans to drop outpatient dialysis facilities—which serve approximately 90% of Medicare ESRD patients undergoing dialysis—from their plan networks in favor of home-based dialysis, which currently is not widely used by ESRD beneficiaries. These opponents also argued that eliminating time and distance standards for outpatient dialysis could put an excessive burden on ESRD enrollees, especially low-income and minority enrollees, if they were required to either switch dialysis modalities (if that were an option) or travel longer distances for treatments. On June 24, 2020, a dialysis patient group filed suit in federal court to halt the rule on the grounds it discriminated against patients who needed outpatient dialysis.

This report provides an overview of Medicare ESRD benefits and details how Medicare Advantage differs from original Medicare. It also summarizes the Cures Act changes and the CMS rule.

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Introduction

Starting in calendar year (CY) 2021, all Medicare beneficiaries with end stage renal disease (ESRD) are allowed to enroll in Medicare Advantage (MA) plans, which are an alternative way to receive Medicare-covered benefits and, often, supplemental services. Prior to CY2021, beneficiaries with ESRD, in general, were not allowed to enroll in MA plans but could *be enrolled* in MA plans in limited circumstances. For example, Medicare beneficiaries with ESRD were allowed to remain in MA plans if they were diagnosed with ESRD while enrolled in one. In 2019, there were 534,000 Medicare beneficiaries with ESRD, of whom approximately 25% (131,000) were in MA plans. The CY2021 policy change, which Congress required in the 21st Century Cures Act (Cures Act; P.L. 114-255),[1] is expected to increase the number of MA enrollees with ESRD by 83,000 (more than 60%) over six years, with half the increase in CY2021.[2]

Congress enacted the Cures Act change for several reasons. Most ESRD patients undergo thrice-weekly dialysis treatments to stay alive, and many have other chronic health conditions that require medical care, such as diabetes, heart disease, or hypertension. Patient advocates and lawmakers have said that ESRD patients, because of their complex medical conditions, could benefit from joining MA plans, which are required to ensure continuity of care and integration of services.[3] In addition, MA plans include a cap on annual enrollee out-of-pocket spending, which is not a feature of original, or *fee-for-service* (FFS), Medicare.[4] Because ESRD beneficiaries have high medical bills, they may realize savings by enrolling in an MA plan.

Private insurers that sponsor MA plans have expressed concern about expanded ESRD enrollment due, in part, to the high cost of covering such enrollees.[5] Congress and the Centers for Medicare & Medicaid Services (CMS) attempted to address the issue by requiring the organ acquisition costs associated with kidney transplants for ESRD patients to be paid by FFS Medicare rather

[1] See §17006 of the Increasing Choice, Access, and Quality in Health Care for Americans Act, which was Division C of the 21st Century Cures Act (P.L. 114-255). See CRS Report R44730, *Increasing Choice, Access, and Quality in Health Care for Americans Act (Division C of P.L. 114-255)*.

[2] Centers for Medicare & Medicaid Services (CMS), "Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, Proposed Rule," 85 *Federal Register*, 9180, February 18, 2020, at https://www.federalregister.gov/documents/2020/02/18/2020-02085/medicare-and-medicaid-programs-contract-year-2021-and-2022-policy-and-technical-changes-to-the.

[3] See Dialysis Patient Citizens, "Medicare Advantage," fact sheet, at https://www.dialysispatients.org/policy-issues/promote-financial-security/medicare-advantage/; and statement on a related bill, H.R. 5659, the Expanding Seniors Receiving Dialysis' Choice Act of 2016, which passed the House on September 21, 2016, by Representative Bilirakis, "Bilirakis Bill to Help End Stage Renal Disease Patients," press release, July 8, 2016, at https://bilirakis.house.gov/media/press-releases/bilirakis-bill-help-end-stage-renal-disease-esrd-patients.

[4] See Kathryn A. Coleman, Director of Medicare Drug and Health Plan Contract Administration Group, CMS, *HPMS Memo, Final Contract Year 2021 Part C Benefits and Evaluation*, April 8, 2020, p. 6, at https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly (hereinafter, Coleman, *HPMS Memo*).

[5] Tim Courtney and Rachel Stewart, *Increased ESRD Beneficiary Enrollment Flexibility Presents a Potential Financial Challenge for Medicare Advantage Plans in 2021*, Wakely, White Paper, February 2019, p. 3, at https://www.wakely.com/sites/default/files/files/content/increased-esrd-beneficiary-enrollment-flex-presents-potential-financial-challenge.pdf (hereinafter, Courtney and Stewart, *Increased ESRD Beneficiary Enrollment Flexibility*).

than by MA plans. Still, MA plan sponsors told CMS the proposed changes in payment to comply with the Cures Act would not adequately account for the increased costs.[6]

In preparation for the Cures Act change, on June 2, 2020, CMS issued a final rule to govern MA plan operations for CY2021.[7] The rule implemented changes in MA enrollment, payment, and other issues specifically related to ESRD beneficiaries. In addition, the rule made more general changes in MA program operations, including codifying network adequacy requirements.

MA plan networks consist of contracted providers and facilities that agree to provide care to MA plan enrollees.[8] In most cases, MA enrollees must use providers and facilities in their plan's network; in some cases, however, MA enrollees may use providers outside of their network, possibly with higher cost sharing. Plans are allowed to limit the providers and facilities from which enrollees can seek care (i.e., establish a network), as long as the plans make benefits available and accessible to each enrollee with reasonable promptness and in a manner that assures continuity in the provision of benefits,[9] consistent with the prevailing community pattern of care delivery in the area.[10] As part of MA program changes, the rule codified existing CMS guidelines that quantify measures of health care network adequacy, such as the minimum number of network providers and medical facilities in an area, and limits on the length of time and the geographic distance that MA plans may require their enrollees to travel to receive in-network services.[11] However, the final rule waived these explicit time and distance limits for one type of provider—outpatient dialysis facilities—that had been included in previous network adequacy guidance. CMS justified the change on the grounds that it would allow MA plans to offer enrollees a broader array of dialysis services, including home-based dialysis.[12]

[6] Starting in 2021, when organ acquisition costs for kidney transplant are paid by fee-for-service (FFS) Medicare, historical FFS Medicare expenditures attributed to organ acquisition also are removed from the MA benchmarks. The president and CEO of America's Health Plans wrote, "We remain concerned with the methodology CMS proposes to exclude organ acquisition costs for kidney transplant from MA benchmarks. The magnitude of the cost carve-out and the resulting impacts on premiums and benefits could be very significant in many urban areas. Given the potential impacts on all MA enrollees, we reiterate the request in our comments on the CY2021 Advance Notice that CMS provide more transparency regarding the calculation of the carve-out factors." Letter from Matthew Eyles, President and CEO of America's Health Insurance Plans (AHIP), to Seema Verma, CMS Administrator, April 6, 2020, at https://www.ahip.org/wp-content/uploads/AHIP-Comment-Letter-on-MA-Proposed-Rule-CY2021-2022.pdf.

[7] CMS, "Medicare Program; Contract Year 2021 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, and Medicare Cost Plan Program," 85 *Federal Register* 33796, June 2, 2020, at https://www.federalregister.gov/documents/2020/06/02/2020-11342/medicare-program-contract-year-2021-policy-and-technical-changes-to-the-medicare-advantage-program. Hereinafter, CMS, "Medicare Program," 85 *Federal Register* 33796.

[8] In addition to agreeing to provide care to network enrollees, the contracts with providers and facilities establish the amounts the MA plan will pay providers and facilities to provide that care. Those amounts are based on a negotiation between the plan and the providers and facilities, and they may differ from rates the Medicare program otherwise would pay on behalf of beneficiaries in original Medicare.

[9] Social Security Act (SSA) §1852(d)(1).

[10] 42 C.F.R. §422.112(a).

[11] SSA §1852(d)(1) and 42 C.F.R. §422.112(a).

[12] Ibid; CMS, "Medicare Program," 85 *Federal Register* 33856. CMS also points out that eliminating the time and distance standards for outpatient dialysis facilities, and instead requiring the plans attest to the adequacy of their networks, does not waive the statutory and regulatory requirement that plans provide access to Medicare required dialysis services with reasonable promptness and in a manner that ensures continuity of benefits, consistent with "the prevailing community pattern of health care delivery in the area" (42 C.F.R. §422.112(a)(10)). Regulations also require MA plans to arrange for out-of-network specialty care if network providers are unavailable or inadequate to meet an enrollee's needs (42 C.F.R. §422.112(a)(3)).

Commercial insurers that advocated for the rule said eliminating requirements regarding time and distance limits for outpatient dialysis facilities would encourage greater competition among dialysis providers seeking to join MA plan networks. They asserted that the change could improve plans' ability to negotiate reductions in reimbursement to dialysis providers.[13] MA plans already had an incentive to offer home dialysis as an alternative to outpatient dialysis, because the U.S. market for outpatient dialysis is dominated by two national companies, which may make it difficult for MA plans to negotiate favorable financial terms when developing their provider networks. However, the existing for-profit chains also dominate the home dialysis market, which means that, ultimately, new entrants to the market may be needed to increase competition. (See "MA Plan Concerns About ESRD Payments and Dialysis Provider Competition," below.)

Dialysis operators and provider groups opposed eliminating the quantified time and distance requirements for outpatient dialysis providers. They posited that this change would allow MA plans to reduce the number of outpatient dialysis facilities in their networks—facilities that currently serve approximately 90% of Medicare ESRD patients undergoing dialysis. Opponents of the rule are concerned that MA plans instead would meet CMS network requirements by offering home-based dialysis, which is not widely used (although CMS has mounted a series of efforts to expand the treatment[14]) and is not feasible for some beneficiaries.[15]

CMS indicates that if network dialysis providers are incapable of meeting enrollees' medical needs because the burden of enrollees' travel to in-network providers proves inconsistent with prevailing community patterns of care, MA plans would have to arrange for out-of-network care at in-network cost-sharing rates. Nonetheless, patient groups that oppose the rule argue that eliminating the time and distance requirements for outpatient dialysis providers would discourage some beneficiaries with ESRD from ever enrolling in MA plans. They also claim the change would put an excessive burden on those who enrolled in MA plans prior to 2021, especially low-income and minority enrollees, who could be forced to travel long distances for thrice-weekly treatments.[16] On June 24, 2020, a dialysis patient group filed suit in federal court to halt the CMS final rule on the grounds it was discriminatory.[17]

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[13] "We appreciate and support CMS' policies to enhance network contracting options to promote innovation, increase access, and reduce costs for people with end state renal disease (ESRD)," Letter from Matthew Eyles, President and CEO of AHIP, to Demetrios Kouzoukas, Principal Deputy Administrator and Director of the Center for Medicare, March 6, 2020, at https://www.ahip.org/ahip-comments-to-the-2021-advance-notice-for-ma-capitation-rates-and-part-c-and-part-d-payment-policies/. See also CMS, "Medicare Program," 85 *Federal Register* 33858; Letter from Mark A. Newsom, Vice President of Public Policy, Humana, to Joseph J. Simons, Chairman of the Federal Trade Commission, "RE: Competition and Consumer Protection in the 21st Century Hearings, Project Number P181201," August 20, 2018, at https://www.ftc.gov/system/files/documents/public_comments/2018/08/ftc-2018-0048-d-0054-155291.pdf.

[14] Department of Health and Human Services (HHS), "HHS Launches President Trump's 'Advancing American Kidney Health' Initiative," July 10, 2019, at https://www.hhs.gov/about/news/2019/07/10/hhs-launches-president-trump-advancing-american-kidney-health-initiative.html.

[15] United States Renal Data System (USRDS), Supplemental Table D-1 in "Executive Summary: Overview of Kidney Disease in the United States," in *USRDS Annual Data Report*, 2019, at https://www.usrds.org/annual-data-report/ (hereinafter, USRDS, "Overview of Kidney Disease"). Also see Medicare Payment Advisory Commission (MedPAC), Chart 11-3 in *July 2020 Data Book: Health Care Spending and the Medicare Program*, July 17, 2020, at http://www.medpac.gov/-documents-/data-book.

