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Medicare Coverage of End-Stage Renal Disease (ESRD)

(name redacted)

Analyst in Health Care Financing

Updated August 16, 2018

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End-stage renal disease (ESRD) is the last 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 a regular course of dialysis (a process that removes harmful waste products from an individual's bloodstream) or a kidney transplant to survive.

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 that individuals were allowed to enroll in Medicare based on a specific medical condition rather than on age.

Medicare benefits for ESRD beneficiaries, including those under the age of 65 who qualify based on the disease, include a thrice-weekly dialysis treatment and coverage for kidney transplant. There is an initial waiting period for coverage for ESRD patients under the age of 65, and coverage for such enrollees terminates 12 months after a patient ends dialysis or after 36 months of follow-up care (including immunosuppressive medications) after a kidney transplant. Many beneficiaries with ESRD also require Medicare services to treat related, chronic health conditions, such as diabetes or heart disease. Because Medicare beneficiaries with ESRD have higher-than-average health care costs, they account for about 7% of Medicare fee-for-service (FFS) spending, while making up about 1% of total program enrollment (FFS and managed care combined). In total, FFS Medicare covers about three-fourths of all U.S. medical spending to treat ESRD.

Over the years, Congress has enacted a number of changes to Medicare ESRD-related benefits in an effort to improve the quality of services and control program costs. For example, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA; P.L. 110-275) instituted a "bundled" payment system for ESRD dialysis providers, which took effect in 2011. The 21st Century Cures Act (CURES; P.L. 114-255) will allow Medicare-eligible individuals with ESRD to enroll in Medicare Part C Medicare Advantage (MA) managed care plans, beginning in 2021. Currently, ESRD patients are not allowed to enroll in most MA plans, with the exception of some special-needs plans. As a result, ESRD patients do not have access to some of the enhanced benefits offered by MA providers.

This report provides background on the ESRD Medicare benefit, including information about the disease, Medicare enrollment criteria, covered services, other health care coverage for ESRD, and the Medicare reimbursement policy. The report concludes with a discussion of outstanding payment and coverage issues in ESRD care.

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Introduction

End-stage renal disease (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 a regular course of dialysis (a process that removes harmful waste products from an individual's bloodstream) or a kidney transplant to survive.

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).¹ The legislation marked the first time that individuals were allowed to enroll in Medicare based on a specific medical condition rather than on the basis of age. In the years since the legislation was enacted, Medicare has become the main source of health care coverage for individuals with ESRD.

Medicare benefits for ESRD beneficiaries, including those under the age of 65 who qualify based on the disease, include thrice-weekly dialysis treatments and coverage for kidney transplant. There is an initial waiting period for coverage for ESRD patients under the age of 65, and coverage for such enrollees terminates 12 months after a patient ends dialysis or after 36 months of follow-up care (including immunosuppressive medications) after a kidney transplant.² Many Medicare beneficiaries with ESRD also require Medicare services to treat related, chronic health conditions, such as diabetes and heart disease. Because Medicare beneficiaries with ESRD have higher-than-average health care costs, they account for about 7% of Medicare fee-for-service (FFS) spending, while making up about 1% of program enrollment (FFS and managed care combined). In total, FFS Medicare covers three-fourths of U.S. annual medical spending to treat ESRD.³

Over the years, Congress has enacted a number of changes to Medicare ESRD benefits in an effort to improve the quality of services and control program costs. For example, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA; P.L. 110-275) imposed a “bundled” payment system for dialysis providers, which took effect in 2011. (See “Medicare Reimbursement for ESRD Services.”) The 21st Century Cures Act (CURES Act; P.L. 114-255), enacted in 2016, will allow Medicare-eligible individuals with ESRD to enroll in Medicare Part C private managed care plans, beginning in 2021. (See “Medicare Advantage Enrollment.”)

This report provides background on the ESRD Medicare benefit, including information about the disease, Medicare enrollment criteria, other health care coverage for ESRD, and Medicare

¹ An individual under the age of 65 who is medically determined to have end-stage renal disease (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. Social Security Act (SSA) §226A. Also see “Social Security Amendments of 1972.”

² Centers for Medicare & Medicaid Services (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> (hereinafter CMS, *Medicare Coverage*). 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 that the patient starts a new 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 under Part B, begin in the month in which a regular course of renal dialysis is resumed. See SSA §226A(c).

³ In 2015, the fee-for-service Medicare program paid about three-fourths of all medical spending for ESRD-prevalent patients. United States Renal Data System, chapter 9 in *Annual Data Report 2017*, vol. 2, at https://www.usrds.org/2017/view/v2_09.aspx. Hereinafter United States Renal Data System, *Annual Data Report 2017*.

reimbursement policy. The report concludes with a discussion of outstanding payment and coverage issues in ESRD care.

ESRD Progression and Treatment

As noted above, ESRD is the final stage of CKD and is defined as a substantial and irreversible failure of kidney function. Individuals with ESRD suffer from a buildup of fluid and waste products in their bodies because their kidneys can no longer filter blood and perform other essential functions.⁴ The condition is fatal without treatment. (See “Main Treatments for ESRD.”) The two leading medical conditions that can affect kidney function and contribute to ESRD are diabetes and high blood pressure. Other illnesses that can contribute to kidney failure include heart disease, autoimmune conditions, genetic diseases, and kidney disorders.⁵

ESRD differs from acute kidney injury (AKI), where the kidneys cease to function over a short period, such as a matter of days. AKI can be caused by a heart attack or drug abuse, for example, and can be temporary. Medicare covers some services for AKI patients through its ESRD provider payment system.⁶ (See “Acute Kidney Injury.”)

ESRD Prevalence and Incidence

According to the United States Renal Data System, 703,243 Americans were receiving treatment for ESRD in 2015, compared to 56,434 receiving treatment in 1980.⁷ Those figures refer to the *prevalence* of ESRD, which is the total number of people receiving treatment for the disease. (See **Figure 1**.) In 2015, 124,114 patients were being newly treated for ESRD, which is known as the *incidence* of ESRD; in 1980, 17,903 patients were being newly treated.⁸

The ESRD *incidence rate*—the number of people being newly treated for ESRD within a set population—is higher among certain racial and ethnic groups, including Native Hawaiians/Pacific Islanders, African Americans, and Hispanics, than among whites. However, since 2000, there has been a significant reduction in the excess risk of developing ESRD among minority populations.⁹ Researchers have identified socioeconomic and biological factors that may contribute to the racial disparities in development and treatment of ESRD.¹⁰

⁴ National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, “What Is Chronic Kidney Disease?” at <https://www.niddk.nih.gov/health-information/kidney-disease/chronic-kidney-disease-ckd/what-is-chronic-kidney-disease>.

⁵ National Kidney Foundation, “Kidney Disease: Causes,” at <https://www.kidney.org/atoz/content/kidneydiscuses>.

⁶ CMS, “Acute Kidney Injury and ESRD Facilities,” at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/AKI-and-ESRD-Facilities.html>.

⁷ United States Renal Data System, *Annual Data Report 2017*, Tables 1.1 and 1.3. The United States Renal Data System collects and analyzes information about chronic kidney disease (CKD) and ESRD. The organization is funded by the National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases. ESRD incidence and prevalence, as used throughout the report, refer to treated cases of ESRD—that is, patients started or currently on renal replacement therapy (dialysis or transplantation); the terms do not refer exclusively to disease occurrence.

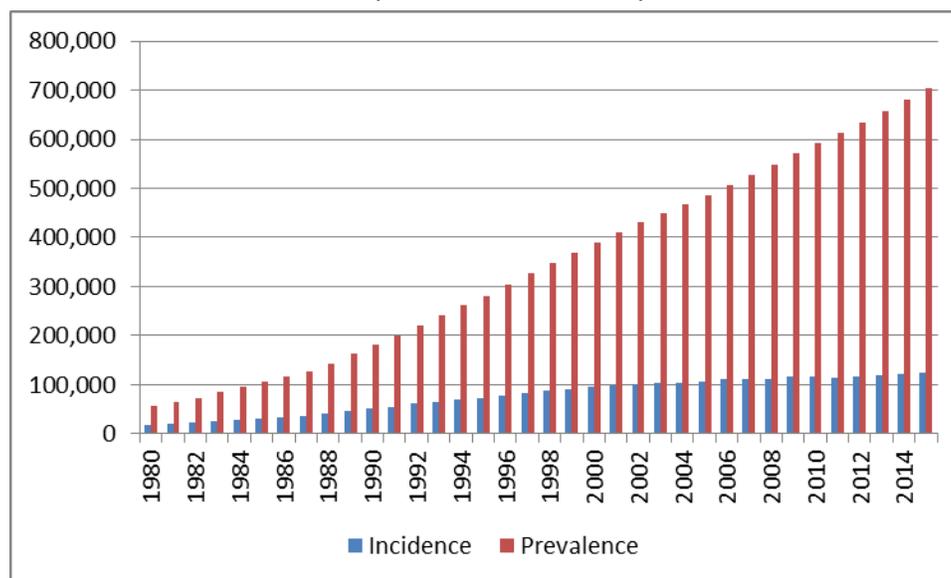
⁸ United States Renal Data System, *Annual Data Report 2017*, Tables 1.1 and 1.3.