[16] Letter from LaVarne A. Burton, President and CEO of American Kidney Fund, to Seema Verma, CMS Administrator, April 6, 2020, at https://www.kidneyfund.org/assets/pdf/advocacy/comment-letters/akf-comment-letter-ma-proposed-rule-april-2020.pdf. In the letter, the group said "eliminating requirements for adequate access to in-center facilities would essentially exclude MA plans as a viable option for ESRD beneficiaries. To ensure meaningful access to MA plans, CMS should maintain time and distance standards for dialysis services."

[17] Dialysis Patient Citizens v. Azar, Case 1:20-cv-01664 18-20 (U.S. District Court for the District of Columbia 2020).

In addition to the new rule, the ongoing Coronavirus Disease 2019 (COVID-19) pandemic heightens concerns about potential disruptions in dialysis care; for 2021, ESRD enrollees will choose whether to switch to MA plans or between plans in the midst of this increased uncertainty. The pandemic has accelerated CMS efforts to expand home dialysis so patients do not have to leave their homes three times a week for services. In addition, some patients hospitalized with COVID-19 require dialysis, increasing hospitals' dialysis use and further straining the system. (See "Stakeholder and Support Agency Positions and Reactions to the Rule.")

This report begins with an overview of Medicare coverage of ESRD services, including dialysis treatment modalities and outpatient dialysis payment methodology. It also briefly discusses the market for outpatient dialysis services. The report then describes the MA program (and how it differs from original Medicare), including program payments to plans, enrollment of ESRD beneficiaries, and historical network adequacy standards. It then describes provisions in the Cures Act that eliminated the prohibition of enrollment by beneficiaries with ESRD into MA plans. In addition, it describes selected provisions in CMS's final rule related to implementing the Cures Act provision, including changes to MA ESRD payments and MA network adequacy standards for outpatient dialysis. The report summarizes the positions of different stakeholders and concludes with issues to consider for plan year 2021 and beyond.

Coverage and Payment of ESRD Services Under Original Medicare

ESRD is the final stage of chronic kidney disease (CKD), which is the gradual decrease of kidney function over time. Individuals with ESRD have substantial and permanent loss of kidney function and require either regular dialysis (a process that removes harmful waste products from an individual's bloodstream) or a kidney transplant to survive.[18]

Summary of Fee-for-Service ESRD Benefits

In 1972, Congress enacted legislation allowing qualified individuals with ESRD under the age of 65 to enroll in the federal Medicare health care program (Social Security Amendments of 1972; P.L. 92-603). The legislation marked the first time individuals were allowed to enroll in Medicare based on a specific medical condition rather than on age.[19] Medicare now accounts for more than three-fourths of all spending on U.S. patients with ESRD.[20] Medicare ESRD benefits include thrice-weekly dialysis treatments (at outpatient centers, at home, or, for hospitalized patients, at inpatient medical facilities) and coverage for kidney transplants, including the costs of kidney acquisition. ESRD enrollees under the age of 65 face an initial waiting period for coverage, and coverage terminates 12 months after a patient ends dialysis or after 36 months of follow-up care after a kidney transplant.[21]

[18] CRS Report R45290, *Medicare Coverage of End-Stage Renal Disease (ESRD)*.

[19] An individual under the age of 65 who is medically determined to have ESRD and who is undergoing treatment is eligible to enroll in Medicare if he or she has worked in Social Security-covered employment for a minimum number of quarters or is entitled to an annuity under the Railroad Retirement Act. If an individual has an insufficient work history, he or she may be able to qualify for Medicare based on the work history of a spouse, parent, or guardian (SSA §226A).

[20] Figure 2 in USRDS, "Overview of Kidney Disease."

[21] CMS, *Medicare Coverage of Kidney Dialysis & Kidney Transplant Services*, revised July 2017, p. 13, at https://www.medicare.gov/Pubs/pdf/10128-Medicare-Coverage-ESRD.pdf. If a patient has had a kidney transplant that later fails, entitlement to Medicare Part A and eligibility to enroll in Part B begin the month the patient starts a new

Individuals who qualify for Medicare based on ESRD rather than age are eligible for all Medicare-covered services, including Medicare Part A coverage of hospital care and Part B coverage of physician and post-acute care services.[22] Such beneficiaries also may enroll in the voluntary Part D prescription drug program. Part A and Part B benefits are called *original*, or *fee-for-service* (FFS), Medicare, because Medicare pays providers and facilities for each item or episode of service. Medicare Part C (MA) plans offer Part A and Part B benefits through private insurers and, generally, as part of a managed care network of providers. Medicare beneficiaries under the age of 65 who qualify for Medicare based on ESRD up until CY20201 were allowed to enroll in MA plans only in limited circumstances. Once enrolled, MA enrollees are covered for the same items and services provided under original Medicare (see "Medicare Advantage," below); however, unlike FFS Medicare, MA plans are paid a per-person monthly amount regardless of the actual amount of health care a beneficiary used in the month.

Dialysis Treatment Modalities for ESRD Patients

There are two main forms of treatment for ESRD—kidney transplants and dialysis. A kidney transplant is the preferred treatment for ESRD, but it is not the most common treatment due to a shortage of donor kidneys. At present, the estimated waiting time for a kidney is nearly five years, making it difficult to expand this treatment option. As of June 2020, 101,360 people were on the waiting list for a kidney transplant. The waiting list is maintained by the United Network for Organ Sharing.[23] Overall, in 2017, about 30% of U.S. individuals with a diagnosis of ESRD had been treated with a functioning kidney transplant. (See **Table 1**, below.)

The remaining 70% of individuals with ESRD in 2017 depended on dialysis, which is the process of filtering an individual's blood with a solution known as a dialysate to remove harmful wastes, salt, and water—a process that otherwise would be performed by functioning kidneys. (See **Table 1**, below.) Dialysis also helps to control blood pressure and the levels of other chemicals in the blood. Dialysis does not cure ESRD, and it carries other health risks. However, many people undergoing dialysis are able to carry on a range of normal activities. Dialysis usually is started when an individual has lost 85%-90% of kidney function. Average life expectancy for an individual on dialysis is 5-10 years, although people can live far longer.[24]

course of dialysis. If an individual ended a course of dialysis but later needs to resume treatment, entitlement to Part A and eligibility to enroll in Part B begin in the month in which a regular course of renal dialysis is resumed. See SSA §226A(c).

[22] CRS Report R40425, *Medicare Primer*.

[23] United Network for Organ Sharing, "National Data," at https://www.unos.org/data/transplant-trends/#waitlists_by_organ/. In June 2020, about 1,796 patients were awaiting a kidney/pancreas transplant.

[24] National Kidney Foundation, "Dialysis," at https://www.kidney.org/atoz/content/dialysisinfo.

Table 1. 2017 U.S. End Stage Renal Disease (ESRD) Patients, by Treatment Type

	Patients (Thousands)	Percentage
Total	**746.6**	**100**
Dialysis	**523.7**	**70**
In-Center Hemodialysis	458.6	61
Home Hemodialysis[a]	9.5	1
Peritoneal Dialysis[a]	52.7	7
Unknown	2.9	0.4
Functioning Graft/Transplant	**222.8**	**30**

Source: Compiled by Medicare Payment Advisory Commission (MedPAC) from the United States Renal Data System. See MedPAC, Chart 11-3 in *July 2020 Data Book: Health Care Spending and the Medicare Program*," July 17, 2020, at http://www.medpac.gov/-documents-/data-book.

Notes: Totals may not equal sum of components due to rounding. Data include both Medicare (fee-for-service and Medicare Advantage) and non-Medicare patients. The "Functioning Graft/Transplant" category includes patients who have a functioning graft at the start of the year in question or who receive a transplant during the year in question.

a. Hemodialysis and peritoneal dialysis are home dialysis methods.

There are two main types of dialysis, hemodialysis and peritoneal dialysis. The following sections describe them in greater detail.

Hemodialysis

Hemodialysis is the most common form of dialysis. In hemodialysis, an external machine acts as an artificial kidney (dialyzer). Blood is removed from the body through a system of tubes, with access usually through a vein in an arm, and is filtered and replaced. Hemodialysis typically lasts four hours at a time and is performed three times a week at a dialysis center. A form of hemodialysis can be carried out by a patient in his or her home. Home hemodialysis may involve more frequent and longer sessions and can include nocturnal treatments.[25]

Peritoneal Dialysis

In peritoneal dialysis, a patient's blood is cleaned inside his or her body, using a catheter inserted into the abdominal cavity.[26] Dialysis solution flows through the catheter into a patient's belly to absorb wastes and other fluids. After a few hours, the solution and wastes are drained. This type of dialysis is often performed at home or other clean, private locations outside of a dialysis center, such as an outpatient location. Peritoneal dialysis may work better for certain populations that may not be able to tolerate hemodialysis, such as children or elderly patients with heart disease.[27]

[25] National Institutes of Health (NIH), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), "Hemodialysis," at https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/hemodialysis.

[26] NIH, NIDDK, "Peritoneal Dialysis," at https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/peritoneal-dialysis.

[27] CMS, Section 10, Chapter 11: "End Stage Renal Disease (ESRD)," in *Medicare Benefit Policy Manual*, revised March 1, 2019, at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf. Section 10 also discusses different types of peritoneal dialysis.

Overview of Outpatient Facility and Home Dialysis Providers

CMS defines an *ESRD facility* as an entity that provides outpatient maintenance dialysis services, home dialysis training and support services, or both. The regulations categorize ESRD facilities as either hospital-based or independently operated.[28] To receive Medicare reimbursement for maintenance dialysis services, ESRD facilities must be certified by CMS as meeting safety and quality standards.[29]

There were about 7,441 dialysis facilities in the United States in 2018. Of those, 95% were freestanding dialysis facilities and 5% were hospital-based. Of the total number of dialysis centers, 88% were for-profit and 12% were nonprofit. Most dialysis facilities (83%) are located in urban areas.[30]

The U.S. dialysis industry is dominated nationally by two for-profit companies: DaVita Inc. and Fresenius Medical Group, which together accounted for 75% of Medicare FFS-reimbursed dialysis treatments in 2018. Patients also may obtain outpatient dialysis at facilities owned by hospitals and other nonprofit and for-profit providers, including physician groups. There are limited data on dialysis provider concentration at the local level. A 2017 study that compared dialysis providers in 2001 with dialysis providers in 2011 found that approximately half of the local dialysis markets became more highly concentrated during the period. The consolidation did not limit patient choice, on average.[31]

DaVita

DaVita, headquartered in Delaware, operated 2,753 outpatient dialysis centers in 46 states and the District of Columbia in 2019, serving about 207,000 patients. DaVita also provided acute inpatient dialysis services in about 900 U.S. hospitals.[32] Outpatient dialysis made up 82% of DaVita services and 78% of revenues, whereas home-based dialysis accounted for 13% of services and 16% of revenues; hospital services and revenues made up the rest.

According to DaVita, approximately 90% of the dialysis patients it serves have health care coverage through a government health care program, with 74% covered by original Medicare and MA plans. Medicare payments accounted for 59% of DaVita's U.S. dialysis revenues for 2019, whereas private health insurance payers accounted for 31%, Medicaid and Managed Medicaid plans for 6%, and other government programs for 4%.

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[28] Regulations governing ESRD conditions for coverage can be found at 42 C.F.R. §494.

[29] CMS, "Dialysis," at https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html. As part of the Bipartisan Budget Act of 2018 (BBA 2018; P.L. 115-123), Congress amended SSA §1865 to allow HHS to use outside accreditation bodies for its dialysis facility survey and certification program, as long as the accreditation bodies met specified conditions and requirements.

[30] MedPAC, Table 6-3 in Chapter 6: "Outpatient Dialysis Services," in *Report to the Congress: Medicare Payment Policy*, March 13, 2020, at http://medpac.gov/docs/default-source/reports/mar20_medpac_ch6_sec.pdf?sfvrsn=0 (hereinafter, report cited as MedPAC, *Medicare Payment Policy*). MedPAC, Chart 11-1 in *July 2020 Data Book: Health Care Spending and the Medicare Program*, at http://www.medpac.gov/-documents-/data-book.

[31] Kevin F. Erickson et al. "Consolidation in the Dialysis Industry, Patient Choice, and Local Market Competition," *Clinical Journal of the American Society of Nephrology*, vol. 12, no. 3 (March 2017): pp. 536-545, at doi:10.2215/CJN.06340616.

[32] DaVita Inc., "SEC Filing Details: 2019 10-K," February 21, 2020, p. 3, at https://investors.davita.com/financial-information/sec-filings?field_nir_sec_form_group_target_id%5B%5D=471&field_nir_sec_date_filed_value=2020&items_per_page=10#views-exposed-form-widget-sec-filings-table.

Although Medicare accounts for the majority of DaVita's dialysis revenue, private health insurance payers, which pay significantly higher rates for dialysis services than Medicare, generate nearly all of DaVita's profits, according to the company.

Fresenius

Fresenius is headquartered in Germany, with a North American headquarters in Massachusetts.[33] In 2019, North American sales accounted for 70% of the company's revenues. Fresenius Kidney Care operates more than 2,500 outpatient renal dialysis and home dialysis training facilities in the United States, serving more than 206,000 people.[34]

Fresenius and DaVita together have a significant share of the home dialysis market, and both companies have indicated they want to expand their home dialysis business.[35] In addition, there are nonprofit and smaller home dialysis providers,[36] and some large companies are taking steps to get into the market. For example, CVS Health has set up a subsidiary—CVS Kidney Care—but is in the early stages of its efforts.[37]

Original Medicare Payment for Dialysis Services

When the ESRD benefit was first implemented, Medicare paid health care providers separate amounts for tests, supplies, drugs, and covered services billed for ESRD patients. Over the years, Congress made a number of changes to the payment system in an effort to control costs, including paying dialysis providers a composite rate for many services. As part of the Medicare Improvements for Patients and Providers Act of 2008 (P.L. 110-275), Congress required CMS to implement a prospective payment system (PPS) for Medicare dialysis services. A PPS is a method of payment in which amounts or rates of payment are established in advance for a defined period and generally are based on an episode of care, regardless of the actual amount of care used.

The ESRD PPS, which was phased in over a four-year period starting in 2011, provides a single, bundled payment to a certified ESRD facility for each dialysis treatment. Patients generally are allowed up to three dialysis treatments per week, either in a dialysis center or at a patient's home. Additional treatments may be covered on the basis of medical necessity. The PPS bundled payment covers dialysis and necessary support services, such as training, laboratory tests, drugs related to ESRD treatment, and ESRD-related supplies.[38] Physicians are paid separately for care (see "Nephrologist Payments," below).

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[33] Fresenius, *2019 Annual Report*, at https://annualreport.fresenius.com/2019/.

[34] Letter from C. M. Cameron Lynch, Senior Vice President for Government Affairs, Fresenius, to Seema Verma, CMS Administrator, "Re: CMS-4190-P: Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly," April 6, 2020, at https://www.regulations.gov/document?D=CMS-2020-0010-0218.

[35] Tara Bannow, "Cost Savings, Disruption Threat Pushing More Providers into Home Dialysis," *Modern Healthcare*, January 26, 2019, at https://www.modernhealthcare.com/article/20190126/NEWS/190129974/cost-savings-disruption-threat-pushing-more-providers-into-home-dialysis.

[36] Other providers of home dialysis include U.S. Renal Care (https://www.usrenalcare.com/) and American Renal Associates (https://www.americanrenal.com/). See also Mark E. Neumann, "Large Providers Continue Strong Growth in Home Dialysis," *Nephrology News and Issues*, August 1, 2019, at https://www.healio.com/news/nephrology/20190723/large-providers-continue-strong-growth-in-home-dialysis.

[37] CVS Health, "CVS Kidney Care Launches Home Dialysis Clinical Trial," July 17, 2019, at https://payorsolutions.cvshealth.com/insights/cvs-kidney-care-launches-home-dialysis-clinical-trial.

[38] For more information on the prospective payment system (PPS) system, see CRS Report R45290, *Medicare*

A portion of Medicare reimbursement to dialysis providers is tied to a provider's success in meeting specific quality-of-care measures.[39] Under the ESRD Quality Incentive Program (QIP), CMS annually evaluates whether outpatient dialysis facilities meet a detailed set of standards. Facilities that fall short of the CMS requirements can have their Medicare reimbursement reduced by up to 2%.[40]

CMS also is operating a series of pilot programs designed to test new approaches to paying for ESRD care:

- CMS has been overseeing a five-year pilot program to evaluate coordinated care models for serving ESRD beneficiaries. Under the CMS Comprehensive ESRD Care (CEC) model, which runs from 2015 through 2020, physicians, dialysis clinics, and other providers have formed ESRD Seamless Care Organizations (ESCOs) to care for ESRD patients. ESCOs are reimbursed based on clinical and financial outcomes, including spending on dialysis services, for the ESRD beneficiaries they treat. According to CMS, the model aims to encourage dialysis providers to broadly address beneficiaries' health needs.[41]
- On September 18, 2020, CMS announced a final rule to institute a new pilot program, beginning January 1, 2021, designed to increase home dialysis and kidney transplantation by altering Medicare payment rates under the ESRD PPS and the Medicare Physician Fee Schedule. The pilot program applies to FFS Medicare and encompasses providers and facilities in 30% of U.S. hospital referral regions, which CMS chose at random. Participation is mandatory for providers and facilities chosen for the pilot, although ESRD beneficiaries retain the right to choose their providers.[42] The model is intended to test whether adjusting FFS payment rates will improve rates of home dialysis and kidney transplants and whether doing so will improve or maintain quality of care.

Coverage of End-Stage Renal Disease (ESRD).

[39] CMS, "ESRD Quality Incentive Program," at https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/. Authority for the Quality Incentive Program (QIP) is §153(c) of the Medicare Improvements for Patients and Providers Act of 2008 (P.L. 110-275).

[40] Not all facilities are subject to the QIP standards. For example, a facility must treat a minimum number of cases to fall under review. Any percentage reduction is applied to all Medicare payments for related services performed by the facility receiving the reduction during the applicable payment year.

[41] CMS, "Comprehensive ESRD Care Model (CEC Model) Fact Sheet," at https://innovation.cms.gov/Files/fact-sheet/cec-fs.pdf, and CMS, "Comprehensive ESRD Care Model," at https://innovation.cms.gov/innovation-models/comprehensive-esrd-care. The CEC Model has separate financial arrangements for larger and smaller dialysis organizations. Large dialysis operators, defined as those with 200 or more dialysis facilities, will be eligible for shared savings payments, will be liable for shared losses, and will have higher levels of risk compared with their smaller counterparts. Non-large dialysis organizations, including chains with fewer than 200 dialysis facilities, independent dialysis facilities, and hospital-based dialysis facilities, will have the option of participating in a one-sided track where they can receive shared savings payments but will not be liable for payment of shared losses or participating in a track with higher risk and the potential for shared losses.

[42] CMS, "Medicare Program; Specialty Care Models to Improve Quality of Care and Reduce Expenditures," 85 *Federal Register* 61114, September 29, 2020, at https://www.federalregister.gov/documents/2020/09/29/2020-20907/medicare-program-specialty-care-models-to-improve-quality-of-care-and-reduce-expenditures; 42 C.F.R. Part 512 [CMS-5527-F] RIN 0938-AT89. The program will include a positive adjustment on home dialysis and home dialysis-related claims during the initial three years of pilot. CMS will make upward or downward performance-based adjustments on claims between July 1, 2022, and June 30, 2027, depending on the rates of home dialysis utilization, kidney transplant wait lists, and living donor transplants among the beneficiaries in the pilot.

- On July 10, 2019, CMS announced the Kidney Care Choices (KCC) model (formerly the Comprehensive Kidney Care [CKC] model). The KCC model includes financial incentives for physicians, dialysis centers, and other providers that coordinate care for participating beneficiaries with chronic kidney disease or ESRD and for reducing the total cost of care for these beneficiaries. It also provides financial incentives for successful transplants.[43]

Home Dialysis Payments

The Medicare benefit covers the training and equipment needed for beneficiaries to perform dialysis in a home setting, including delivery, installation, monitoring, and maintenance of home dialysis supplies and equipment.[44] In recent years, Congress and CMS have modified the Medicare ESRD benefit in an effort to expand use of home dialysis, based on data indicating comparable outcomes and satisfaction with home-based care versus other types of dialysis.[45] Since 2011, dialysis providers have been paid the same rate for offering home-based dialysis as for providing outpatient dialysis at one of their facilities.[46] Dialysis providers also may receive an add-on to the PPS payment for having a nurse provide self-dialysis training for patients starting home dialysis, including as many as 15 training sessions for peritoneal dialysis and 25 for home hemodialysis.[47]

In the Bipartisan Budget Act of 2018 (P.L. 115-123) Congress allowed the use of telehealth for ESRD patients undergoing home dialysis. (In addition, CMS has waived certain regulations governing home dialysis, relaxed some standards for home dialysis, and increased the use of telehealth during the COVID-19 pandemic.[48])

[43] CMS, "Kidney Care Choices (KCC) Model," at https://www.cms.gov/newsroom/fact-sheets/kidney-care-choices-kcc-model. Providers will receive adjusted Medicare payments based on care for beneficiaries with chronic kidney disease Stages 4 and 5 and ESRD. Providers may elect from three different payment options that set out different levels of reward- and risk-sharing.

[44] CMS, Section 30.1, Chapter 11: "End Stage Renal Disease (ESRD)," in *Medicare Benefit Policy Manual*, revised March 1, 2019, at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf.

[45] Christopher Chan and Jeffrey Perl, "Dialysis Modality and Survival: Done to Death," *Seminars in Dialysis,* July 2018, p. 315-324.

[46] CMS, Section 30.1, Chapter 11: "End Stage Renal Disease (ESRD)," in *Medicare Benefit Policy Manual*, revised March 1, 2019, at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf. Dialysis providers are not allowed to bill Medicare beneficiaries directly for dialysis items and services included under the Medicare ESRD PPS bundled payment. A dialysis provider receives the same Medicare payment rate for home patients as it would receive for an outpatient facility. The dialysis provider is responsible for the overall management of the home dialysis patient, including ensuring the patient is provided with functional equipment and supplies. This means the provider is responsible for delivering, installing, monitoring, and maintaining supplies and equipment necessary to furnish all modalities of home dialysis.

[47] CMS, Section 30.2, Chapter 11: "End Stage Renal Disease (ESRD)," in *Medicare Benefit Policy Manual*, revised March 1, 2019, at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c11.pdf. The payment accounts for nursing time for each training treatment that is furnished and adjusted by the geographic area wage index. The training add-on payment adjustment is available for adult and pediatric beneficiaries and applies to both peritoneal dialysis and hemodialysis training treatments.

[48] Edwina Brown and Jeffrey Perl, "Increasing Peritoneal Dialysis Use in Response to the COVID-19 Pandemic: Will It Go Viral?," *Journal of the American Society of Nephrology*, vol. 31, issue 8 (August 2020), at https://jasn.asnjournals.org/content/early/2020/07/31/ASN.2020050729. CMS, "End Stage Renal Disease (ESRD) Facilities: CMS Flexibilities to Fight COVID-19," updated July 9, 2020, at https://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers.

The Trump Administration in 2019 set a goal of having 80% of new ESRD patients receiving either home dialysis or a transplant by 2025, as part of a larger initiative on combatting kidney disease.[49] In July 2020, CMS proposed changes to Medicare payments for dialysis services that would provide two-year add-on payments to the ESRD PPS bundle for adoption of advanced equipment for home-based dialysis as an additional incentive for expanded home dialysis services.[50]

The share of Medicare ESRD beneficiaries who are using home dialysis increased from 10% in 2013 to 12% in 2018.[51] However, the increase in home dialysis growth slowed between 2014 and 2017, partly due to a shortage of the solutions needed for peritoneal dialysis. There are also differences in utilization among different segments of the ESRD population. For example, research has found that Whites and Asian Americans have been more likely to use home dialysis than other racial or ethnic groups, although differences have been narrowing.[52] Younger ESRD patients are also more likely to use home dialysis.[53]

There are a number of reasons for low usage of home dialysis, including low patient awareness, lack of education and training for enrollees and physicians, health and living conditions that make it impossible for beneficiaries to perform home dialysis, and lack of support services needed to assist those performing dialysis at home.[54] Although some beneficiaries may switch between

[49] HHS, "HHS Launches President Trump's 'Advancing American Kidney Health' Initiative," July 10, 2019, at https://www.hhs.gov/about/news/2019/07/10/hhs-launches-president-trump-advancing-american-kidney-health-initiative.html. However, according to a report by the U.S. Government Accountability Office (GAO), "physicians and other stakeholders we interviewed estimate that 15 to 25% of dialysis patients could realistically be on home dialysis." GAO, *End-Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home Dialysis*, GAO-16-125, October 15, 2015, at p. 15, at https://www.gao.gov/products/GAO-16-125.