⁹ United States Renal Data System, *Annual Data Report 2017*, chapter 1. See also Centers for Disease Control and Prevention, “National Chronic Kidney Disease Fact Sheet 2017,” at https://www.cdc.gov/diabetes/pubs/pdf/kidney_factsheet.pdf.

¹⁰ Susanne Nicholas, Kamyar Kalantar-Zadeh, and Keith Norris, “Racial Disparities in Kidney Disease Outcomes,” *Seminars in Nephrology*, vol. 33, issue 5 (September 2013), pp. 409-415.

Figure 1. End-Stage Renal Disease (ESRD) Patients in the United States

Number of new ESRD patients and total ESRD patients, 1980-2015



Source: United States Renal Data System, Tables 1.1 and 1.3 in *Annual Data Report 2017*, vol. 2, at https://www.usrds.org/2017/view/v2_09.aspx. Hereinafter United States Renal Data System, *Annual Data Report 2017*.

Notes: Figure is based on unadjusted incidence and prevalence data. *Incidence* refers to the number of people being newly treated for ESRD each year; *prevalence* refers to the total number of people receiving ESRD treatment. Because prevalence reflects both the incidence and the course of the disease, the continued increase in ESRD prevalence trends could reflect not only newly incident cases but also longer survival of ESRD patients, according to the United States Renal Data System.

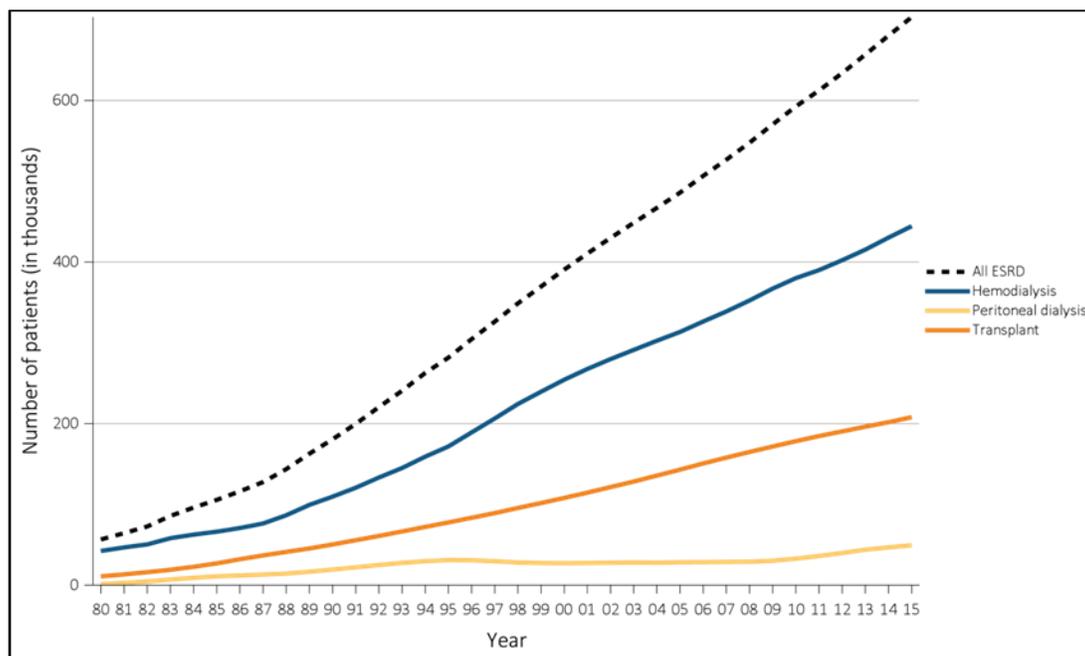
Main Treatments for ESRD

The main treatments for ESRD are kidney transplant and dialysis. At the close of 2015, 63% of prevalent ESRD patients were receiving hemodialysis, 7% were being treated with peritoneal dialysis, and 30% had been treated with a functioning kidney transplant.¹¹ (See **Figure 2**.)

¹¹ United States Renal Data System, *Annual Data Report 2017*, chapter 1.

Figure 2. Mode of Treatment for ESRD Patients

Number of prevalent ESRD patients treated with dialysis or a kidney transplant, 1980-2015



Source: United States Renal Data System, *Annual Data Report 2017*, Figure I.8 and Table D.1.

Kidney Transplant

In a transplant, an individual receives a healthy donor kidney from a living volunteer or a deceased person. The donor kidney usually is positioned in a patient's lower abdomen, and the failed kidneys may be left in place unless they pose a threat of infection or other complications.¹² Individuals who undergo successful transplants usually must take immunosuppressive drugs for the rest of their lives to minimize the risk that their bodies will reject the donor kidneys. (See "Medicare Coverage of Immunosuppressive Drugs.")

Although a kidney transplant is the preferred treatment for ESRD, it is not the most common treatment. Some individuals may not meet medical qualifications for a transplant.¹³ Even people who are prime candidates for a transplant may have difficulty obtaining one due to a severe shortage of donor kidneys. As of June 2018, there were 95,091 people on the waiting list for a kidney transplant. The waiting list is maintained by the United Network for Organ Sharing.¹⁴

¹² National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, "Kidney Transplant," at <https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/kidney-transplant>. Live donors are preferred due to a higher success rate.

¹³ See background information on the kidney transplant evaluation process from the University of California, Davis Transplant Center, "Evaluation Process," at http://www.ucdmc.ucdavis.edu/transplant/learnabout/learn_eval_process.html. University of California, Davis, has the nation's highest-volume kidney transplant program.

¹⁴ United Network for Organ Sharing, "Transplant Trends," at https://www.unos.org/data/transplant-trends/#waitlists_by_organ/. There were about 1,660 patients awaiting a kidney/pancreas transplant in June 2018.

Dialysis

Dialysis refers to 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.¹⁵ 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 requiring dialysis is 5-10 years, although people can live far longer.¹⁶

There are two main types of dialysis, as described below.

Hemodialysis

Hemodialysis is the most common form of dialysis.¹⁷ 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.

Peritoneal Dialysis

In peritoneal dialysis, a patient's blood is cleaned inside his or her body, using a catheter inserted into the abdominal cavity.¹⁸ 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 may be performed at home or other clean, private locations outside of a dialysis center. 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.¹⁹

Other Treatments

Medicare covers other ESRD treatments, including hemofiltration, which uses hollow artificial membranes to remove fluid and toxic substances from the blood. According to CMS, the procedure may be covered three times a week. Another Medicare-covered treatment is ultrafiltration, which removes excess fluid from the blood by exerting pressure on a dialysis

¹⁵ National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, "Kidney Failure," at <https://www.niddk.nih.gov/health-information/health-communication-programs/nkdep/learn/living/kidney-failure/dialysis/Pages/dialysis.aspx>.

¹⁶ National Kidney Foundation, "Dialysis," at <https://www.kidney.org/atoz/content/dialysisinfo>.

¹⁷ National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, "Hemodialysis," at <https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/hemodialysis>.

¹⁸ National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, "Peritoneal Dialysis," at <https://www.niddk.nih.gov/health-information/kidney-disease/kidney-failure/peritoneal-dialysis>.

¹⁹ CMS, Section 10—Definitions Relating to ESRD in "End Stage Renal Disease," chapter 11 in *Medicare Benefit Policy Manual*, revised June 3, 2016, at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c11.pdf>. (Hereinafter CMS, *Medicare Benefit Policy*) Section 10 also discusses different types of peritoneal dialysis.

membrane. Ultrafiltration does not substitute for dialysis and is used when excess fluid cannot be removed easily during regular hemodialysis.²⁰

Medicare Coverage of ESRD

Social Security Amendments of 1972

Modern dialysis was developed in the 1940s, and the first successful kidney transplants took place during the 1950s.²¹ ESRD patients initially had difficulty obtaining the new treatments because of cost and limited availability. In one example, Seattle's King County Medical Society in the early 1960s appointed a special panel of laypersons to allocate the limited number of dialysis slots in that area.²²

In 1965, Congress established the Medicare program under Title XVIII of the Social Security Act to provide health coverage to citizens or permanent residents of the United States who are at least 65 years of age and who have met certain work requirements.²³ In the Social Security Amendments of 1972, Congress expanded Medicare eligibility to include (1) individuals receiving Social Security Disability Insurance benefits and (2) qualified individuals diagnosed with ESRD.²⁴

Under the 1972 legislation, as amended, an individual under 65 years of age 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.²⁵ Beneficiaries who qualify for Medicare on the basis of ESRD are eligible for premium-free Medicare Part A and may enroll in Part B.²⁶ For these beneficiaries, there is a waiting period for Medicare services. (See "Waiting Periods and Time Limits for Medicare Based on ESRD.") 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

²⁰ CMS, *Medicare Benefit Policy*, chapter 11. See also CMS, "National Coverage Determination (NCD) for Ultrafiltration, Hemoperfusion and Hemofiltration (110.15)," at <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?ncdid=55&ver=1>.