[50] CMS, "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program," 85 *Federal Register* 42132, July 13, 2020, at https://www.federalregister.gov/documents/2020/07/13/2020-14671/medicare-program-end-stage-renal-disease-prospective-payment-system-payment-for-renal-dialysis.

[51] Chapter 6 in MedPAC, *Medicare Payment Policy*, pp. 170 and 182.

[52] Jenny Shen et al., "Expanded Prospective Payment System And Use of and Outcomes With Home Dialysis by Race and Ethnicity in the United States," *Clinical Journal of the American Society of Nephrology*, vol. 14, no. 8 (August 7, 2019), pp 1200-1212, at https://cjasn.asnjournals.org/content/14/8/1200/tab-article-info. According to the study from 2005-2007, a higher proportion of White and Asian patients initiated home dialysis than did Black and Hispanic patients. From 2005 to 2013, as home dialysis use increased, racial/ethnic differences narrowed.

[53] "Executive Summary: Overview of Kidney Disease in the United States," in *USRDS Annual Data Report*, 2019, p. 32, at https://www.usrds.org/annual-data-report/.

[54] Christopher Chan et al, "Exploring Barriers and Potential Solutions in Home Dialysis: An NKF-KDOQI Conference Outcomes Report," *American Journal of Kidney Diseases*, vol. 73, issue 3 (March 2019), pp. 363-371, at https://www.sciencedirect.com/science/article/abs/pii/S0272638618310606?via%3Dihub (online publication December 2018). According to the findings,

> Clinical, operational, policy, and societal barriers were identified that need to be overcome to ensure that dialysis patients have the freedom to choose their treatment modality. Education of patients and patient partners, as well as health care providers, about home dialysis therapy, if offered at all, is often provided in a cursory manner. Lack of exposure to home dialysis therapies perpetuates a lack of familiarity and thus a hesitancy to refer patients to home dialysis therapies. Patient and care partner support, both psychosocial and financial, is also critical to minimize the risk for burnout leading to dropout from a home dialysis modality. Thus, the facilitation of home dialysis therapy will require a systematic change in chronic kidney disease education and the approach to dialysis therapy initiation, the creation of additional incentives for performing home dialysis, and breakthroughs to simplify the performance of home dialysis modalities.

In addition, GAO identified potential changes in CMS payment policy and other policy that could affect use of home dialysis. See GAO, *End-Stage Renal Disease: Medicare Payment Refinements Could Promote Increased Use of Home*

home and in-center dialysis, given the training and equipment required, beginning home dialysis can be a complicated process.

Further, even though PPS payment is the same for home-based and in-center dialysis, providers may have incentives to prefer in-center dialysis, such as unused capacity.[55] According to the Government Accountability Office (GAO), from 1988 to 2008, the growth in outpatient dialysis capacity outpaced the growth in the dialysis patient population and, "as a result, dialysis facilities may have had a greater financial incentive to treat patients in facilities in an effort to use this expanded capacity." GAO predicts a realistic goal would be to have 15%-25% of ESRD patients in home-based dialysis.[56]

Nephrologist Payments

Nephrologists, physicians who specialize in diseases that affect the kidneys, play a central role in the treatment of patients with ESRD. Nephrologists diagnose the disease, chart a course of treatment, provide counseling regarding dialysis and transplant options, and monitor routine patient care.

Medicare pays nephrologists, and other approved practitioners, a monthly per patient rate for most outpatient dialysis-related services, which is separate from the ESRD PPS.[57] Certain additional services are billed separately to Medicare, in accordance with the Medicare Physician Fee Schedule. Physicians also bill Medicare separately for training patients to perform home hemodialysis, self-hemodialysis, and various forms of self-peritoneal dialysis.[58]

Nephrologist services can be provided in an office or another covered setting, such as a dialysis facility. For patients receiving treatment in a dialysis facility, the physician payment rate varies based on the number of patient visits during a month and the ESRD beneficiary's age. Physicians and practitioners managing ESRD patients who perform home-based dialysis are paid a single monthly rate based on the ESRD beneficiary's age. A physician or practitioner is required to have at least one face-to-face visit with a home dialysis patient each month.[59]

Nephrologists work in individual or group practices, in academic settings, or at health care institutions. Many have long-standing relationships with specific outpatient dialysis facilities where they refer and monitor patients.[60] In addition, there are numerous other administrative and

Dialysis, GAO-16-125, October 15, 2015, at https://www.gao.gov/products/GAO-16-125 (hereinafter, GAO-16-125).

[55] GAO-16-125, p. 12.

[56] GAO-16-125, p. 15.

[57] CMS, Section 140.1 in Chapter 8: "Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims," in *Medicare Claims Processing Manual*, revised July 31, 2020, at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c08.pdf.

[58] CMS, Section 140.1 in Chapter 8: "Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims," in *Medicare Claims Processing Manual*, revised July 31, 2020, p. 119, at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c08.pdf.

[59] CMS, Section 140.1 in in Chapter 8: "Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims," in *Medicare Claims Processing Manual*, revised July 31, 2020, at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c08.pdf. BBA 2018 allows ESRD beneficiaries undergoing home dialysis to receive monthly face-to-face clinical assessments via telehealth services, so long as the individual receives a face-to-face assessment without the use of telehealth (1) at least monthly for the initial three months of home dialysis and (2) after the initial three months, at least once every three consecutive months.

[60] American College of Physicians, "Nephrology," at https://www.acponline.org/about-acp/about-internal-medicine/subspecialties/nephrology. "Many nephrologists work in individual or group practices seeing patients in consultation for other physicians and following patients with chronic kidney disease longitudinally. Nephrologists may also provide

financial ties between the practitioners and dialysis facilities. Here are some examples from dialysis provider DaVita's 2019 *Annual Report*:

- DaVita contracts with more than 1,000 nephrologists to serve as medical directors at its dialysis facilities.[61] (Medicare has long required that participating dialysis clinics have medical directors.[62])
- DaVita carries out joint ventures in which it owns a majority share of an outpatient dialysis clinic and nephrologists, hospitals, management services organizations, or other providers own a minority share. Approximately 26% of DaVita's net U.S. dialysis revenues in 2019 came from such joint ventures.[63]
- DaVita operates a subsidiary, Nephrology Practice Solutions, that provides recruitment, staffing, and management services to nephrologist practices. The subsidiary also owns and operates nephrology practices in multiple states.

In addition to these relationships, dialysis providers and physician groups are establishing joint ventures designed to provide more comprehensive, coordinated care for individuals with kidney disease. The new models build on existing CMS pilot programs in which practitioners are paid based on outcomes rather than on the number of services performed.[64]

Some have expressed concerns about a lack of transparency regarding dialysis joint ventures with physician groups, amid evidence that patients may be steered to centers in which nephrologists have a financial interest.[65] In 2014, for example, DaVita agreed to pay $350 million to resolve claims it violated the False Claims Act by paying kickbacks to physicians and physician groups to induce the referral of patients to its dialysis clinics.[66]

ESRD Patient Spending and Demographics

In addition to Medicare coverage of dialysis and transplants, many Medicare beneficiaries with ESRD have other chronic health conditions that require medical care, such as diabetes, heart disease, or hypertension. According to CMS, the projected per capita monthly cost for a FFS Medicare enrollee in 2020 is about $1,000. By comparison, the projected FFS per capita monthly cost for a Medicare beneficiary with ESRD undergoing dialysis is about $8,000.[67] Because of

in-hospital consultation as part of their practice. Nephrologists also oversee dialysis units which may be associated with their own practice, may be free-standing, or affiliated with a hospital."

[61] The term *medical director* refers to a physician who oversees the medical care and other specified care and services in a health care organization or facility.

[62] Franklin Maddux and Allen Nissenson, "The Evolving Role of the Medical Director of a Dialysis Facility," *Clinical Journal of the American Society of Nephrology*, vol. 10, no. 2 (February 2015), pp. 326-330, at https://doi.org/10.2215/CJN.04920514.

[63] DaVita, *2019 Annual Report*, April 22, 2020, p. 8. DaVita also noted in its *2019 Annual Report* that more than 5,600 nephrologists refer patients to its outpatient centers.

[64] Fresenius, "InterWell Health to Provide Population Health Management for Nation's Renal Patients," December 18, 2019, at https://www.prnewswire.com/news-releases/interwell-health-to-provide-population-health-management-for-nations-renal-patients-300977161.html.

[65] Jeffrey Berns, Aaron Glickman, and Matthew McCoy, "Dialysis-Facility Joint-Venture Ownership—Hidden Conflicts of Interest," *New England Journal of Medicine*, vol. 379, no. 14 (October 4, 2018), pp. 1295-1297.

[66] U.S. Department of Justice, "DaVita to Pay $350 Million to Resolve Allegations of Illegal Kickbacks," October 22, 2014, at https://www.justice.gov/opa/pr/davita-pay-350-million-resolve-allegations-illegal-kickbacks.

[67] CMS, "Early Preview– CY2021 Medicare Advantage Ratebook Growth Rates," December 3, 2019, at https://www.cms.gov/files/document/2021-early-preview-ma-growth-rates.

their higher average costs, Medicare FFS beneficiaries with ESRD account for about 7% of Medicare FFS spending and make up about 1% of total program enrollment (FFS and MA combined).

Compared with the overall Medicare FFS population, FFS dialysis patients are disproportionately younger, non-White, and poor. In 2018, 48% of FFS dialysis patients were dually eligible for Medicare and Medicaid, compared with 17% of all FFS beneficiaries, and nearly half were under the age of 65. Overall, in 2018, 47% of Medicare FFS dialysis beneficiaries were White, 35% were African American, 8% were Hispanic, 4% were Asian, and 6% were classified as other.[68] By comparison, of all other FFS beneficiaries, 81% were White, 10% were African American, 3% were Hispanic, 2% were Asian, and 5% were classified as other. Studies have shown that Blacks are more likely than Whites to progress from CKD to ESRD and are less likely to obtain a kidney transplant or home dialysis.[69]

Medicare Advantage

MA is an alternative way for beneficiaries to receive Medicare-covered benefits. In general, companies offer MA plans in areas of their choosing, generally consisting of counties or groups of counties or, in the case of MA regional preferred provider organization (PPO) plans, states or groups of states, as defined by the Secretary.[70]

All items and services covered under original Medicare also are covered by MA plans, except hospice.[71] MA plans also may offer reduced cost sharing or Medicare Part D drug coverage and supplemental benefits not covered under original Medicare.[72]

Although the required Medicare benefits are available to MA enrollees just as they are to enrollees in original Medicare, MA plans and original Medicare differ in terms of payments, beneficiary costs, and the providers and facilities from whom enrollees can receive care.

- **Medicare Payments**. There are two different payments to consider:
    - *Medicare Payments to Plans:* Unlike original Medicare, in which CMS pays medical providers and facilities for each covered item, procedure, episode, or spell of illness, CMS pays MA plans a risk-adjusted per capita monthly amount to provide all required Part A and Part B benefits to enrollees,[73] regardless of the number of services an enrollee uses in a

[68] MedPAC, Table 6-1 in Chapter 6: "Outpatient Dialysis Services, in *Report to the Congress: Medicare Payment Policy*, March 13, 2020, at http://medpac.gov/docs/default-source/reports/mar20_medpac_ch6_sec.pdf?sfvrsn=0.

[69] Keith Norris et al, "Hemodialysis Disparities in African Americans: The Deeply Integrated Concept of Race in the Social Fabric of Our Society," *Seminars in Dialysis*, vol. 30, no. 3 (May 2017), pp. 213-223, at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5418094/.

[70] 42 C.F.R. §422.2.

[71] MA plans are required to cover all Medicare required benefits except hospice. If an MA enrollee chooses hospice, the hospice benefit is paid through original Medicare but the beneficiary remains enrolled in his or her MA plan and retains access to his or her doctors and supplemental benefits.

[72] Except for certain statutorily specified high-cost items and services, cost sharing for items and services under an MA plan may be higher or lower than cost sharing required under original Medicare. Cost sharing under the MA plan must be at least actuarially equivalent to cost sharing under original Medicare; however, plans can reduce cost sharing for items and services as a supplemental benefit under the plan.

[73] Risk adjustment compensates plans for the higher expected cost of enrollees who are older or have identified, underlying health conditions, such as heart disease or diabetes. It also reduces plan payments for the lower expected cost of enrollees who are younger and healthier.

month. The capitated payment is based on a statutory formula that takes into account spending in original Medicare.[74] (See "Medicare Payments to MA Plans for ESRD Enrollees.")

- *MA Plan Payments to Providers and Facilities:* MA plans negotiate with medical providers and facilities that join their network (i.e., *in-network providers*) to determine the amount the MA plan will pay the provider or facility for providing care to plan enrollees; the negotiated payment amount may differ from the amount paid under original Medicare. If a plan enrollee receives care from a provider or facility that is outside of the plan's network, the provider or facility is paid the amount they would have received under original Medicare.[75] However, the enrollee may be required to pay all or a portion of that cost, depending on, for example, whether the care was an emergency or urgently needed care, whether the beneficiary was directed by his or her network provider to see a non-network specialist, or whether the plan's provider network was inadequate to serve the beneficiary's needs.[76]

- **Medicare Advantage Premium.** Under original Medicare, beneficiaries who choose to enroll in Part B must pay a monthly premium.[77] To be eligible to enroll in an MA plan, a beneficiary must be eligible for Part A, enrolled in Part B, and have a plan that serves his or her area. MA enrollees pay the Part B premium but also may be required by their plan to pay an MA premium. The MA premium may reflect the plan's ability to provide required benefits relative to the maximum amount of payment allowed under the statute, the value of supplemental benefits, or both.[78] (Note that an MA plan may change its premium from year to year, as discussed in "Considerations for Plan Year 2021 and Beyond," below.)
- **Out-of-Pocket Costs**. Under original Medicare, there is no out-of-pocket (OOP) cap on beneficiary spending for deductibles, coinsurance, and co-payments. MA plans have a 2021 maximum OOP limit for in-network service of $7,550.[79] MA plans may offer OOP limits that are lower than this cap. (Note that an MA plan

[74] For more information, see MedPAC, "Medicare Advantage Program Payment System," at http://medpac.gov/docs/default-source/payment-basics/medpac_payment_basics_20_ma_final_sec.pdf?sfvrsn=0.

[75] See CMS, "MA Payment Guide for Out of Network Payments," updated April 15, 2015, at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/oonpayments.pdf.

[76] CMS, *Understanding Medicare Advantage Plans*, at https://www.medicare.gov/Pubs/pdf/12026-Understanding-Medicare-Advantage-Plans.pdf.

[77] CRS Report R40082, *Medicare Part B: Enrollment and Premiums*.

[78] An analysis by the Kaiser Family Foundation (KFF) found that 60% of MA enrollees in 2020 did not pay an additional premium for their MA plan that included the Part D prescription drug benefit (MAPD). Of enrollees who paid a premium for their MAPD plan in 2020, the average premium was $63. Meredith Freed, Anthony Damico, and Tricia Neuman, "A Dozen Facts About Medicare Advantage in 2020," KFF, at https://www.kff.org/medicare/issue-brief/a-dozen-facts-about-medicare-advantage-in-2020/.

[79] Although many MA plans choose the counties to include in their service areas, one type of MA plan—MA regional preferred provider organizations (PPOs)—agrees to serve entire regions of states and groups of states, as defined by the HHS Secretary. The maximum out-of-pocket (OOP) cap that applies to regional PPO plans (for in- and out-of-network care) for 2021 is $11,300. Prior to 2021, when calculating maximum OOP limits, CMS did not take into account the OOP costs of beneficiaries with ESRD; CMS will begin phasing in those expenditures in 2021. The maximum OOP cap for all MA enrollees will increase as ESRD expenditures are phased in. See Coleman, *HPMS Memo*, p. 6.

may change its out-of-pocket maximum from year to year, as discussed in "Considerations for Plan Year 2021 and Beyond," below.)

- **Limited Selection of Providers**. Under original Medicare, beneficiaries can seek care from any qualified Part A provider with an agreement to participate in Medicare or any qualified Part B supplier who accepts assignment on either a participating or a nonparticipating basis.[80] In contrast, an MA enrollee's choice of provider may be restricted to those in the plan's network (see "Background on Network Adequacy"). Most MA plans are required to develop contracted networks of health care providers and facilities from which enrollees can receive benefits. However, enrollees' ability to seek nonemergency care outside of the MA network can vary by plan type. For example, PPOs allow enrollees to receive nonemergency out-of-network care, usually with higher cost sharing than in-network care. MA regional PPO plans—plans that agree to offer coverage to beneficiaries living in regions designated by CMS—are not required to have contracted networks of providers to fulfill network requirements in certain areas, thus providing even greater provider choice in those circumstances.[81] (Note that an MA plan may change its provider network from year to year, as discussed in "Considerations for Plan Year 2021 and Beyond," below.)

Medicare Payments to MA Plans for ESRD Enrollees

As mentioned above, Medicare pays private plans a monthly capitated amount to provide all required Medicare benefits to beneficiaries who enroll in their plans. For non-ESRD enrollees, the plan payment is determined based on a comparison of each plan's estimated cost of providing Medicare covered services (*bid*) with the maximum amount the federal government will pay for providing those services in the plan's service area (*benchmark*). If a plan's bid is less than the benchmark, the plan's payment equals its bid plus a rebate, which must be returned to enrollees in the form of additional benefits, reduced cost sharing, reduced Part B or Part D premiums, or some combination of these options. If a plan's bid is equal to or greater than the benchmark, its payment will be the benchmark amount and each enrollee in that plan will pay an additional premium, equal to the amount by which the bid exceeds the benchmark.

Benchmarks for non-ESRD aged and disabled enrollees are calculated as a percentage of per capita spending by beneficiaries in FFS Medicare. The percentages are 95%, 100%, 107.5%, or 115%, with higher percentages applied to counties with lower FFS spending. For example, the

[80] A Medicare participating physician or practitioner agrees to accept assignment for all Medicare beneficiaries for whom they provide services and acknowledges the Medicare payment amount, including coinsurance, as payment in full. Non-participating physicians or practitioners may choose to accept assignment on a service-by-service basis and are allowed limited balance billing above a reduced Medicare payment amount.

[81] 42 C.F.R. §422.112(a)(ii) allows MA regional plans, with CMS approval, to meet network adequacy requirements using methods other than contracted providers. "A regional PPO may establish a network that meets the statutory network adequacy requirements throughout 85% of a region. In that part of the region, the plan may charge higher cost sharing for out-of-network services. But in the part of the region without a network, the plan cannot charge higher cost sharing for out-of-network services." MedPAC, *Report to Congress: Issues in a Modernized Medicare Program*, June 2005, p. 64, at http://www.medpac.gov/docs/default-source/reports/June05_ch3.pdf?sfvrsn=0. As of September 2020, most MA enrollees were in a local coordinated care plan, such as a local health maintenance organization or a local PPO (95.0%). Regional PPO enrollees make up 4.7% of all MA enrollment, and private fee-for-service enrollees (0.3%) and medical savings account enrollees (0.03%) make up the remaining enrollment. See CMS, "Monthly Contract and Enrollment Summary Reports," at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-Contract-and-Enrollment-Summary-Report.

25% of counties with the lowest FFS spending receive the highest percentage (115%) of per capita FFS as their MA benchmark. The 25% of counties with the highest FFS spending receive the lowest percentage (95%) of per capita FFS. Benchmarks may be increased for high-quality plans, with quality measured by a five-star rating system. Overall, benchmarks are subject to a limit based on the level of benchmarks calculated using the methodology that applied prior to the Patient Protection and Affordable Care Act (P.L. 111-148). Finally, payments (after the bid and benchmark comparison) are risk adjusted to account for the higher cost of older or sicker beneficiaries and the relatively lower cost of younger or healthier beneficiaries.

Payments to MA plans for ESRD enrollees using dialysis are not determined based on bids and benchmarks, as described above.[82] Instead, Medicare payments for enrollees using dialysis are, in general, based on 100% of the statewide per capita spending for beneficiaries on dialysis in FFS Medicare, risk adjusted by an ESRD risk adjustment model for enrollees undergoing dialysis. MA beneficiaries with ESRD pay the same plan premiums as those without ESRD who are enrolled in the same plan. ESRD payments are not adjusted by plan quality.

ESRD Enrollment

In 2019, 532,000 Medicare enrollees with ESRD had Medicare Part A benefits. Of those beneficiaries, 401,000 were in original Medicare and 131,000 were in Medicare private plans, equating to MA enrollment of about 25% of all ESRD beneficiaries.[83] By comparison, about 39% of all Medicare beneficiaries were enrolled in MA plans in 2020.[84]

The lower MA enrollment reflects, in part, long-standing policies that have prevented ESRD beneficiaries from joining MA plans. Currently, Medicare beneficiaries with ESRD may be enrolled in MA plans *only if* the beneficiaries

- developed ESRD while already enrolled in an MA plan;
- developed ESRD while receiving health benefits through the same organization (such as an employer group health plan) that offers the MA plan;
- had a kidney transplant and no longer require dialysis but are entitled to Medicare due to age or disability; or
- have an ESRD Medicare Special Needs Plan (SNP) in their geographic area. A SNP is an MA plan that exclusively enrolls, or enrolls a disproportionate percentage of, special needs individuals, such as those with severe or disabling chronic conditions.[85]

An ESRD beneficiary who is enrolled in an MA plan that is later discontinued has a one-time right to join another MA plan.

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[82] Medicare payments to plans vary by dialysis status, with a different payment and risk-adjustment model for enrollees using dialysis, those who have had a recent transplant, and those with a functioning transplant. For more information, see RTI International, *Report to Congress: Risk Adjustment in Medicare Advantage*, December 2018, p. 30, at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/RTC-Dec2018.pdf.

[83] CMS, "Medicare Program," 85 *Federal Register* 33886. Not all Medicare private plans are considered MA plans. For example, plans paid by Medicare based on the cost of services used by the enrollees or based on demonstration authority are not considered MA plans.

[84] MedPAC, Chart 9-1 in *July 2020 Data Book*: *Health Care Spending and the Medicare Program*, p. 121, at http://www.medpac.gov/-documents-/data-book.

[85] SSA §1859(a)(6).

Patient advocates and lawmakers have said ESRD patients, with their more complex medical conditions and comorbidities, could benefit from joining MA plans.[86] MA plans, for example, are required to ensure continuity of care and integration of services, including offering each enrollee a primary care provider, implementing programs for coordinating plan services with community and social services available in the area, and developing systems to address enrollee barriers to prescribed treatments and regimens.[87]

As mentioned above, unlike FFS Medicare, MA plans are subject to annual enrollee OOP caps, which could be particularly beneficial for ESRD beneficiaries under the age of 65 who have high medical costs. (See also "Considerations for Plan Year 2021 and Beyond," below.) Some Medicare beneficiaries may have an alternative option for a plan with an OOP spending cap—a Medigap policy—that might not be available to all ESRD beneficiaries. FFS Medicare beneficiaries over the age of 65 have a guaranteed right to purchase supplemental Medigap coverage, which provides additional protection from high OOP costs, such as annual deductibles or cost sharing.[88] By contrast, there is no general federal requirement that insurers sell Medigap plans to Medicare beneficiaries under the age of 65 who qualify for Medicare based on disability, including those with ESRD. However, according to the Department of Health and Human Services (HHS), 33 states require insurers to offer at least one type of Medigap policy to Medicare beneficiaries under the age of 65.[89] Some insurers voluntarily sell Medigap plans to younger Medicare enrollees, even when there is no state requirement to do so. If permitted by state law, insurers may use medical underwriting and charge higher premiums for Medigap plans when selling to those under the age of 65, which could make the plans cost-prohibitive for younger ESRD patients.