²¹ Carl Gottschalk and Susan Fellner, "History of the Science of Dialysis," *American Journal of Nephrology*, vol. 17, no. 3-4 (1997), pp. 289-298, at <https://www.karger.com/Article/ShowPic/169116/?image=000169116-1.jpg>; and Alden Doyle, Robert Lechler, and Laurence Turka, "Organ Transplantation: Halfway Through the First Century," *Journal of the American Society of Nephrology*, vol. 15, no. 12 (2004), pp. 2965-2971, at <http://jasn.asnjournals.org/content/15/12/2965.full>.

²² Shana Alexander, "Medical Miracle and Moral Burden of a Small Committee: They Decide Who Lives, Who Dies," *Life*, November 9, 1962, p. 102, at <https://books.google.com/books?id=qUoEAAAAMBAJ&lpg=PA102&pg=PA102#v=onepage&q&f=false>.

²³ CRS Report R40425, *Medicare Primer*.

²⁴ CRS Report RS22195, *Social Security Disability Insurance (SSDI) and Medicare: The 24-Month Waiting Period for SSDI Beneficiaries Under Age 65*.

²⁵ See Social Security Administration POMS, "DI 45001.001 End-Stage Renal Disease (ESRD) Entitlement Provisions," from September 10, 2013 to present, at <https://secure.ssa.gov/poms.nsf/lnx/0445001001>. A Social Security credit (or "quarter of coverage") is based on a dollar amount of wages or self-employment income earned by an individual during a calendar year. The amount of earnings needed to earn a credit changes annually under a statutory formula based on average wage growth. A worker can earn up to four credits a year. See Social Security Administration, "How You Earn Credits," at <https://www.ssa.gov/pubs/EN-05-10072.pdf>.

²⁶ CMS, "Original Medicare (Part A and B) Eligibility and Enrollment," at <https://www.cms.gov/Medicare/Eligibility-and-Enrollment/OrigMedicarePartABEligEnrol/>.

spouse, parent, or guardian, which makes ESRD coverage available to people of all ages. The 1972 law was the first time individuals of all ages were made eligible for Medicare based on a categorical disease.²⁷

Medicare Benefit Structure

The Social Security Amendments of 1972 did not create a new end-stage renal disease (ESRD) program; rather, they allowed qualified ESRD patients to enroll in Medicare. Medicare currently has four distinct parts: Medicare Part A (Hospital Insurance), Part B (Supplementary Medical Insurance), Part C (Medicare Advantage, or MA), and Part D (outpatient prescription drugs). In general, under Medicare

- Individuals entitled to Part A receive coverage primarily for inpatient hospital services, skilled nursing care, hospice care, and some home health services. Most persons aged 65 or older are automatically entitled to premium-free Part A because they or their spouse paid Medicare payroll taxes for at least 40 quarters (10 years) on earnings covered by either the Social Security or the Railroad Retirement system. Under Part A, individuals pay cost sharing for Medicare inpatient hospital benefits per spell of illness. Additional co-payments and charges apply to stays of more than 60 days.
- Beneficiaries entitled to Part A may enroll in Part B, which covers physician services, hospital outpatient services, some home health services, durable medical equipment, preventive services, and prescription drugs administered by a physician. Medicare beneficiaries generally pay a Part B premium that varies depending on income, and there is generally 20% coinsurance for Part B services. Together, Medicare Parts A and B represent “original” Medicare, or *fee-for-service* Medicare.
- Beneficiaries entitled to Part A and enrolled in Part B may receive these covered services through a Medicare Part C, or MA, private plan. The federal government pays private health plans that choose to participate in Part C a per person, or *capitated*, monthly amount to provide all services covered under Parts A and B (except for hospice care). MA plans may provide additional items or services not covered under Part A or B. Some MA plans charge enrollees an additional premium. In general, cost sharing for enrollees in an MA plan may differ from amounts that would be charged if the beneficiary were in Medicare Part A or B.
- Beneficiaries entitled to Part A and/or enrolled in Part B may enroll in Part D, which covers outpatient prescription drugs through private, stand-alone drug plans (PDP) or through MA plans that include a Part D benefit (MA-PD). Part D premiums and cost sharing vary by plan and by income (i.e., whether an enrollee qualifies for an additional low-income subsidy or must pay an income-based premium surcharge).

Source: For updated annual figures on deductibles, premiums, and other cost sharing, see CRS Report R40425, *Medicare Primer* and CRS Report R40611, *Medicare Part D Prescription Drug Benefit*.

Notes: For Medicare Part A, a spell of illness, also referred to as the benefit period, begins when a beneficiary is admitted for inpatient hospital services and ends after 60 consecutive days in which the beneficiary was neither an inpatient of a hospital nor a resident of a skilled nursing facility. See SSA §1861(a).

Medicare ESRD Enrollment Statistics

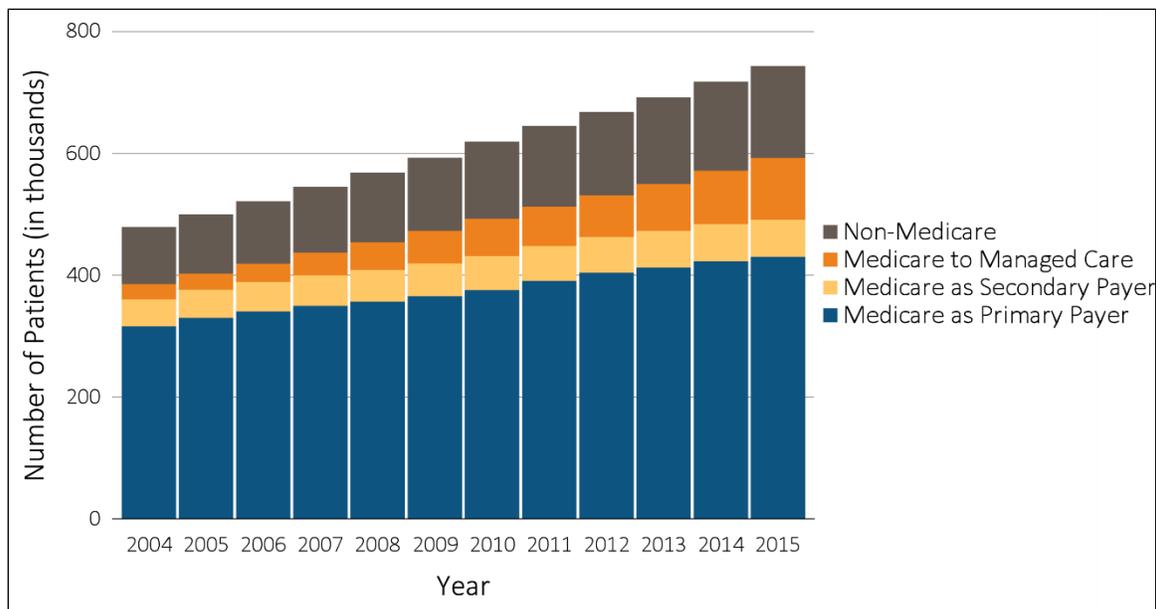
Figure 3 illustrates the Medicare status of the ESRD point-prevalent population (the total number of patients in active treatment for ESRD at set date in the year) from 2004 to 2015. Of the ESRD prevalent patients in the United States as of December 31, 2015, about 59% had Medicare as their primary payer (including individuals dually eligible for Medicare and Medicaid), 8% had Medicare as a secondary payer, 14% were in Part C MA plans, and 19% had non-Medicare coverage (including those pre- and post-Medicare coverage).²⁸ Required enrollee cost sharing for

²⁷ In 2000, Congress waived the two-year SSDI waiting period for Medicare eligibility for individuals with Amyotrophic Lateral Sclerosis (ALS, or Lou Gehrig’s disease). The change was made as part (§115) of that year’s consolidated appropriations bill, P.L. 106-554.

²⁸ CRS Report RL33587, *Medicare Secondary Payer: Coordination of Benefits*. Generally, Medicare is the “primary payer” for medical services for covered beneficiaries, meaning that it pays health claims first. If a beneficiary has other health insurance, that insurance is billed after Medicare has made payments, in order to fill all, or some, of any gaps in

ESRD-related services, and the scope of the covered services, vary depending on the specific health plan and the type of services required. Likewise, reimbursement to Medicare and private providers varies among health plans.

Figure 3. Types of Coverage for Individuals with ESRD in 2015



Sources: United States Renal Data System, *Annual Data Report 2017*, Table 9.3. Data from the Medicare Enrollment Database (EDB) and dialysis claims information were used to categorize payer status as Medicare as primary payer, Medicare as secondary payer, Medicare Advantage managed care plans, or non-Medicare.

Notes: Data are based on ESRD point-prevalence figures as of December 31, 2015. Beneficiaries enrolled in Medicare may have secondary sources of coverage, such as Medigap or Medicaid. Medicare Secondary Payer refers to individuals who qualify for Medicare based on ESRD, but are covered by employer-sponsored insurance, which acts as the primary payer for ESRD services for a set period of time (see “Employer-Sponsored Health Plans”). Non-Medicare patients include patients who were pre- or post-Medicare entitlement, including patients in the three-month waiting period for ESRD services.

Medicare spends far more on medical services for beneficiaries with ESRD than for other beneficiaries. In 2013, Medicare spent \$61,996 per ESRD beneficiary, compared to \$9,889 per non-ESRD beneficiary.²⁹ Medicare per-capita spending for all beneficiaries was \$10,478 in 2013, the most recent data available.

Medicare coverage. In certain situations, however, federal Medicare Secondary Payer (MSP) statutes prohibit Medicare from making payments for an item or service when payment has been made, or can reasonably be expected to be made, by another insurer such as an employer-sponsored group health plan. For individuals whose Medicare eligibility is based solely on ESRD, any group health plan coverage they receive through their employer or their spouse’s employer is the primary payer for the first 30 months of ESRD benefit eligibility. After 30 months, Medicare becomes the primary insurer. (See “Employer-Sponsored Health Plans.”)

²⁹ MedPAC and the Medicaid and CHIP Payment and Access Commission (MACPAC) joint publication, *DataBook: Beneficiaries Dually Eligible for Medicare and Medicaid*, January 2018, p. 18, at https://www.macpac.gov/wp-content/uploads/2017/01/Jan18_MedPAC_MACPAC_DualsDataBook.pdf.

Medicare-Covered Services for Treatment of ESRD

Individuals who become eligible for Medicare on the basis of ESRD are eligible for all Medicare-covered items and services, not just those related to ESRD. Medicare enrollees incur routine out-of-pocket costs, including co-payments and deductibles, if they do not have supplemental coverage that wraps around Medicare.

In addition to other Medicare-covered health care, ESRD-related services include the following:

- Medicare Part A coverage of inpatient services in an approved hospital for covered kidney transplants, as well as the cost of care for a kidney donor. Part A also will cover inpatient dialysis for patients admitted to a hospital or skilled nursing facility for special care.³⁰ (See “Kidney Transplant.”)
- Medicare Part B coverage for doctors’ services during a kidney transplant; dialysis treatments in Medicare-certified outpatient facilities, such as freestanding dialysis centers or outpatient centers in hospitals; and related services, such as patient training in a certified dialysis facility or a beneficiary’s home. Part B also provides coverage of immunosuppressive drugs for individuals who have had a Medicare-covered kidney transplant and of specified drugs, such as erythropoiesis-stimulating agents used to treat anemia. In addition, Part B covers other drugs administered by a physician.³¹ Individuals who qualify for Medicare on the basis of ESRD but delay enrolling in Part B must pay a late-enrollment penalty.³² However, individuals who initially qualified for Medicare based on age or disability but delayed enrolling in Part B or stopped Part B payments may enroll if they are later diagnosed with ESRD and have any late-enrollment penalty removed.³³
- Medicare Part C is available to ESRD patients only in limited circumstances, such as when an individual already was enrolled in a MA plan at the time of an ESRD diagnosis. The CURES Act (P.L. 114-255) will allow people already diagnosed with ESRD to enroll in Medicare Part C plans, beginning in 2021. (See “Medicare Advantage Enrollment.”)
- Medicare Part D provides coverage for outpatient prescription drugs filled at a pharmacy, including many oral medications used by ESRD patients and prescription medications for related conditions, such as high blood pressure. In 2016, about 90% of ESRD patients undergoing dialysis in fee-for-service

³⁰ CMS, Medicare Learning Network (MLN), “Skilled Nursing Facility (SNF) Consolidated Billing as It Relates to Dialysis Coverage,” *MLN Matters* no. SE0435, updated April 2013, at <https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE0435.pdf>.

³¹ Medicare Part B will cover some oral drugs as part of the bundled payment for dialysis services. For example, starting in 2018, Part B covers calcimimetic medications under the ESRD payment system. Calcimimetic medications include the intravenous medication Parsabiv and the oral medication Sensipar. Some of the drugs were previously covered under Medicare Part D. CMS, *Medicare Coverage*, p. 34.

³² CRS Report R40082, *Medicare: Part B Premiums*.

³³ CMS, “Signing Up for Medicare with ESRD,” at <https://www.medicare.gov/people-like-me/esrd/getting-medicare-with-esrd.html#collapse-3177>. See also CMS, “Medicare for People with ESRD,” Slide 11, at <https://www.cms.gov/Outreach-and-Education/Training/CMSNationalTrainingProgram/Medicare-Modules/Medicare-ESRD.html>. There is no special enrollment period for people with ESRD.

Medicare had Part D or other sources of drug coverage that were at least as comprehensive as Part D.³⁴

Waiting Periods and Time Limits for Medicare Based on ESRD

The exact point at which an individual who qualifies for Medicare based on ESRD becomes eligible for covered services varies depending on the type of treatment needed and whether the person has other health care coverage. As noted, Medicare also imposes time limits on coverage for individuals under the age of 65 who end dialysis or who undergo a successful kidney transplant.

Waiting Periods

Medicare waiting periods for coverage of services begin at the point of an individual's ESRD treatment or diagnosis—whether or not an individual has qualified for Medicare already.³⁵ If an individual under the age of 65 is eligible for Medicare based on ESRD but does not enroll immediately, the individual may qualify for up to 12 months of retroactive coverage, once he or she enrolls.³⁶

In general, beneficiaries who qualify for Medicare based on ESRD

- Are eligible for Medicare coverage beginning on the first day of the fourth month of dialysis treatment if they are receiving dialysis treatments in a certified outpatient facility.³⁷
- May be eligible for benefits as early as their first month of eligibility if they take part in a home dialysis training program in a Medicare-approved training facility, begin home dialysis training before the third month of dialysis, and expect to finish home dialysis training and give self-dialysis treatments.³⁸
- Are eligible for coverage during their first month of Medicare eligibility if they are admitted to a Medicare-approved hospital to undergo a kidney transplant. Patients may be eligible for Medicare two months prior to a kidney transplant provided they are hospitalized in a Medicare-approved hospital in preparation for the transplant.

³⁴ MedPAC, chapter 6 in *Report to the Congress: Medicare Payment Policy*, March 2018, p. 156.

³⁵ CMS, *Medicare Benefit Policy*, chapter 11. For example, if an individual failed to submit a timely application for Medicare or chose not to apply for Medicare, the 30-month coordination period still would be calculated with a start date based on the month in which he or she could have enrolled if an application had been made.

³⁶ CMS, *Medicare Coverage*, p. 13.

³⁷ For enrollees who have coverage under an employer group health plan, the group health plan will be the sole payer during the three-month transition. See “Employer-Sponsored Health Plans.”

³⁸ Social Security Administration, “DI 45001.001 End-Stage Renal Disease (ESRD) Entitlement Provisions,” at <https://secure.ssa.gov/poms.nsf/lnx/0445001001>; and CMS, *Medicare Coverage*. In an effort to spur greater use of home dialysis, the End-Stage Renal Disease Amendments of 1978 (P.L. 95-292) eliminated the three-month waiting period for Medicare coverage if a beneficiary elected home dialysis treatment, subject to certain requirements. In addition, §2145 of the Omnibus Budget Reconciliation Act of 1981 (P.L. 97-35) instituted a new reimbursement formula that provided greater incentives for home dialysis treatment.

Time Limits

Medicare entitlement for an enrollee that is based solely on ESRD ends when the enrollee is no longer considered in the “end stage” of kidney disease. A beneficiary is no longer end stage when dialysis has been stopped for 12 months or a kidney transplant has been successful for 36 months. If a patient’s kidney transplant later fails, the individual is entitled to Part A and eligible to enroll in Part B in the month that he or she starts a new course of dialysis. Likewise, if an ESRD patient ends a course of dialysis but later needs to resume dialysis treatments, he or she would be entitled to Part A and eligible to enroll under Part B in the month when a regular course of dialysis is resumed.³⁹

Other Health Coverage for ESRD Patients

Medicare beneficiaries with ESRD have comprehensive coverage but still can face significant out-of-pocket costs for such things as prescription drug co-payments, annual deductibles, and cost sharing for dialysis visits and hospital care. Some ESRD beneficiaries may purchase supplemental health care coverage, such as Medigap policies, to help cover some of these costs. Other patients may have been covered by an employer-sponsored health plan prior to their ESRD diagnosis or may qualify for other federal health benefits, such as Medicaid. In addition, ESRD patients under the age of 65 may choose to enroll in individual health care plans rather than in Medicare. Medicare may limit or prohibit ESRD-related benefits for individuals who have other health care coverage. This section will outline sources of supplemental or alternative coverage for ESRD patients and associated regulations that affect Medicare payments.

Employer-Sponsored Health Plans

Individuals who are diagnosed with ESRD may already have health care coverage through an employer-sponsored health insurance plan, including a retiree health plan. If an individual is not already enrolled in Medicare on the basis of age or disability at the time of his or her ESRD diagnosis, and is covered through a commercial group health plan, the individual continues to receive primary ESRD and other health coverage through the commercial health plan for 30 months after qualifying for Medicare.⁴⁰ During the coordination period, if an individual enrolls in Medicare, the program acts as the secondary payer, meaning that Medicare may be billed for covered ESRD services and other health care services that are not fully reimbursed by the group health plan. After 30 months, Medicare becomes the primary payer. Group health plans may not impose higher costs or place limits on services to ESRD patients during the coordination period that differ from those provided to other enrollees.⁴¹

Individuals with ESRD who have group health coverage may delay enrolling in Medicare Parts A and B during the 30-month coordination in order to avoid paying Part B premiums. Under Medicare rules, individuals with ESRD who delay signing up for Medicare Parts A and B until the end of the 30-month coordination period will not face a Part B late enrollment penalty. However, the individuals would not have secondary Medicare coverage for out-of-pocket

³⁹ SSA §226A(c) and Social Security Administration, “HI 00820.030 Termination of R-HI,” at <https://secure.ssa.gov/poms.nsf/lnx/0600820030>.