Although MA care coordination and limits on OOP spending may be attractive features for ESRD beneficiaries, MA plans often have contracted networks of providers from whom enrollees receive care. As such, MA enrollees may have access to a more limited number of physicians, dialysis centers, and other health care providers than FFS beneficiaries.

Background on Network Adequacy

In general, MA plans are required to develop contracted networks of medical providers and facilities from whom their enrollees can receive covered benefits. Though MA plans may limit the number of providers and facilities in their network, the network must be sufficient to ensure required Medicare benefits are available and accessible to each enrollee with reasonable promptness and are consistent with community standards of care, taking into account the number and distribution of providers in a geographic area and other factors that CMS determines

[86] See Dialysis Patient Citizens, "Medicare Advantage," fact sheet, at https://www.dialysispatients.org/policy-issues/promote-financial-security/medicare-advantage/; and statement on a related bill, H.R. 5659, the Expanding Seniors Receiving Dialysis' Choice Act of 2016, which passed the House on September 21, 2016, by Representative Bilirakis, "Bilirakis Bill to Help End Stage Renal Disease Patients," press release, July 8, 2016, at https://bilirakis.house.gov/media/press-releases/bilirakis-bill-help-end-stage-renal-disease-esrd-patients.

[87] 42 C.F.R. §422.112(b).

[88] CMS, "Medicare Program: Recognition of NAIC Model Standards for Regulation of Medicare Supplemental Insurance," 74 *Federal Register* 18810, April 24, 2009.

[89] Medicare.gov, "When Can I Buy Medigap?," at https://www.medicare.gov/supplements-other-insurance/when-can-i-buy-medigap. According to HHS, some states provide Medigap rights to everyone with Medicare under the age of 65. Other states provide these rights only to people eligible for Medicare because of disability or only to people with ESRD. (In addition, see MedicareResources.org, "Medigap Eligibility for Americans Under Age 65 Varies by State," at https://www.medicareresources.org/medicare-eligibility-and-enrollment/medigap-eligibility-for-americans-under-age-65-varies-by-state/.)

appropriate.[90] In short, "the plan must ensure that contracted providers are distributed so that no enrollee residing in the service area must travel an unreasonable distance to obtain covered services."[91]

Over the years, CMS has developed an automated, objective process to evaluate network adequacy based on criteria such as the number and location of specified provider and facility types. CMS has issued specific network criteria as sub-regulatory guidance, which is generally followed by plans but does not have the legal force of a regulation.[92]

For plan year 2020, to meet network adequacy criteria, MA plans must contract with both (1) a minimum number of providers and facilities for each specified specialty/type and (2) a sufficient number of specified providers and facilities to ensure that 90% of beneficiaries residing in a county have access to at least one of each type of provider and facility within set maximum time and distance standards.[93] The maximum time and distance standards vary by provider and facility type and by county type; county types are defined as counties that are part of (1) large metro areas, (2) metro areas, (3) micro areas, (4) rural areas, as well as (5) counties with extreme access considerations (CEAC), all of which are based on population size and density (see **Table 2**).[94]

Nephrologists and outpatient dialysis facilities are included in the specified network criteria. For example, for 2020, MA plans must contract with a sufficient number of outpatient dialysis centers such that 90% of beneficiaries in a rural county in their service area have access to a center within 55 minutes or 50 miles from their home. Maximum time and distance standards are shorter for metro or large metro areas and longer for CEACs, as shown in **Table 2**.[95] Under a CMS exceptions process, a plan may request new criteria if it cannot meet the published criteria in a particular area due to a provider or facility shortage.[96]

The Medicare Payment Advisory Commission (MedPAC) found the maximum distance criteria for MA network adequacy for dialysis centers exceeded the typical travel distances that new ESRD beneficiaries in FFS Medicare traveled to obtain dialysis for most types of counties. When calculating driving distances of new FFS dialysis beneficiaries, MedPAC found the median distance to be 6 miles and the 25th and 75th percentiles to be approximately 3 miles and 13 miles, respectively. Beneficiaries in rural counties traveled farther than those in urban areas (with median travel distances of approximately 11 miles and 5.5 miles, respectively.) According to

[90] SSA §1852(d)(1) and 42 C.F.R. §422.112(a).

[91] CMS, Chapter 4: "Benefits and Beneficiary Protections," in *Medicare Managed Care Manual*, April 22, 2016, p. 78, at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Internet-Only-Manuals-IOMs-Items/CMS019326.

[92] CMS, *Medicare Advantage Network Adequacy Criteria Guidance*, January 10, 2017, at https://www.cms.gov/Medicare/Medicare-Advantage/MedicareAdvantageApps/Downloads/.MA_Network_Adequacy_Criteria_Guidance_Document_1-10-17.pdf.

[93] It may be the case that after the minimum number criteria are met, additional providers or facilities must be added to the network to fulfill the maximum time and distance criteria.

[94] CMS created county size designations based on "approaches used by the United States Census Bureau in its classification of 'urbanized areas' and 'urban clusters,' and by the Office of Management and Budget (OMB) in its classification of 'metropolitan' and 'micropolitan.'" The CMS measure is based on county population and population density. CMS proposed codifying the designations that had applied prior to the proposed rule, and those designations were finalized as proposed. CMS, "Medicare Program," 85 *Federal Register* 9094.

[95] CMS, "Medicare and Medicaid Programs: Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly," 85 *Federal Register* 9095-9096, February 18, 2020.

[96] See GAO, *Medicare Advantage: Actions Needed to Enhance CMS Oversight of Provider Network Adequacy*, GAO-15-710, August 31, 2015, at https://www.gao.gov/products/GAO-15-710.

MedPAC's findings, "the maximum distance standard applied for MA network adequacy is 10 miles for large metro areas. For all other areas, maximum distance standards range from 30 to 90 miles. Although the network adequacy distance standard is a maximum, it is worth noting that the standard for areas (other than large metro areas) vastly exceeds the range of distances commonly traveled for dialysis in FFS Medicare."[97]

Table 2. Selected Time and Distance Medicare Advantage (MA) Network Adequacy Standards

(time in minutes, distance in miles)

Provider/	Large Metro		Metro		Micro		Rural		CEAC[a]	
Facility Type	Max Time	Max Dist.	Max Time	Max Dist.	Max Time	Max Dist.	Max Time	Max Dist.	Max Time	Max Dist.
Nephrology	30	15	45	30	80	60	90	75	125	110
Outpatient Dialysis	20	10	45	30	65	50	55	50	100	90

Source: Centers for Medicare & Medicaid Services (CMS), "Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly, Proposed Rule," 85 *Federal Register* 9095, February 18, 2020, at https://www.federalregister.gov/documents/2020/02/18/2020-02085/medicare-and-medicaid-programs-contract-year-2021-and-2022-policy-and-technical-changes-to-the.

Notes: All geographic designations are based on population size and density at the county level, as defined by CMS. For details, see CMS, "Medicare Program," 85 *Federal Register* 9094. Dist. = distance.

a. CEAC = counties with extreme access considerations.

MA Program Changes Related to ESRD in the 21st Century Cures Act

The Cures Act requires that, starting in 2021, individuals who qualify for Medicare on the basis of ESRD—rather than on the basis of age—be allowed to enroll in MA plans. Recognizing the higher average cost of ESRD beneficiaries as compared with other Medicaid beneficiaries, and to more accurately pay plans for enrollees with ESRD and CKD, the Cures Act included special provisions pertaining to ESRD and CKD:[98]

- **Kidney Acquisition Costs.** Instead of requiring MA plans to pay for the high costs associated with kidney acquisition, including Medicare-covered expenses for a kidney donor, from the MA plan's capitated payment, the Cures Act requires that kidney acquisition costs be paid by FFS Medicare. The Cures Act also requires the HHS Secretary to remove the estimated cost of kidney acquisition from all MA payments, which means reducing the per capita FFS

[97] Letter from Francis J. Crosson, MedPAC Chairman, to Seema Verma, CMS Administrator, "RE: CMS-4190-P," April 3, 2020, pp. 16-17, at http://www.medpac.gov/docs/default-source/comment-letters/04032020_ma_partd_comment_v2_sec.pdf?sfvrsn=0.

[98] See description of §17006 in CRS Report R44730, *Increasing Choice, Access, and Quality in Health Care for Americans Act (Division C of P.L. 114-255)*.

spending estimate used in the benchmark for aged and disabled beneficiaries and the ESRD payment rates starting in 2021.[99]

- **Kidney Disease-Related Risk Adjustment.** The HHS Secretary must evaluate the impact of adding CKD variables to the MA risk-adjustment model for aged and disabled beneficiaries. Any subsequent changes to the model are to be phased in by 2022, which may result in higher payments for sicker beneficiaries.[100]
- **Quality Ratings.** The HHS Secretary must evaluate whether the current MA quality rating system should be adjusted to account for ESRD enrollees. Plan quality ratings are displayed on Medicare.gov to assist beneficiaries when deciding whether to enroll in an MA plan or which plan to choose. In general, high-quality ratings also may increase benchmarks used to determine plan payments for aged and disabled enrollees. However, MA plan payments for ESRD enrollees are not adjusted by plan quality.

CMS projects that ESRD enrollment in MA plans will increase by 83,000 due to the Cures Act changes. The increase is assumed to take place over six years, although half of the additional beneficiaries (41,500) are expected to enroll in MA plans in the first year, 2021.[101] In spite of the payment and risk-adjustment changes in the Cures Act, MA plans have expressed concern about whether they will receive sufficient compensation for the more expensive ESRD patients.[102] As discussed in the next section, health plans' concerns are based on the level of CMS payments,[103] as well as "rising dialysis costs given little competition in a market dominated by DaVita and Fresenius."[104]

MA Plan Concerns About ESRD Payments and Dialysis Provider Competition

Recent insurer-sponsored analyses suggest MA payments for ESRD enrollees undergoing dialysis fall short of the cost of serving these beneficiaries. By one estimate, for some MA plans, the cost of serving ESRD enrollees exceeds premium income (i.e., Medicare payment and beneficiary premiums) by 12%.[105] This loss may be due, in part, to how the OOP cap is calculated. CMS sets the maximum OOP cap at the 95th percentile of projected beneficiary OOP spending for the year ($7,550 for 2021). This means that 95% of beneficiaries in original Medicare have projected OOP spending that will be below $7,550 in 2021. However, CMS "has not traditionally used out-of-

[99] CMS, "Medicare Program," 85 *Federal Register* 33825.

[100] The HHS Secretary added an additional chronic kidney disease variable to the two chronic kidney disease variables already in the risk-adjustment model, with phase-in of the new model starting in 2019. For additional information, see CMS, *Advance Notice of Methodological Changes for Calendar Year (CY) 2019 for the Medicare Advantage (MA) CMS-HCC Risk Adjustment Model, Part I*, December 27, 2017, p. 10, at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Announcements-and-Documents-Items/2019Advance.

[101] CMS, "Medicare Program," 85 *Federal Register* 33796.

[102] Matthew Eyles, "AHIP Detailed Comments on Advance Notice of Methodological Changes for Calendar Year (CY) 2021 for Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies," AHIP, March 6, 2020, pp. 3-4, at https://www.ahip.org/wp-content/uploads/AHIP-2021-Advance-Notice-Comment-Letter_WakelyReport.pdf (hereinafter, Eyles, "AHIP Detailed Comments").

[103] Eyles, "AHIP Detailed Comments," pp. 3-4.

[104] Better Medicare Alliance, "Medicare Advantage Group Pushes Back on Kidney Treatment Expansion," at https://www.bettermedicarealliance.org/news/medicare-advantage-group-pushes-back-on-kidney-treatment-expansion/.

[105] Courtney and Stewart, *Increased ESRD Beneficiary Enrollment Flexibility*, p. 3.

pocket spending data for beneficiaries with diagnoses of ESRD in this process."[106] Because of ESRD beneficiaries' very poor health, they have much higher spending than non-ESRD beneficiaries. As a result, whereas 5% of a plan's non-ESRD enrollees likely would reach the OOP maximum in a year and stop paying cost sharing for subsequent care, all or nearly all of a plan's ESRD enrollees likely would reach the OOP maximum in a year and stop paying cost sharing on subsequent care. When a beneficiary reaches the OOP maximum, the plan—rather than the beneficiary—must pay for subsequent care. As CMS sets the OOP maximum, plans attempting to recoup any losses may look to increasing premiums or reducing supplemental benefits for all enrollees. CMS plans to begin incorporating ESRD spending data into the OOP cap calculation starting in 2021.

The authors of the study cited above suggest that another possible reason for the 12% loss on each ESRD enrollee is plans' ability or inability to negotiate favorable payment rates to dialysis providers that they must have in their plan networks.[107] In developing their provider networks, MA plans, in general, must contract in or near the plan's service area with providers and facilities that will serve their enrollees. The terms of those contracts, which include the amounts plans agree to pay for services and, correspondingly, the amounts providers and facilities are willing to accept for providing those services, are negotiated between each MA plan, on the one side, and each provider or provider group and each facility or health system, on the other.[108] Negotiations may start with the payment amount provided under original Medicare (such as the ESRD PPS), but reimbursement may be raised or lowered depending on the conditions in the local market and which party—the plan or the provider/facility—has a stronger bargaining position. However, although there have been studies examining MA payments to network hospitals and the degree to which those rates are greater or less than rates under FFS Medicare, a comparable analysis of MA rates to outpatient dialysis centers is not available.[109]

Final Rule for 2021 Enrollment of ESRD Beneficiaries in MA Plans with Respect to Network Requirements

On June 2, 2020, CMS issued a final rule setting a number of MA requirements for CY2021. This final rule included regulations governing kidney acquisition costs, risk adjustment, and other issues related to the ESRD transition, including network adequacy.

As part of the final rule, CMS codified its existing sub-regulatory guidance on network adequacy, with some exceptions. The sub-regulatory guidance on network adequacy included a list of provider specialty and facility types subject to network adequacy reviews—including (a) requirements for a minimum number of providers/facilities and (b) set maximum time and

[106] Coleman, *HPMS Memo*, p. 6.

[107] Courtney and Stewart, *Increased ESRD Beneficiary Enrollment Flexibility*, p. 3.

[108] Regulations limit the amount of provider payments that can depend on meeting specified goals (42 C.F.R. §422.208).

[109] A recent analysis aggregating nationwide data found that MA plans pay 5.6% less than FFS for hospital services, after accounting for hospital network, geographic area, and case mix. However, this finding may differ substantially based on the specific conditions of a particular market. See Laurence C. Baker et al., "Medicare Advantage Plans Pay Hospitals Less Than Traditional Medicare Pays," *Health Affairs*, vol. 35, no. 8 (August 2016), p. 1444. Additionally, a Congressional Budget Office (CBO) analysis examined average MA payment rates paid by three large insurance carriers to hospitals for 200 metropolitan statistical areas (MSAs). CBO found that average MA plan payments in the MSA at the 90th percentile of the distribution were 6% higher than the average FFS rate and that the average MA rate in the MSA at the 10th percentile of the distribution was 2% below the average FFS rate. CBO, *An Analysis of Private-Sector Prices for Hospital Admissions*, 2017-02, April 2017, p. 2, at https://www.cbo.gov/publication/52567.

distance standards. The sub-regulatory guidance also included an exceptions policy if it was impossible for a plan to meet the adequacy standards.

Going forward, MA plans still must contract with a minimum number of providers and facilities of each specified specialty and type. However, the rule loosened criteria for maximum time and distance standards. Under the rule, in micro, rural, and CEAC counties, starting in 2021, plans are required to contract with a sufficient number of providers and facilities to ensure that 85% of beneficiaries (rather than the current 90%) have at least one provider/facility type within published maximum time and distance standards. The rule also allowed a 10 percentage point "credit" toward meeting the time and distance criteria for plans that established telehealth contracts with specified provider types, including nephrologists. Further, the rule allowed an additional 10 percentage point credit for plans serving states with laws that limit health care facility competition.[110] The credits for contracting with telehealth providers and for serving states that limit health care facility competition can be applied together; if both credits apply, an MA plan would be required to contract with a sufficient number of providers and facilities to ensure that 65% of beneficiaries in micro, rural, or CEAC counties and 70% of beneficiaries in metro or large metro areas have at least one provider/facility type within published maximum time and distance standards. Though the rule did not change the maximum time and distance standards, it allowed plans to require a larger percentage of potential enrollees to travel farther for in-network Medicare-covered care.

Of particular focus to the ESRD community, the final rule did not include outpatient dialysis facilities on the list of providers subject to time and distance criteria. Instead, CMS will require MA plans to attest they have adequate networks of such providers. CMS said the policy change was designed to encourage MA plans to offer more choices for ESRD patients undergoing dialysis, including home dialysis. CMS also noted that MA plans are required to cover services at an out-of-network provider when network providers are unavailable or inadequate to meet an enrollee's medical needs. When a beneficiary receives care from an out-of-network facility because a network facility is not available or unable to meet the beneficiary's needs, the beneficiary pays the in-network cost sharing and the MA plan pays the facility the amount it would have received if the beneficiary were in original Medicare, an amount that could be lower than the MA plan's contracted rates.[111]

Stakeholder and Support Agency Positions and Reactions to the Rule

The proposed rule and publication of the final rule spurred controversy and a court challenge, as MA plans, dialysis providers, and patient groups reached different conclusions about the rule's potential impact.

[110] State Certificate of Need (CON) laws, for example, require a hospital to demonstrate need in the community before it can expand or build a new hospital. Limiting the number of hospitals or facilities in an area may make it more challenging for MA plans to develop contracted networks in those areas, because there are fewer hospitals to negotiate with. CMS, in the final rule, indicated that, "CON laws restrict the supply and competition for healthcare services and increase costs.... When MA organizations must pay more for benefits as the research demonstrates happens when there are fewer providers or facilities with which to contract, that reduces access to benefits offered by MA organizations." CMS, "Medicare Program," 85 *Federal Register* 33856.

[111] See also CMS, *MA Payment Guide for Out of Network Payments*, updated April 15, 2015, at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/downloads/oonpayments.pdf. For information on how to appeal to an MA plan for coverage of out-of-network outpatient dialysis services, see Medicare.gov, "Appeals If You Have a Medicare Health Plan," at https://www.medicare.gov/appeals-if-you-have-a-medicare-health-plan.

MA Plans

MA plan sponsors told CMS their plans already had been taking a financial loss on each ESRD enrollee. According to the plan sponsors, overall, the proposed changes in payment for ESRD beneficiaries to comply with the Cures Act would not adequately account for the increased costs of the new ESRD enrollees, and the expected influx of new enrollees in 2021 could pose a large burden. Plans indicate that inadequate payments for ESRD enrollees could force them to set higher premiums, increase OOP limits (up to the CMS-specified maximum), or reduce supplemental benefits for all enrollees.[112]

However, MA plan sponsors told CMS the changes in network adequacy requirements (switching from measuring only outpatient dialysis to determine access to dialysis services to requiring an attestation that enrollees have access to dialysis services, whether through outpatient clinics or home dialysis) could improve their financial position. This change could increase plans' ability to negotiate discounts with outpatient dialysis providers, thus reducing their cost of providing dialysis benefits to ESRD enrollees. One of the insurer-funded studies noted above said relaxing MA network adequacy requirements for dialysis-related services could "potentially facilitate increased provider competition to perform these types of services."[113] The report did not provide detailed information on expected savings or the time period for realizing major shifts in dialysis delivery from outpatient to home-based dialysis. Further, home dialysis may be an imperfect substitute for outpatient dialysis care for a portion of Medicare beneficiaries, making it unclear the extent to which greater network flexibility to substitute in-home care for outpatient dialysis care will actually increase competition. The outlook is further complicated by the fact that the two largest outpatient dialysis providers, DaVita and Fresenius, are also the main providers of home-based dialysis services.

Dialysis Providers

Fresenius, in a comment letter on the proposed rules, stated, "We urge CMS to consider, however, that weak network adequacy standards will not lead to reductions in the total cost of care. Rather, weak standards will result in plan design that discriminates against beneficiaries with ESRD."[114]

Nephrologists

In a comment letter to CMS on the proposed rule, the American Society of Nephrologists (ASN) encouraged CMS to "avoid a wholesale removal of time and distance protections." The group added that ESRD patients and physicians were in the midst of significant changes in care delivery, including new CMS pilot programs, more innovative dialysis equipment, expanded telehealth, and new providers. According to ASN,

> In such a dynamic environment, it seems logical to ASN that network adequacy in the future might be achieved differently than it was in the past … While ASN does not advocate for CMS to eliminate these standards for the entire kidney patient population, ASN would

[112] Eyles, "AHIP Detailed Comments," pp. 3-4. Though CMS sets the maximum OOP limit, plans may offer a lower OOP limit.

[113] Eyles, "AHIP Detailed Comments," pp. 3-4.

[114] Letter from C. M. Cameron Lynch, Senior Vice President for Government Affairs, Fresenius, to Seema Verma, CMS Administrator, "Re: CMS-4190-P: Medicare and Medicaid Programs; Contract Year 2021 and 2022 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicaid Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly," April 6, 2020, at https://www.regulations.gov/document?D=CMS-2020-0010-0218.

> welcome the opportunity to dialogue with the agency over what might constitute network adequacy in the future, particularly regarding home dialysis patients.[115]

Patient Groups

In comments on the proposed rule, patient groups expressed concern about how MA plans may respond to removing outpatient dialysis centers from the list of facilities subject to automated quantitative assessment of network adequacy. Patient groups expressed concern that it would incentivize MA plans to drop outpatient dialysis centers, including centers that beneficiaries are accustomed to using, in favor of in-home dialysis, which is not an option for certain beneficiaries, such as those with housing insecurity or a lack of caregiver support. The patient groups noted that this change could discourage ESRD beneficiaries from enrolling in MA plans, depending on how individual plans set up their provider networks.[116]

On June 24, 2020, a dialysis patient group (Dialysis Patient Citizens, or DPC) filed suit in federal court to halt the rule on the grounds it discriminated against patients who needed outpatient dialysis.[117] The group said the rule treats ESRD patients differently than other beneficiaries by not holding MA plans to the same network adequacy standards (i.e., the time and distance standards) that apply to other provider specialty and facility types that treat beneficiaries with other diseases. The group also disagreed with CMS's assertion that it is sufficient that MA plans attest to the adequacy of their dialysis networks, noting that CMS has required other providers in MA plan networks to meet the objective, quantitative measures of network adequacy.[118]

In addition, DPC said the rule is particularly worrisome given the low health and economic status of the ESRD population. In its lawsuit, DPC noted that ESRD patients "are some of the most vulnerable people in the country. Many are of extremely limited means, and many are minorities…. The disease exacerbates patients' vulnerability because dialysis is very expensive, and the length and frequency of treatment commonly impedes continued employment."[119]

The ongoing COVID-19 pandemic also heightens concerns about potential disruptions in dialysis care, as ESRD patients begin enrolling in MA plans for 2021. The pandemic has made it more difficult for patients to receive routine dialysis, as outpatient clinics have implemented new protective protocols, grappled with shortages of personal protective equipment, and dealt with illness among their staff. In addition, 20%-30% of individuals hospitalized for COVID-19

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[115] Letter from Anupam Agarwal, President, American Society of Nephrology, to Seema Verma, CMS Administrator, April 6, 2020, at https://www.asn-online.org/policy/webdocs/ASN_Comment_Letter_on_Proposed_Rule_for_Medicare_Advantage_3.6.20.pdf.

[116] CMS, "Medicare Program," 85 *Federal Register* 33858-33859.