⁴⁰ For example, for an individual receiving dialysis at an outpatient center, the 30-month coordination period would start in the fourth month of dialysis.

⁴¹ CRS Report RL33587, *Medicare Secondary Payer: Coordination of Benefits*, by (name redacted) .

expenses related to their medical care.⁴² In addition, if an ESRD patient signs up for Part A, but not for Part B prior to the end of the coordination period, the individual subsequently will be allowed to enroll in Part B only during the annual Medicare open enrollment period (January 1-March 31), with coverage effective the following July. Depending on timing, the delay in signup could result in a Part B late enrollment surcharge for some ESRD beneficiaries.⁴³

Further, an ESRD patient who does not enroll in Medicare Parts A and B before the end of the 30-month coordination period could face a gap in coverage. When Medicare becomes the primary payer at the end of the 30-month coordination period, a group health plan may reduce ESRD-related coverage for the Medicare-eligible enrollee (but otherwise may not differentiate between the ESRD enrollees and other group health plan enrollees).⁴⁴

If an ESRD beneficiary with group health coverage was enrolled in Medicare based on ESRD and Medicare enrollment lapsed due to termination of dialysis or a successful kidney transplant, the individual could re-enroll in Medicare and would be subject to another 30-month coordination period.⁴⁵

Medicaid ESRD Coverage

According to a recent report, 42% of Medicare ESRD patients also are enrolled in Medicaid. Medicaid is a joint federal-state program that finances the delivery of primary and acute medical services, as well as long-term services and supports (LTSS), to a diverse, low-income population, including children, pregnant women, adults, individuals with disabilities, and people aged 65 and older.⁴⁶

Individuals who qualify for both Medicare and Medicaid are known as *dual-eligible individuals*. In total, ESRD beneficiaries make up about 1% of total Medicare enrollment and 2.4% of dual-eligible enrollment.⁴⁷

For dual eligibles, Medicare is the primary payer and Medicaid is the payer of last resort. For example, dual eligibles with ESRD receive hospital care, physician services, dialysis treatments, prescription drugs, and other health care services through Medicare. Medicaid provides assistance

⁴² Social Security Administration, “HI 00801.247 Medicare as Secondary Payer of ESRD Benefits,” <https://secure.ssa.gov/poms.nsf/lnx/0600801247>; and Social Security Administration, *End Stage Renal Disease*, SSA Publication No. 64-107, September 2016, <https://www.ssa.gov/pubs/EN-64-107.pdf>.

⁴³ CMS, Training Module #6, “Medicare for People with End Stage Renal Disease,” December 2017, <http://healthcare.oregon.gov/shiba/Documents/Training-Modules/2017-advanced-module-6-esrd.pdf>. Individuals who enroll only in Part A or Part B and not in Part D may face a similar late enrollment penalty for Part D services. The annual Part D open enrollment period is from October 15 to December 7, with coverage effective January 1. Persons entitled to Part A are also eligible to enroll in Part B. Individuals may enroll in Part A for a premium at age 65 if not eligible for premium-free Part A. If an individual enrolls in premium A, one must also enroll in B; however, such an individual could enroll in B only.

⁴⁴ Individuals who do not enroll in Medicare may face higher costs for some ESRD-related services such as immunosuppressive drugs and may not have employer group coverage for the costs for a kidney donor.

⁴⁵ CMS, *Medicare Coverage*, p. 16, <https://www.medicare.gov/Pubs/pdf/10128-Medicare-Coverage-ESRD.pdf>.

⁴⁶ CRS In Focus IF10322, *Medicaid Primer*, and MedPAC and the Medicaid and CHIP Payment and Access Commission (MACPAC) joint publication, *DataBook: Beneficiaries Dually Eligible for Medicare and Medicaid*, January 2018, p. 18, at https://www.macpac.gov/wp-content/uploads/2017/01/Jan18_MedPAC_MACPAC_DualsDataBook.pdf. Figure is based on 2013 data.

⁴⁷ CRS In Focus IF10399, *Overview of the ACA Medicaid Expansion*. MACPAC data do not indicate how ESRD dual eligibles first became eligible for Medicaid. In general, individuals may qualify for Medicaid if they meet set criteria (e.g., elderly, children, or pregnant women) and financial thresholds (i.e., income and sometimes assets limits).

with some or all Medicare premiums and cost sharing, and it covers services such as long-term care not provided by Medicare. The exact level of Medicaid benefits provided to dual eligibles varies based on beneficiary income and other criteria.⁴⁸ Dual eligibles who qualify for both Medicare and Medicaid and are already enrolled in Medicaid (but not Medicare) at the time of an ESRD diagnosis have Medicaid as their primary payer during any three-month Medicare waiting period.

The per person Medicare annual cost for treating a dual eligible with ESRD was \$77,785 in 2013, compared to the \$16,636 cost of treating a dual eligible who did not have ESRD.⁴⁹

Medicare Supplemental Health Insurance (Medigap)

Medicare beneficiaries aged 65 and older have the opportunity to buy private Medigap policies to cover expenses not paid by Medicare, such as deductibles, coinsurance, and co-payments.⁵⁰ Medigap products are regulated jointly by the states and the federal government. Federal law establishes a six-month Medigap open enrollment period, beginning on the first day of the first month that an individual is both at least aged 65 and enrolled in Medicare Part B. During this open enrollment period, insurers cannot (1) refuse to sell qualified individuals any Medigap policy the insurer offers; (2) base an individual's policy premiums on his or her health conditions; or (3) impose a waiting period, among other protections.⁵¹

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, more than 30 states require insurers to offer at least one type of Medigap policy to individuals under the age of 65.⁵² 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 very expensive for younger ESRD patients.

Commercial Health Insurance Plans in the Individual Market

The Patient Protection and Affordable Care Act (ACA; P.L. 111-148, as amended) imposed a number of federal requirements on health plans offered in the private insurance market—particularly the individual market (also known as the non-group market).⁵³ These requirements

⁴⁸ CMS, “Dual Eligible Beneficiaries under Medicare and Medicaid,” at https://www.cms.gov/Outreach-and-Education/Medicare-Learning-NetworkMLN/MLNProducts/downloads/Medicare_Beneficiaries_Dual_Eligibles_At_a_Glance.pdf.

⁴⁹ MedPAC and MACPAC joint publication, *DataBook: Beneficiaries Dually Eligible for Medicare and Medicaid*, January 2018, p. 18, at https://www.macpac.gov/wp-content/uploads/2017/01/Jan18_MedPAC_MACPAC_DualsDataBook.pdf. The per capita Medicaid cost for ESRD dual eligibles was \$14,612 in 2013, compared to \$11,040 for non-ESRD dual eligibles. Figures include managed care spending.

⁵⁰ CMS, *Choosing a Medigap Policy: A Guide to Health Insurance for People with Medicare*, 2017, p. 21, at <https://www.medicare.gov/Pubs/pdf/02110-Medicare-Medigap.guide.pdf>. Hereinafter CMS, *Choosing a Medigap Policy*.

⁵¹ CMS, *Choosing a Medigap Policy*, p.21.

⁵² CMS, *Choosing a Medigap Policy*, p. 40.

⁵³ CRS Report R45146, *Federal Requirements on Private Health Insurance Plans*. The private market often is described as having three segments: non-group (or individual), small group, and large group. Most individuals and families obtain private insurance through small- or large-group coverage, such as employer-sponsored insurance; some individuals and families purchase private insurance on their own in the individual market.

made private insurance in the individual market more accessible for individuals with preexisting conditions.

Following are the main ACA provisions that affect the scope and cost of private health care coverage for ESRD patients in the individual market:

- Plans are prohibited from basing eligibility and premiums on health-related factors or denying benefits based on health conditions.⁵⁴
- Health insurance exchanges must be in operation in every state, providing a marketplace where individuals can shop for private insurance coverage.⁵⁵ Individuals purchasing coverage through the individual exchanges may be eligible to receive financial assistance. Eligibility for such assistance is based on income and provided in the form of premium tax credits and cost-sharing subsidies.⁵⁶
- Most plans offered in the individual market (both inside and outside the individual exchanges) must offer a core package of health services, known as the *essential health benefits* (EHB).⁵⁷ Each state's EHB package is based on a single reference insurance plan (i.e., the *EHB benchmark plan*) sold in the state, and there is considerable variation among states in the specific benefits that are included. EHBs also may change over time.⁵⁸ For the 2018 coverage year, 49 states and the District of Columbia include dialysis as an EHB.⁵⁹
- Consumer cost sharing is capped for services included in the EHB package. The cap, adjusted annually, applies to providers that participate in a health plan's contracted network, which can include dialysis facilities. For 2018, the cost-sharing limit is \$7,350 for an individual plan and \$14,700 for a family plan.⁶⁰
- Plans generally are prohibited from setting limits on how much they spend for covered EHBs either during the entire period an individual is enrolled in the plan (lifetime limits) or during a plan year (annual limits). Plans are permitted to place lifetime and annual limits on covered benefits that are not considered EHBs, to the extent that such limits are permitted by federal and state law.⁶⁷

⁵⁴ 42 U.S.C. §300gg-3 and 42 U.S.C. §300gg-4. This does not apply to Medigap policies.

⁵⁵ CRS Report R44065, *Overview of Health Insurance Exchanges*, by (name redacted) .

⁵⁶ CRS Report R44425, *Health Insurance Premium Tax Credits and Cost-Sharing Subsidies*, by (name redacted) .

⁵⁷ CRS Report R44163, *The Patient Protection and Affordable Care Act's Essential Health Benefits (EHB)*, by (name redacted) .

⁵⁸ Because each state selects its own EHB benchmark plan, there is considerable variation in EHB coverage from state to state. This variation occurs in terms of specific covered services and in terms of amount, duration, and scope. In addition to EHB variation by state, benefit coverage among plans within a state may differ. States may allow individual market plans that offer the EHB to substitute benefits.

⁵⁹ Arkansas does not include dialysis as an EHB. Information is based on a Congressional Research Service analysis of all states' 2017 EHB benchmark plan summary documentation. According to the Department of Health and Human Services (HHS), in plan years 2017, 2018, and 2019, the EHB benchmark plan is a plan that was sold in 2014. For plan year 2020 and after, the final 2019 HHS notice of benefits and payment parameters provides states with greater flexibility by establishing standards for states to update their EHB benchmark plans. For more information, see <https://www.cms.gov/ccio/resources/data-resources/ehb.html>.

⁶⁰ HHS, "Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2018; Amendments to Special Enrollment Periods and the Consumer Operated and Oriented Plan Program," 81 *Federal Register* 94058-94183, December 22, 2016.

Insurers may not sell individual market policies to individuals who are entitled to benefits under Medicare Part A or who are enrolled under Part B, knowing that the policies would duplicate their Medicare benefits.⁶¹ At the same time, however, there is no requirement that ESRD patients who qualify for Medicare enroll in the Medicare program. Individuals with ESRD who are eligible for Medicare but who have not enrolled may choose to buy an individual market plan instead (either on or off the exchanges). Further, individuals with ESRD may sign up for coverage through the individual exchanges and may be eligible for financial assistance (i.e., premium tax credits and cost-sharing subsidies) available through the individual exchanges.⁶²

Eligibility for financial assistance through the individual exchanges ends if an ESRD patient enrolled in an individual market exchange plan subsequently secures Medicare coverage.⁶³ An individual who is eligible for Medicare but who delays enrolling in the program in order to buy an individual market plan could be subject to a Part B late-enrollment penalty if he or she later ends exchange coverage and signs up for Medicare.

CMS Proposed Regulations Regarding Premium Subsidies

Since the ACA market reforms took effect in 2014, dialysis providers and nonprofit groups that receive donations from dialysis firms have provided premium assistance and other cost-sharing subsidies to ESRD patients who enroll in individual plans in the private market.

According to the Centers for Medicare & Medicaid Services (CMS), the number of ESRD patients enrolled in individual market commercial plans doubled between 2014 and 2015 and increased as much as fivefold in some states over that period. CMS expressed concern that dialysis facilities and nonprofit organizations supported by dialysis firms were using premium and other assistance for “the inappropriate ‘steering’ of individuals eligible for or entitled to Medicare or Medicaid into individual market plans” so that the providers could bill at higher rates than were allowed under Medicare. Specific concerns noted by CMS included the following:

- Some third-party payers discontinued premium assistance for ESRD patients if the patients received a kidney transplant, creating a potential loss in insurance coverage for such individuals. The policy of ending premium assistance upon receipt of a transplant also could make it harder for patients to qualify for a transplant, because health care providers require proof that a patient will have insurance coverage after a transplant to cover the cost of immunosuppressive drugs and other related health expenses.
- ESRD patients who accepted premium assistance to enroll in private health plans were not always informed that private insurers could refuse to accept the third-

⁶¹ SSA §1882(d)(3).

⁶² CMS, “Frequently Asked Questions Regarding Medicare and the Marketplace,” August 1, 2014, p. 10, at https://www.cms.gov/Medicare/Eligibility-and-Enrollment/Medicare-and-the-Marketplace/Downloads/Medicare-Marketplace_Master_FAQ_4-28-16_v2.pdf. According to CMS, generally, individuals with ESRD who are currently enrolled in Medicare based on ESRD cannot disenroll prospectively. Following the application for Medicare, the law provides that Medicare coverage ends one year after the termination of regular dialysis or 36 months after a successful kidney transplant. However, a beneficiary may withdraw their original Medicare application. The individual is required to repay all costs covered by Medicare, pay any outstanding balances, and refund any benefits received from the SSA or RRB. Once all repayments have been made, the withdrawal can be processed as though the individual was never enrolled in Medicare at all (i.e., retroactively).

⁶³ Internal Revenue Service, “Eligibility for Minimum Essential Coverage for Purposes of the Premium Tax Credit: Notice 2013-41,” at <http://www.irs.gov/pub/irs-drop/n-13-41.pdf>.

party assistance, possibly exposing the patients to a loss of coverage during a plan year.

In December 2016, CMS issued a final interim rule to provide additional protections to patients with ESRD who received premium support to enroll in private health care plans rather than in Medicare.⁶⁴ Under the rule, ESRD patients receiving premium support from dialysis providers—either directly or through a third party—would have had a right to comprehensive information about their health care options, comparative costs of coverage under Medicare and other health care plans, and information about the providers’ contributions to third parties subsidizing the patients’ premiums. In addition, dialysis providers and third-party entities providing premium assistance to ESRD patients would have had to inform enrolling health care plans of their assistance and receive assurances from the insurer that premium contributions would be accepted for the course of a plan year.⁶⁵

Commercial dialysis providers and the nonprofit group Dialysis Patient Citizens challenged the CMS rule in court.⁶⁶ In their lawsuit, the organizations said that CMS did not follow proper notice and comment procedures in publishing the rule and claimed that the rule would cause immediate harm to dialysis patients by disrupting their care, exposing them to additional costs, and potentially denying them access to health insurance. In February 2017, the court issued an injunction stopping the rule from taking effect.⁶⁷ In April 2018, a coalition of health insurers and businesses wrote a letter asking the Secretary of Health and Human Services (HHS) to take action to end what they also called the steering of ESRD patients into commercial coverage.⁶⁸

Medicare Reimbursement for ESRD Services

When the ESRD benefit was first implemented, Medicare paid health care providers separate amounts for tests, supplies, drugs, and covered services billed to ESRD patients.⁶⁹ Over the years, Congress has made a number of changes to the payment system in an effort to control costs. Most recently, 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.⁷⁰ A PPS is a method of payment in which amounts or rates of payment are

⁶⁴ CMS, “Medicare Program: Conditions for Coverage for End-Stage Renal Disease Facilities—Third Party Payment,” 81 *Federal Register*, p. 90255, December 14, 2016, at <https://www.gpo.gov/fdsys/pkg/FR-2016-12-14/pdf/2016-30016.pdf>.

⁶⁵ CMS, “Medicare Program: Conditions for Coverage for End-Stage Renal Disease Facilities—Third Party Payment,” 81 *Federal Register*, p. 90255, December 14, 2016, at <https://www.gpo.gov/fdsys/pkg/FR-2016-12-14/pdf/2016-30016.pdf>.

⁶⁶ DaVita, “Dialysis Community Seeks Emergency Relief to Block CMS’ Unlawful ‘Midnight’ Rule Harming Patients,” January 6, 2017, *PR Newswire*, at <http://www.prnewswire.com/news-releases/dialysis-community-seeks-emergency-relief-to-block-cms-unlawful-midnight-rule-harming-patients-300387240.html>. *Dialysis Patient Citizens vs. Sylvia Mathews Burwell*, (U.S. District Court Eastern District of Texas 2017).

⁶⁷ Dan Mangan, “Dialysis Providers Win Victory in Fight over Third-Party Financial Aid to Patients,” CNBC, January 13, 2017, at <http://www.cnbc.com/2017/01/13/dialysis-providers-win-victory-in-fight-over-financial-aid-to-patients.html>.

⁶⁸ Letter to HHS Secretary Alex Azar, April 16, 2018, at https://www.ahip.org/wp-content/uploads/2018/04/ESRD-Steering-Letter_4.16_FINAL_Embargoed.pdf.

⁶⁹ Shailender Swaminathan, Vincent Mor, Rajnish Mehrotra, and Amal Trivedi, “Medicare’s Payment Strategy for End-Stage Renal Disease Now Embraces Bundled Payment and Pay-for-Performance to Cut Costs,” *Health Affairs*, vol. 31, no. 9 (September 2012), pp. 2051–2058.

⁷⁰ CMS, “End-Stage Renal Disease (ESRD) Prospective Payment System (PPS),” at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-10-27.html>.

established in advance for a defined period and generally are based on an episode of care, regardless of the actual amount of care used.

Since CMS began the phase-in of the PPS in 2011, annual increases in Medicare fee-for-service spending have been modest, relative to historic trends. Medicare fee-for-service spending for beneficiaries with ESRD was \$33.9 billion in 2015, an increase of 2.4% from \$33.1 billion in 2014.⁷¹ Medicare ESRD spending, when measured on a per-beneficiary rather than an aggregate basis, has decreased or has increased minimally from 2010 to 2015.⁷² So, most of the growth in Medicare spending over the period has been due to the increase in covered lives. Following is information about current ESRD payment systems, including payment for dialysis and transplants.⁷³

Reimbursement for Outpatient Dialysis Facilities

CMS defines an ESRD facility as an entity that provides outpatient maintenance dialysis services, home dialysis training and support services, or both. ESRD facilities can be hospital based or independently operated.⁷⁴ To receive Medicare reimbursement for routine dialysis services, ESRD facilities must be certified by CMS as meeting safety and quality standards.⁷⁵

The ESRD PPS, which was phased in over a four-year period starting in 2011, provides a single, bundled payment for each dialysis treatment in a certified ESRD facility. 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 (primarily erythropoiesis-stimulating agents, vitamin D, and iron).⁷⁶ Beneficiaries pay coinsurance equal to 20% of the Medicare-approved amount for each dialysis treatment.

PPS Formula

The ESRD PPS per treatment payment is determined by adjusting the base rate by a number of factors. The base rate, which applies to both adult and pediatric patients, is updated each year

⁷¹ United States Renal Data System, *Annual Data Report 2017*, chapter 9. According to the report, Medicare Parts A, B, and D expenditures can be calculated from claims submitted for payment for health care provided to these individuals but not for those enrolled in MA managed care plans. Medicare pays for services provided through MA plans on a risk-adjusted, per-capita basis and not by specific claims for services. About 20% of ESRD beneficiaries are in MA plans.

⁷² United States Renal Data System, *Annual Data Report 2017*, data for Figure 9.1. According to the report, most of the savings from the PPS change accrued to dialysis facilities, as CMS initially set the bundled payment rate at 98% of what spending would have been under utilization patterns prior to the PPS.

⁷³ Medicare benefit payments, including payments to hospitals, are being reduced by 2% due to sequestration under the Budget Control Act of 2011 (P.L. 112-25). Subsequent legislation extended the sequester through FY2027.

⁷⁴ Regulations governing ESRD conditions for coverage can be found in 42 C.F.R. §494.

⁷⁵ CMS, "Dialysis," at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html>. As part of the Bipartisan Budget Act of 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, so long as the accreditation bodies meet specified conditions and requirements.

⁷⁶ CMS, "Dialysis," at <https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/GuidanceforLawsAndRegulations/Dialysis.html>. The PPS also is designed to take into account providers' capital-related costs for offering dialysis services. The payment includes dialysis-related drugs that would have been covered under both Part B and Part D prior to the bundled payment.

based on a market-basket index designed to capture changes in the costs of dialysis-related goods and services.⁷⁷

In determining the per treatment payment, CMS adjusts the PPS base rate to account for differences in the health profile of patients and operating costs among dialysis providers:

- **Patient Characteristics.** For adult patients, the PPS base rate is adjusted to account for factors including how long a patient has been undergoing dialysis; age; body surface area; low-body-mass index; and four co-morbidity, or associated disease, categories.⁷⁸ For pediatric patients, the adjustments include two age categories and two types of dialysis.
- **Facility-Level Characteristics.** CMS uses three adjustments: (1) a low-volume adjustment for ESRD facilities that provide a smaller number of dialysis treatments, (2) a geographic wage index adjustment, and (3) a rural adjustment for facilities in rural areas.⁷⁹ For pediatric patients, only the wage index applies.
- **Patient Training.** CMS provides a home or self-dialysis training add-on payment.
- **High-Cost Outliers.** CMS provides additional reimbursement for facilities that treat high-cost outlier patients, based on variations in the type or amount of medically necessary care.
- **New Drugs.** CMS also adjusts the base payment to provide a transitional add-on reimbursement for new injectable or intravenous drugs that do not fit into existing categories under the PPS base rate.⁸⁰ Under the bundled payment, ESRD facilities are responsible for furnishing renal dialysis services either directly or under arrangement. An exception to the policy is oral-only drugs and biologicals, which are not paid under the ESRD PPD until January 1, 2025.

When initially implementing the PPS, CMS set the bundled payment rate at 98% of the existing cost of dialysis services. In the American Taxpayer Relief Act of 2012 (P.L. 112-240), Congress authorized CMS to gradually reduce, or rebase, the PPS base rate to take into account cost savings from a sharp decrease in the use of intravenous drugs for treating anemia, along with

⁷⁷ The market-basket measure is adjusted to capture improvements in productivity that affect costs. Based on the index, CMS has set a PPS per treatment base rate of \$232.37 for calendar year 2018, compared to the 2017 base rate of \$231.55. 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,” *Federal Register*, November 1, 2017, p. 50740, at <https://www.gpo.gov/fdsys/pkg/FR-2017-11-01/pdf/2017-23671.pdf>. See also “CMS Proposed Updates to Policies and Payment Rates for End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury (CMS 1674-P),” June 29, 2017, at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-06-29.html>.

⁷⁸ The co-morbidity categories include two chronic conditions—sickle cell anemia and myelodysplastic syndrome—caused by blood cells that do not work properly. The categories also include two acute conditions—gastrointestinal tract bleeding with hemorrhage and pericarditis, which is inflammation around the heart. See “ESRD PPS Patient Level Adjustments,” at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/Patient-Level-Adjustments.html>.

⁷⁹ For more information on the specific adjustments see CMS, *Medicare Benefit Policy*, Sections 50 and 60 and chapter 11.

⁸⁰ CMS, “Implementation of the Transitional Drug Add-On Payment Adjustment,” January 10, 2018. Effective January 1, 2018, injectable, intravenous, and oral calcimimetics qualify for the transitional payment. Calcimimetics, used to treat CKD-related bone and mineral disorders, are the only drugs that qualify for payment using the transitional add-on payment.

other payment revisions.⁸¹ Congress has included provisions in the Protecting Access to Medicare Act of 2014 (P.L. 113-93) and other statutes making further adjustments to the PPS.⁸²

Quality Incentive Program

The ESRD Quality Incentive Program (QIP) ties a portion of the Medicare PPS reimbursement to providers' success in meeting specific quality-of-care measures.⁸³ Under the 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%.⁸⁴

Dialysis facilities are evaluated on both clinical and data reporting factors.⁸⁵ Clinical factors include the effectiveness of dialysis treatments, the number of unplanned patient readmissions to a hospital, and the rate of infections incurred by in-center hemodialysis outpatients. CMS makes QIP scores available online.⁸⁶ Dialysis centers must display documents detailing their overall QIP score and their performance on each quality measure identified for that year. The documents must be in English and Spanish.

Acute Kidney Injury

Medicare covers services for individuals with AKI who already were eligible for Medicare. Since January 2017, CMS has reimbursed providers for dialysis services administered to AKI patients in both Medicare-certified hospitals and outpatient facilities.⁸⁷ Previously, Medicare covered AKI dialysis services as part of hospital-based care. Under the Trade Preferences Extension Act of 2015 (P.L. 114-27), Congress expanded the reimbursement to outpatient centers to reduce the amount of time that AKI patients must remain in the hospital and to provide transitional services to patients, such as those who have had kidney transplants and are waiting for their new kidney to begin functioning.⁸⁸

⁸¹ From 2007 to 2012, there was a major reduction in the use of erythropoiesis-stimulating agents in dialysis due to enactment of the bundled payment system and a change in Food and Drug Administration labeling for the drugs.

⁸² These laws also delayed the addition of oral-only drugs to the PPS. Inclusion of oral drugs was further delayed to 2025 under the ABLE Act, P.L. 113-295. CMS, 80 *Federal Register*, "Medicare Program; End-Stage Renal Disease Prospective Payment System, and Quality Incentive Program; Final Rule," p. 27928, at <https://www.gpo.gov/fdsys/pkg/FR-2015-11-06/pdf/2015-27928.pdf>.

⁸³ 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).

⁸⁴ 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 reduction is applied to all payments for related services performed by the facility receiving the reduction during the applicable payment year.

⁸⁵ CMS, "ESRD QIP Payment Year 2018 Program Details," at <https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/ESRDQIP/Downloads/PY-2018-Program-Details.pdf>.

⁸⁶ Dialysis Facility Compare, at <https://www.medicare.gov/dialysisfacilitycompare/#search>.

⁸⁷ CMS, "Acute Kidney Injury and ESRD Facilities," at <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ESRDpayment/AKI-and-ESRD-Facilities.html>.

⁸⁸ CMS, "42 C.F.R. Parts 413, 414, and 494," 81 *Federal Register*, 77866, at November 4, 2016, <https://www.gpo.gov/fdsys/pkg/FR-2016-11-04/pdf/2016-26152.pdf>.

Medicare ESRD Comprehensive Care Model

CMS is overseeing a five-year pilot program to evaluate coordinated care models for serving ESRD beneficiaries.⁸⁹ Under the CMS Comprehensive ESRD Care (CEC) model, which is to run from 2015 through 2020, physicians, dialysis clinics, and other providers have formed ESRD Seamless Care Organizations (ESCOs) to care for ESRD patients. ESCOs are accountable for 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. There are 37 ESCOs.⁹⁰

Practitioner Payments

CMS pays physicians, who typically are nephrologists, and other practitioners a monthly per-patient rate for most outpatient dialysis-related services.⁹¹ Services covered under the provider payments include analyzing the type of dialysis best suited to a patient, assessing whether a patient requires a special diet, making an initial determination regarding whether a patient is a candidate for a kidney transplant, ordering required tests, performing physical assessments, and reviewing diagnostic and other data. The payment does not include related surgical services, administration of the hepatitis B vaccine, interpretation of certain tests, and performance of a complete (as opposed to initial) evaluation of whether a patient meets the criteria for a kidney transplant.⁹²

Practitioner 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 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.

In February 2018, Congress enacted the Bipartisan Budget Act of 2018 (BBA 2018; P.L. 115-123). BBA 2018 expands the use of telehealth services for ESRD patients undergoing home dialysis.⁹³ Beginning in 2019, BBA will allow 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

⁸⁹ CMS, "Comprehensive ESRD Care Model," at <https://innovation.cms.gov/initiatives/comprehensive-esrd-care/>. The demonstration began in September 2015 and will run until December 31, 2020.

⁹⁰ CMS, "Comprehensive ESRD Care Model (CEC Model) Fact Sheet," at <https://innovation.cms.gov/Files/fact-sheet/cec-fs.pdf>.

⁹¹ CMS, Section 140 in "Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims," chapter 8 in *Medicare Claims Processing Manual*, revised November 10, 2016, at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c08.pdf>.

⁹² CMS, Section 140 in "Outpatient ESRD Hospital, Independent Facility, and Physician/Supplier Claims," chapter 8 in *Medicare Claims Processing Manual*, revised November 10, 2016, at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c08.pdf>.

⁹³ The Bipartisan Budget Act of 2018 changes amended SSA §§1881(b)(3) and 1834(m). Telehealth is the use of electronic information and telecommunications technologies to support remote clinical health care, patient and professional health-related education, and other health care delivery functions. Under current law (SSA §1834(m)), the Medicare program restricts telehealth payments by the type of services provided, the geographic location where the services are delivered, the type of institution delivering the services, and the type of health care provider.

three months of home dialysis and (2) after the initial three months, at least once every three consecutive months.

Transplantation

Medicare provides reimbursement for medical services associated with a kidney transplant performed in a hospital that is an approved Medicare transplant facility. Medicare Part A covers the cost of hospital inpatient services for the ESRD patient, as well as the full cost of laboratory tests and pre-surgery, surgical, and post-surgical care for a kidney donor, including any necessary care for complications directly tied to the transplant.⁹⁴ Medicare Part B covers physicians' services for the ESRD patient and donor, as well as the cost of immunosuppressive drugs.⁹⁵ (See "Medicare Coverage of Immunosuppressive Drugs.") Medicare also reimburses approved medical facilities for costs connected to the acquisition of a cadaver kidney.

Certain costs are not covered by Medicare, including travel and room-and-board expenses by a donor or a transplant recipient. If an individual has ESRD and requires a pancreas transplant, Medicare will cover the transplant if it is done at the same time as or after a kidney transplant.⁹⁶

Issues in Medicare ESRD Coverage

Medicare Advantage Enrollment

Medicare Part C (MA) plans cover Part A and Part B services and also may offer supplemental benefits to their enrollees. CMS provides MA plans with monthly per-patient payments that cover the cost of basic health care services but do not cover supplemental services. The CMS payment is risk adjusted, meaning MA plans receive higher payments from CMS for individuals with identified, underlying health conditions, such as heart disease or diabetes, that make them more costly to cover. MA plans may charge enrollees higher premiums for plans that offer extra benefits. Plans may earn higher payments from CMS if they meet certain specified quality measures each year.

Currently, ESRD beneficiaries may enroll in MA plans only in limited circumstances. ESRD beneficiaries may be in MA plans if they (1) developed ESRD while already enrolled in an MA plan, (2) received health benefits through the same organization (such as a group health plan) that offers the MA plan, (3) had a kidney transplant and no longer require dialysis but are entitled to Medicare due to age or disability, or (4) have a Medicare special-needs plan in their geographic area.⁹⁷ An ESRD beneficiary who is enrolled in an MA plan that is later discontinued has a one-time right to join another MA plan.⁹⁸

Section 17006 of the 2016 CURES Act (P.L. 114-255) will allow all Medicare-eligible individuals who have been diagnosed with ESRD to enroll in MA plans, beginning in 2021. The CURES Act adjusts the MA payment system to account for the higher expected costs of ESRD enrollees.

⁹⁴ CMS, *Medicare Benefit Policy*, Section 140.

⁹⁵ CMS, *Medicare Coverage*, p. 26.

⁹⁶ In some cases, Medicare will pay for a pancreas transplant for an ESRD beneficiary even if an individual does not need a kidney transplant. See Medicare.gov, "Pancreas Transplants," at <https://www.medicare.gov/coverage/transplants-pancreas-adult.html>.

⁹⁷ A Medicare special-needs plan is an MA plan that limits membership to people with specific diseases or health characteristics.

⁹⁸ CMS, *Medicare Coverage*, p. 11.

Under the CURES Act,

- If an MA enrollee with ESRD undergoes a kidney transplant, the costs of kidney acquisition, including Medicare-covered expenses for kidney donors, will be covered through the fee-for-service provisions of Medicare Parts A and B rather than by a specific MA plan.
- The HHS Secretary must evaluate the impact of including CKD in the MA risk-adjustment payment model. Any changes to MA risk adjustment as a result of the evaluation are to be phased in over a three-year period, beginning in 2019, with such changes being fully implemented for 2022 and subsequent years.
- The HHS Secretary must evaluate whether the current MA quality rating system should be adjusted to account for ESRD enrollees.

MA plans often have networks of providers from whom beneficiaries must receive care. Beneficiaries may be required to see a primary caregiver before being referred to a specialist. As such, ESRD beneficiaries who enroll in MA plans may have access to a more limited network of physicians and dialysis centers, as well as other health care providers, than those enrolled in fee-for-service Medicare. At the same time, MA plans may have more ability to coordinate care for ESRD patients across their network of providers and may have lower cost sharing for many services. MA plans, which pay charge premiums, are subject to an annual cap on enrollee out-of-pocket costs, such as co-payments and deductibles. For 2018, the MA out-of-pocket maximum is \$6,700, although plans may offer enrollees a lower cap. The MA limit on out-of-pocket spending could benefit ESRD beneficiaries under the age of 65 who are not able to purchase Medigap coverage, for example.

Medicare Coverage of Immunosuppressive Drugs

Individuals who have had a successful kidney transplant usually take immunosuppressive drugs for the rest of their lives to minimize the risk that their immune systems will reject the donor kidney.⁹⁹ Medicare covers immunosuppressive drugs under Part B if a kidney transplant was covered by Medicare and performed in a CMS-approved facility. Under Part B, beneficiaries pay 20% of the cost of the drugs. If a Medicare ESRD beneficiary has Part B coverage for immunosuppressive drugs, he or she may not file a claim for the drugs under the Part D outpatient drug benefit. (However, if a Medicare beneficiary does not qualify for Part B coverage, he or she may obtain coverage under Part D.)¹⁰⁰

Medicare will cover the lifetime cost of immunosuppressive drugs for individuals who (1) were eligible for Medicare based on age or disability before their ESRD diagnosis or (2) qualified for Medicare due to age or disability after receiving a transplant in a Medicare-approved facility that was covered by Medicare or by a private insurance policy that paid primary to Medicare Part A. Beneficiaries who qualify for Medicare solely on the basis of ESRD are limited to 36 months of Medicare coverage following a successful kidney transplant.¹⁰¹ Once ESRD-only beneficiaries

⁹⁹ Peter Chung-Wen Chang and Donald E. Hricik, “What Are Immunosuppressive Medications? How Do They Work? What Are Their Side Effects?,” in *Kidney Transplantation: A Guide to the Care of Kidney Transplant Recipients*, ed. Dianne B. McKay, Steven M. Steinberg (New York: Springer, 2010), p. 132.

¹⁰⁰ Beneficiaries entitled to Part A who were not eligible for Medicare at the time of the transplant or did not receive the transplant in a Medicare-approved facility still may receive coverage for immunosuppressive drugs by enrolling in a Part D prescription drug plan. If a Medicare beneficiary has coverage for immunosuppressive drugs under Part B, he or she cannot file a claim for the drugs under the Part D voluntary outpatient drug benefit. CMS, *Medicare Coverage*, p. 29.

¹⁰¹ SSA §226A(b)(2).

exhaust their 36 months of Medicare eligibility, they lose Part B coverage for immunosuppressive drugs and must pay for the medications out of pocket, through other insurance, or with third-party assistance.

Lawmakers in the past have introduced legislation to expand Medicare Part B coverage of immunosuppressive drugs for ESRD-only enrollees beyond the current 36-month limit. For example, a bill introduced in the 114th Congress, S. 3487, would have allowed individuals who have undergone a transplant, who are under the age of 65, and who do not have Social Security Disability Insurance or a private group health plan to pay a reduced Medicare Part B premium for immunosuppressive drug coverage.

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