[117] Dialysis Patient Citizens v. Azar, Case 1:20-cv-01664 18-20 (U.S. District Court for the District of Columbia 2020). "[Dialysis Patient Citizens] emphasized [in its comments on the proposed rule] that home-dialysis patients are disproportionately White and affluent, while in-center [outpatient] dialysis patients are disproportionately black or Hispanic and are more likely to live in an economically disadvantaged zip code, be unemployed, and be uninsured or on Medicaid." SSA §1852(b)(1) and §1557 of the Patient Protection and Affordable Care Act (P.L. 111-148) prohibit discrimination, including establishment of plan designs or benefits that would discourage certain MA-eligible individuals from enrolling in the plan.

[118] Dialysis Patient Citizens v. Azar, Case 1:20-cv-01664 18-20 (U.S. District Court for the District of Columbia 2020). Certain other Medicare required services are not subject to the quantitative network adequacy standards, such as home health care, durable medical equipment, and transplant centers. However, these may not be comparable examples relative to dialysis centers, either because caregivers and suppliers deliver care or equipment to the beneficiaries in their homes rather than requiring beneficiaries to travel for items or services or because a beneficiary travels to a location for a single procedure rather than frequent, ongoing treatments.

[119] Dialysis Patient Citizens v. Azar, Case 1:20-cv-01664 18-20 (U.S. District Court for the District of Columbia 2020).

develop kidney-related issues, some requiring dialysis, according to the American Society of Nephrology, which has led to a surge in demand for dialysis services and increased stress on supplies.[120]

Medicare Payment Advisory Commission

MedPAC, in response to the proposed rule, pointed out that beneficiaries with ESRD need access to both nephrologists, to manage their ESRD, and dialysis centers. A MedPAC analysis found that a significant share of nephrologists refer patients to dialysis facilities owned by single companies, which is said may be a response to industry consolidation—with a few companies controlling most facilities—or because a nephrologist may have a joint venture with a specific dialysis provider. MedPAC posits that an MA plan attempting to discourage ESRD enrollment could contract with nephrologists who refer patients exclusively to centers owned by one dialysis company and then contract with a different dialysis provider to meet dialysis network adequacy standards. Doing so would discourage beneficiaries with ESRD from enrolling in that MA plan, as they would not be able to continue to use both their nephrologist and their preferred dialysis center. According to MedPAC, "such practice should be considered discriminatory and should be barred."[121] The issue was not addressed by the Administration in the final rule.

Considerations for Plan Year 2021 and Beyond

Medicare beneficiaries and MA enrollees have an opportunity to assess MA plan options available to them during open enrollment season, which runs from October 15 through December 7 of each year, for plan choices effective for the following year.[122] Each year, MA plans may change aspects of their offerings, such as premiums, deductibles, cost sharing, out-of-pocket maximums, drugs included on their formularies, and providers and medical facilities in their networks, among other factors. As a general rule, it is advisable for beneficiaries to reassess their MA plans for changes in the upcoming year, if they already are enrolled in an MA plan, and to compare the updated plan to other available plan options. A beneficiary's plan may have changed so that it is no longer the best option.

Comparison of MA plans—as well as comparison of non-MA options, such as original Medicare plus a private Medigap policy, if available—can be challenging. When evaluating options, beneficiaries may consider factors such as (1) their own use of medical services over a previous period and whether their health care use is likely to change; (2) the cost sharing associated with the health care they expect to use and, if possible, the likelihood of unexpected additional health care needs; (3) their use of prescription drugs and the costs associated with them; (4) the size of any MA or Medigap monthly premium; and (5) the level of the out-of-pocket MA or Medigap cap and whether their spending is likely to reach it.

To aid in the task of assessing MA plans, beneficiaries have access to several sources of information. Medicare beneficiaries are mailed a *Medicare & You* handbook,[123] which describes

[120] American Society of Nephrology et al, "Ensuring Optimal Care for People with Kidney Diseases During the COVID-19 Pandemic," at https://renal.org/wp-content/uploads/2020/05/Nephrology-Societies-COVID-19Joint-Statement.pdf.

[121] Letter from Francis J. Crosson, MedPAC Chairman, to Seema Verma, CMS Administrator, "RE: CMS-4190-P," April 3, 2020, pp. 17-18, at http://www.medpac.gov/docs/default-source/comment-letters/04032020_ma_partd_comment_v2_sec.pdf?sfvrsn=0.

[122] See Medicare.gov home page at https://www.medicare.gov/.

[123] Medicare.gov, *Medicare & You Handbook: Medicare & You 2021*, September 2020, at https://www.medicare.gov/

the program and MA options available in their area and includes information about the original Medicare program, with expected premiums and cost sharing. Other sources of information include the "Medicare Compare" tool on the Medicare.gov website, where beneficiaries can compare several plan options side-by-side; the Medicare "Out of Pocket Cost Estimator" may facilitate that calculation.[124] Agents and brokers may offer education or marketing events.[125] In addition, the State Health Insurance Assistance Program provides free, one-on-one health insurance counseling for seniors.[126]

Although several sources of information are available to beneficiaries, research indicates beneficiaries tend to invest a great deal of energy comparing their options the first time they enroll in an MA plan but feel daunted by the prospect of repeating the exercise in subsequent years.[127] Many beneficiaries find it frustrating to compare plans due to the volume of available information or, in the case of the Medicare Compare tool, the difficulty in using available tools to find the information they want. More than a third of beneficiaries indicated that comparing Medicare plans was very or somewhat difficult, and a higher percentage (44%) of those in fair or poor health felt the same way.[128] As such, many may rely on insurance agents, family, friends, doctors, or pharmacists to provide recommendations. Whether by choice or inertia, the majority of beneficiaries do not voluntarily switch plans. Between 2007 and 2016, the percentage of beneficiaries choosing to switch plans in any particular year was between 6% and 11%.[129] A beneficiary who finds, after the start of the year, that his or her MA plan changed in an unanticipated way, such as a change in cost sharing, has an opportunity to switch to a different MA plan during the first three months of each calendar year. After Mach 31, enrollees must remain in their MA plans, barring eligibility for a special enrollment period.[130]

Plan Networks

If a beneficiary enrolls in an MA plan, certain aspects of the plan must remain the same throughout the calendar year, such as the monthly premium or specified cost sharing. However, an MA plan's provider network may change during a plan year. An MA plan is allowed to drop a provider from its network at any time, or the plan may be unable to come to an agreement with a provider over renewing a contract for continued network participation. As discussed, each MA plan is required to have a sufficient number of contracted providers to ensure access to services with reasonable promptness and in a manner that ensures continuity of benefits, consistent with

pub/medicare-you-handbook.

[124] Medicare.gov, "Estimate Medicare Costs," at https://www.medicare.gov/oopc/.

[125] Agents and brokers are required to adhere to guidelines. See CMS, "Medicare Marketing Guidelines," at https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing/FinalPartCMarketingGuidelines.

[126] MedicareHelp, "State Health Insurance Assistance Program (SHIP)," at https://www.medicarehelp.org/state-health-insurance-assistance-programs-ship/.

[127] Gretchen Jacobson et al., "How Are Seniors Choosing and Changing Health Insurance Plans?," KFF, May 13, 2014, at https://www.kff.org/medicare/report/how-are-seniors-choosing-and-changing-health-insurance-plans/.

[128] Wyatt Koma et al., "No Itch to Switch: Few Medicare Beneficiaries Switch Plans During the Open Enrollment Period," KFF, December 2, 2019, at https://www.kff.org/medicare/issue-brief/no-itch-to-switch-few-medicare-beneficiaries-switch-plans-during-the-open-enrollment-period/ (hereinafter Koma et al., "No Itch to Switch").

[129] Koma et al., "No Itch to Switch."

[130] SSA §1851(e)(2)(G). See also Medicare.gov, "Special Circumstances (Special Enrollment Periods)," at https://www.medicare.gov/sign-up-change-plans/when-can-i-join-a-health-or-drug-plan/special-circumstances-special-enrollment-periods.

"the prevailing community pattern of health care delivery in the area."[131] That requirement does not guarantee, however, that a beneficiary will have access to the physician or facility of his or her choice. Even if a beneficiary specifically enrolled in a plan because his or her nephrologist and preferred dialysis center were both in the network, there is no guarantee both provider and center will remain in the network the entire year. Moreover, analyses by the HHS Office of Inspector General found that almost half (47.7%) of the MA provider directories examined contained inaccuracies, such as incorrect phone numbers, providers not practicing at the location listed, or providers no longer taking new patients when they were listed as accepting new patients.[132] Such inaccuracies can further complicate beneficiaries' attempts to enroll in plans with their choice of providers. As noted above, beneficiaries may switch to a different MA plan during the first three months of each calendar year but after that must remain in their MA plan, barring eligibility for a special enrollment period.[133]

Monitoring Access to Providers

In the final rule, CMS cited two methods for monitoring whether beneficiaries are able to access needed care.[134] First, several measures of access to care are included in the calculation of plan quality, as measured through a five-star rating system used for beneficiary education. MA plans that perform well on the quality metrics also are eligible for increased Medicare payments. The star rating measures include a beneficiary's ease at getting needed care and seeing specialists, as well as getting appointments and care quickly. Data for implementing the star measures are captured through the annual Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey. However, the CAHPS survey that might identify problems with access to dialysis services in CY2021 will not be fielded until the beginning of CY2022, and results will not be reported until the fall of CY2022; this method may be too slow to assist an ESRD patient who is having trouble securing the necessary thrice-weekly dialysis appointments at an in-network dialysis center.

The second method cited by CMS for monitoring ESRD enrollees' access to care is through the Complaint Tracking Module (CTM). Each beneficiary who calls *1-800-Medicare* with a complaint about his or her MA plan is to be logged into the CTM. In the final rule, CMS indicated that it "ensure(s) access to all Medicare covered services through monitoring and investigating complaints in the CMS Complaint Tracking Module."[135] CMS is to "monitor and investigate complaints related to access concerns and work with [CMS] regional office caseworkers to resolve issues with the MA plans."[136]

Enrollee Appeals to Plans to Receive Care from an Out-of-Network Provider

In the final rule, CMS reiterated the regulatory requirement for MA plans to arrange out-of-network specialty care for an enrollee if network providers are unavailable or inadequate to meet

[131] SSA §1852(d)(1) and 42 C.F.R. §422.112(a)(10).

[132] CMS, *Provider Directory Review Industry Report Round 3*, November 28, 2018, at https://www.cms.gov/Medicare/Health-Plans/ManagedCareMarketing.

[133] SSA §1851(e)(2)(G). See also Medicare.gov, "Special Circumstances (Special Enrollment Periods)," at https://www.medicare.gov/sign-up-change-plans/when-can-i-join-a-health-or-drug-plan/special-circumstances-special-enrollment-periods.

[134] CMS, "Medicare Program," 85 *Federal Register* 33859.

[135] CMS, "Medicare Program," 85 *Federal Register* 33859.

[136] CMS, "Medicare Program," 85 *Federal Register* 33859.

the enrollee's needs.[137] Further, CMS indicated that, "if network providers are incapable of meeting the enrollee's medical needs because the burden of travel to the in-network dialysis center is inconsistent with the prevailing community pattern of health care delivery in the area, the MA plan must arrange for care outside of the network and at in-network cost-sharing in order to meet the MA plan's obligation under the MA program rules to furnish covered services."[138] The beneficiary, or the beneficiary's representative or doctor, can file an organization determination to receive approval for the care. If the care is denied, that decision can be appealed.[139]

Beyond 2021

It is unclear whether—or how quickly—MA plans could respond to the regulatory changes in MA network adequacy requirements. Final decisions on dialysis network changes may depend, in part, on whether—or how quickly—MA plans can expand capacity to provide in-home dialysis care or secure lower prices for outpatient care from dialysis chains. It also remains to be seen whether ESRD beneficiaries will find MA plans an attractive option for 2021 or for subsequent years.

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[137] 42 C.F.R. §422.112(a)(3).

[138] CMS, "Medicare Program," 85 *Federal Register* 33859.

[139] CMS, "Medicare Managed Care Appeals and Grievances," at https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG.