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Federal Support for Organ Transplantation: Frequently Asked Questions

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Federal Support for Organ Transplantation: Frequently Asked Questions

Organ transplantation is a complex medical procedure, often requiring coordination among multiple entities, medical teams, and medical facilities. It is also unique in that it requires the use of an organ procured from one individual that is then implanted into another individual. The federal government supports organ procurement and transplantation in various ways. For example, the federal government has established a uniform system for allocating organs in the United States and set coverage requirements and payment for organ acquisition and transplantation. In some cases, the federal government directly provides organ transplantation services. This report focuses on federal coverage, financing, and the provision of organ transplantation by federal agencies and health programs, as well as the federal role in private health insurance coverage of such.

SUMMARY

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There is not a standard federal support or coverage for organ transplantation services. Each federal department, agency, program, and private health insurance plan has its own unique policies. Even within a program such as Medicaid, there are baseline federal requirements with flexibilities for states to determine what organ transplantation-related services and which subpopulations are covered, resulting in variability across state Medicaid programs.

This report provides an overview of organ transplantation, defines key terms, addresses the role of key federal agencies in coverage and payment for organ transplantation, including a discussion of the federal role in regulating private health insurance with regard to organ transplantation.

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Introduction

Organ transplantation is a complex medical procedure, often requiring coordination among multiple entities, medical teams, and medical facilities. It is also unique in that it requires the use of an organ procured from one individual that is then implanted into another individual. In addition, organ transplantation involves a complex set of policies, processes, and payments with implications for fairness in the allocation of organs, quality, and patient safety related to procurement, acquisition, and transplantation. All of these complexities are underscored by the fact that the supply of organs is not sufficient to meet the demand.

The federal government supports organ procurement and transplantation in various ways. It has established a system for allocating organs; set coverage requirements and payment for organ acquisition and transplantation; and, in some cases, directly provided organ transplantation, among other activities.

This report provides an overview of organ transplantation, describes key concepts, and addresses the role of selected federal agencies in coverage and payment for organ transplantation, including through a discussion of the federal role in regulating private health insurance with regard to organ transplantation.

What Is an Organ?

There exists both a biological definition of organs and a functional definition for the purpose of transplantation established by statute and regulatory action. These two definitions share some commonalities, but they are not mutually inclusive of each other. Some organs defined by statutes would not be considered organs in a biological sense; inversely, some biologically defined organs are not defined as such in statute or regulation.

Biologically, organs are defined as "a part of the body, composed of more than one tissue, that forms a structural unit responsible for a particular function (or functions)."[1] Examples of organs include the heart, which serves a distinct function of pumping blood through the body; the skin, which protects against germs and regulates body temperate; or the eye, which enables sight.

Statutorily, the National Organ Transplant Act of 1984 (NOTA; P.L. 98-507) defines an organ to mean the kidney, liver, heart, lung, pancreas, and any other human organ specified by the Secretary of Health and Human Services (HHS) by regulation.[2] These organs are generally ones for which there is an established or developing medical procedure to facilitate transplantation. At the time that NOTA was enacted, kidney transplantation was already an accepted medical practice, while heart and liver transplantation was transitioning from experimental to accepted medical practice.[3] The Secretary has expanded the definition through regulation to also include intestine and vascularized composite allografts.[4] **Table 1** describes each organ as defined for this purpose.

[1] Harvey Marcovitch, ed., *Black's Medical Dictionary*, 43rd ed. (A&C Black, 2018).

[2] 42 U.S.C. §274b(d)(2).

[3] U.S. Congress, Senate Health, Education, Labor, and Pensions Committee, *Organ Transplant and Procurement Act of 1984*, 98th Cong., 2nd sess., April 6, 1984, S. Rpt. 98-382, p. 3.

[4] 42 C.F.R. §121.2. Blood vessels considered integral to an organ used in transplantation also are included in the definition of an organ.

Table 1. Organs for Transplantation

Organ	Description
Kidney	One of a pair. The kidneys separate fluid and certain solids from the blood.
Liver	The liver is divided into four lobes. It serves a role in many metabolic processes.
Heart	The heart maintains circulation of blood through the body.
Lung	One of a pair. Primarily acts as a respiratory organ so that blood can absorb oxygen.
Pancreas	Functions in digestion and production of certain hormones responsible for regulating blood sugar levels.
Intestine	Divided into small and large intestine. It takes the form of one continuous tube. Serves primarily in digestion.
Vascularized Composite Allografts	A minimally manipulated body part containing multiple tissue types. Common examples include a face or hand for transplantation.

Source: 42 U.S.C. §274b(d)(2); 42 C.F.R. §121.2; and Harvey Marcovitch, ed., *Black's Medical Dictionary*, 43rd ed. (A&C Black, 2018).

What Is Involved in Organ Donation?

Organ donation involves the surgical removal of an organ from an individual, either living or deceased, to be transplanted into another individual experiencing organ failure. This process raises a number of legal and ethical questions.[5] The legality of organ donation and brain death were addressed at the state level with the adoption of the Uniform Anatomical Gift Act (UAGA; 1968) and the Uniform Determination of Death Act (1981), respectively. These acts were uniform bills created by the Uniform Law Commission intended for adoption throughout the states.[6] Every state and Washington, DC, have adopted some version of these two laws. These two acts created a legal basis by which both living and deceased individuals could donate organs.

The majority of organs are donated by deceased donors. However, certain organs, such as whole kidneys and portions of other organs, can be donated while living. In 2023, there were 23,295 individual organ donors.[7] Of those, 16,336 (70.1%) were deceased and 6,959 (29.9%) were living donors.[8] Each deceased donor generally donates multiple organs. In 2023, 54,054 organs in total were recovered from deceased donors.[9]

[5] For ethical considerations of organ recovery, see Organ Procurement & Transplantation Network (OPTN), *Ethics of Deceased Organ Donor Recovery*, December 2016, https://optn.transplant.hrsa.gov/professionals/by-topic/ethical-considerations/ethics-of-deceased-organ-donor-recovery/.

[6] The Uniform Law Commission provides states with nonpartisan legislation to address issues that affect all states. For more information, see https://www.uniformlaws.org/home.

[7] Based on OPTN data as of August 5, 2024. For more information, see OPTN, "National Data," https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#.

[8] Ibid.

[9] Ibid.

Deceased Organ Donation[10]

Under the typical scenario, when an individual experiences a potentially life-threatening medical event, the individual is transported to a hospital where a medical team provides life-saving care. Organ donation is not considered as an option until the individual is declared functionally brain dead. At that point, the body will be supported by artificial means, such as a ventilator. The purpose of artificial life support is to provide the necessary time to obtain authorization for donation from either a state or national registry of donors or from the individual's family, match the donor with potential transplant recipients, and recover the organs.

If the deceased individual had voluntarily opted in to donation via their state or national registry while alive, that is considered sufficient consent for donation, thus eliminating the need to obtain authorization for donation. If there were no indication that the individual opted in to donate, the organ recovery team would discuss options with the individual's family, which could include authorization for donation.

Organ retrieval is a time-sensitive process due to the limited viability of an organ after death. Therefore, the individual is kept on artificial life support while his or her information is entered into a national computer system to identify a transplant candidate that is a good match. Factors used for organ matching include

- Blood type,
- Tissue type,
- Organ size,
- Donor height and weight,
- Urgency for the transplant candidate,
- Length of time on the organ waitlist,
- Age of both donor and transplant candidate, and
- Geographic distance between donor and transplant candidate.[11]

Once a match is made and accepted by the transplant team, the donor's organs are recovered by a surgical team. The surgical team is not the same as the medical team that was responsible for providing care to the donor. The recovered organ(s) are then transported in a manner that is most expeditious depending on the distance involved (e.g., ambulance, helicopter, airplane) to the transplant hospital where the transplant candidate will receive surgery.

Living Organ Donation[12]

Only certain organs can be donated by a living donor. Specifically, a living donor can donate one of their kidneys or a portion of their liver, lung, pancreas, or intestine. The majority of living

[10] This section is largely adapted from information available on the OPTN website landing page for deceased donation. For more information, see OPTN, "Deceased Donation," https://optn.transplant.hrsa.gov/patients/about-donation/deceased-donation/.

[11] The OPTN maintains a series of detailed policies for matching each type of organ. For more information, see OPTN, *OPTN Policies*, September 3, 2024, https://optn.transplant.hrsa.gov/media/eavh5bf3/optn_policies.pdf.

[12] This section is largely adapted from information available on the OPTN website landing page for living donation. For more information, see OPTN, "Living Donation," https://optn.transplant.hrsa.gov/patients/about-donation/living-donation/living-donation/.

donations are for kidneys—6,293 of 6,959 total organs (90.4%) recovered in 2023.[13] Living donors must meet certain criteria, such as being an adult in good health, understanding the risks involved, and not being coerced into donation.

Generally, living donors choose the recipient of their organ. This is referred to as *directed donation*. The majority of living donors donate organs to someone they know. In 2023, 72.8% of living donors donated to a relative, partner, or unrelated person who they knew.

Directed donation is possible only when the donor and the individual they choose to receive the organ are a match. In other words, the blood type, tissue type, size of organ, and other factors must match. In the case of living kidney donation, individuals who wish to direct a donation to someone but are not a match can use a process referred to as *paired donation*. Paired donation is when one incompatible donor/recipient pair is matched with another incompatible donor/recipient pair. Paired exchanges can become rather complex, as multiple donor/recipient pairs can form a chain that results in all recipients getting a kidney transplantation from a compatible donor. In 2023, 19.1% of living donors were involved in paired donation.

Finally, there are individuals who donate an organ anonymously. These individuals do not know who will receive the organ, and the donors are not known to the recipient. In 2023, 7.3% of living organ donations were made anonymously.

How Are Candidates for Organ Transplantation Identified and Organs Distributed?

Organ transplantation is one of the only medical procedures that uses a part of another person's body. As a result, the ability to get a transplant is limited by the supply of available organs. The nation has managed this by establishing a system by which potential transplant patients enter a waitlist that takes into account many factors in order to match them with an available organ.

Generally, an individual experiencing organ failure who has exhausted all other forms of treatment would be evaluated by a transplant team at a transplant hospital to determine if he or she is a good candidate for an organ transplantation. The federal government does not require transplant hospitals to use specific criteria when determining whether patients would be suitable candidates for transplantation, nor does it require transplant hospitals to have a specific selection process. Listing decisions are complex and involve both medical criteria (e.g., urgent need) and nonmedical criteria (e.g., life expectancy, adherence to medical advice, incarceration status, etc.).[14]

Once an individual is listed as a candidate on the waitlist, he or she remains on the waitlist until an organ becomes available that is suitable for the specific patient. This timeline can differ depending on the specific organ in need and other matching criteria. However, candidates can expect to wait for an extended period of time due to the limited supply of available organs. Of the approximately 104,000 candidates currently on the waitlist, nearly 64% have waited for over one year and 11% have waited five or more years.[15]

[13] Based on OPTN data as of August 5, 2024. For more information see, OPTN, "National Data," https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#.

[14] OPTN, *General Considerations in Assessment for Transplant Candidacy*, 2021, https://optn.transplant.hrsa.gov/professionals/by-topic/ethical-considerations/general-considerations-in-assessment-for-transplant-candidacy/.

[15] Based on OPTN data as of August 5, 2024. For more information see OPTN, "National Data," https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/#.

When an organ becomes available, the candidate is alerted and has to take immediate action to prepare for transplantation surgery.[16]

What Type of Posttransplant Care Do Organ Recipients Need?

Immediate posttransplant care resembles the type of care an individual would get following any similar surgical procedure. Rehabilitation, wound care, and pain management may be among the immediate care needs after the transplant procedure.[17] In addition, transplant recipients need to take certain medications to prevent rejection.[18] These medications are immunosuppressants, intended to prevent the recipient's own immune system from rejecting the transplanted organ.

Coverage and Payment for Organ Transplantation Services by Key Federal Agencies, Departments, and Programs

Several federal agencies and departments provide organ transplantation services directly or arrange to provide them and pay for them. For example, the Indian Health Service (IHS) funds hospitals and health care facilities; some are IHS-owned and operated, and others are tribally owned and operated. Medicare does not provide organ transplantation services directly but does have an oversight role and pays for such services. The following sections address coverage and payment for organ transplantation services by key federal agencies, departments, and federal health coverage programs. The content is organized alphabetically by federal department, agency, or program.

Bureau of Prisons

The Bureau of Prisons (BOP) within the Department of Justice (DOJ) operates the federal prison system, which includes 122 facilities in 35 states. BOP was established in 1930 to house federal prisoners, professionalize the prison service, and ensure consistent and centralized administration of the federal prison system.[19] BOP must confine any offender convicted and sentenced to a term of imprisonment in a federal court. As of the end of FY2023, there were approximately 158,400 prisoners under BOP's jurisdiction, making BOP one of the largest correctional systems in the country.[20] BOP provides medically necessary health care treatment to all prisoners housed in BOP-operated facilities.[21] By statute, BOP is required to "provide for the safekeeping, care, and

[16] For more information on this process, see United Network for Organ Sharing (UNOS), Transplant Living, "Receiving 'the Call,'" https://transplantliving.org/before-the-transplant/waiting-for-your-transplant/receiving-the-call/.

[17] OPTN Patient Affairs Committee, UNOS, *What Every Patient Needs to Know*, , p. 31, https://unos.org/wp-content/uploads/Brochure-113-What-every-patient-needs-to-know.pdf.

[18] According to UNOS, "Rejection is when the organ recipient's immune system recognizes the donor organ as foreign and attempts to eliminate it." UNOS, Transplant Living, "Preventing Rejection," https://transplantliving.org/after-the-transplant/preventing-rejection/.

[19] U.S. Department of Justice (DOJ), Bureau of Prisons (BOP), *About the Bureau of Prisons*, June 2015, p. 1.

[20] DOJ, BOP, "Statistics," https://www.bop.gov/about/statistics/population_statistics.jsp (data on the federal prison population was accessed on April 11, 2024).

[21] DOJ, BOP, *FY2025 Performance Budget, Congressional Submission, Salaries and Expenses*, p. 25.

subsistence of all persons charged with or convicted of offenses against the United States, or held as witnesses or otherwise."[22]

Most medical treatment is provided through in-prison health care clinics operated by BOP. Most clinics have examination rooms, treatment rooms, dental clinics, radiology and laboratory areas, a pharmacy, and administrative offices.[23] When services for acute care cannot be provided at a facility, BOP transports prisoners to a community health care facility or provider (e.g., a hospital). Generally, each BOP facility maintains its own contract with community health care facilities or providers and sets the rate to be paid for providing medical treatment to inmates.[24] BOP transfers prisoners with acute or chronic long-term care needs that cannot be managed through in-prison clinics to one of its Federal Medical Centers (FMCs).[25]

Does BOP Provide for Individuals to Donate Organs?

Federal prisoners are allowed to donate organs, but only to immediate family members (i.e., parents, siblings, and biological children), and can receive an organ donation when BOP deems a transplant to be medically necessary. Federal prisoners are not allowed to list themselves as posthumous organ donors.

Prisoners who chose to donate an organ to an immediate family member must sign a consent form for the donation that indicates that

- the prisoner understands the possible risks of the operation,
- the prisoner agrees to the donation of his or her own free will, and
- the federal government will not be held responsible for any complications or financial obligations.[26]

BOP's patient care policy states that hospitalizations or fees associated with prisoners donating an organ to someone else will not be at the federal government's expense. This encompasses all costs associated with guarding the prisoner at off-site facilities, including any costs associated with the U.S. Marshals Service transporting the prisoner.[27] BOP handles the logistics associated with surgery for organ donation (e.g., arranging for transportation and hospitalization, conducting compatibility testing).[28]

Does BOP Provide for Organ Transplants?

Federal prisoners can receive donated organs if BOP determines an organ transplant is medically necessary. When a prison's clinical director (CD) determines it is medically necessary to evaluate a prisoner's suitability for an organ transplant, the CD will request an organ transplant workup

[22] 18 U.S.C. §4042(a).

[23] U.S. Government Accountability Office (GAO), *Bureau of Prisons: Better Planning and Evaluation Needed to Understand and Control Rising Inmate Health Care Costs*, GAO-17-379, June 2017, p. 8.

[24] Ibid., p. 11.

[25] Federal Medical Centers (FMCs) are BOP facilities with the mission of providing care to prisoners with serious or chronic medical problems. Examples of services provided at FMCs include dialysis for inmates with chronic renal failure, oncology treatment (i.e., chemotherapy and radiation therapy), inpatient and forensic mental health, surgery (i.e., limited orthopedic and general surgery procedures), prosthetics and orthotics, long-term ventilator-dependent management, dementia care, and end-of-life care. Ibid., pp. 13, 64-65.

[26] DOJ, BOP, *Patient Care*, Program Statement 6031.04, p. 45.

[27] Ibid.

[28] Ibid.

from a medical specialist to be performed at the prison.[29] If the specialist concludes the prisoner may be a potential candidate for organ transplantation and the CD recommends that further evaluation is medically appropriate, the prisoner will be evaluated at an appropriate community health care facility, such as a transplant center, in the vicinity of the prison or at an FMC.[30] If the transplant center or FMC deems the prisoner suitable for a transplant, the CD compiles all the prisoner's pertinent records and forwards them to BOP's medical director (MD) for consideration.[31] If the MD determines an organ transplant is medically indicated, the prisoner will be approved for surgery at an appropriate transplant center in accordance with BOP policy, transplant center regulations, and state and federal laws.[32]

If a prisoner receives an organ transplant because it is deemed medically necessary, BOP will cover the direct costs of the procedure for both the prisoner and the organ donor.[33]

Does BOP Provide for Posttransplant Care?

As noted above, a prisoner is responsible for all costs associated with hospitalization if the prisoner is donating an organ to someone else. BOP covers costs for prisoners who receive a donated organ because a transplant is deemed medically necessary.

Does BOP Provide for Immunosuppressive Drugs Posttransplant?

BOP's patient care policy does not address immunosuppressive drugs for prisoners who receive an organ transplant. BOP also does not have clinical guidance regarding prescribing these drugs after an organ transplant. However, immunosuppressive drugs that are prescribed for transplant patients—such as tacrolimus, cyclosporine, mycophenolate mofetil, and azathioprine—are listed on BOP's formulary.[34]

Department of Defense

The Department of Defense (DOD) administers a statutory health benefit through the Military Health System (MHS).[35] The MHS offers health care benefits and services through its TRICARE program to approximately 9.6 million beneficiaries, comprising members and retirees of the uniformed services and their family members.[36] TRICARE offers a range of health care services, including organ transplant services, in military hospitals and clinics (also known as military treatment facilities, or MTFs) and through participating civilian health care providers. With the exception of active-duty servicemembers, beneficiaries are subject to certain cost-sharing

[29] Ibid, p. 45.

[30] Ibid, p. 46.

[31] Ibid.

[32] Ibid.

[33] Ibid.

[34] DOJ, BOP, *Winter 2022 National Formulary Part 2*, https://www.bop.gov/resources/pdfs/2022_winter_formulary_part_2.pdf.

[35] 10 U.S.C. Chapter 55: Medical and Dental Care.

[36] Military Health System (MHS), "Patients by Beneficiary Category," accessed April 17, 2024, https://health.mil/Military-Health-Topics/MHS-Toolkits/Media-Resources/Media-Center/Patient-Population-Statistics/Patients-by-Beneficiary-Category. The term *uniformed services* includes the Armed Forces (Army, Navy, Air Force, Space Force, Marine Corps, and Coast Guard), the Commissioned Corps of the Public Health Service, and the Commissioned Corps of the National Oceanic and Atmospheric Administration. For additional information about the MHS, see CRS In Focus IF10530, *Defense Primer: Military Health System*.

requirements based on beneficiary category, health plan or benefit program, and the sponsor's initial enlistment or appointment date to military service.[37]

Does DOD Provide for Individuals to Donate Organs?

DOD policy stipulates that TRICARE beneficiaries are "without coercion ... afforded the opportunity and provided a convenient mechanism to donate organs and tissues."[38] TRICARE beneficiaries may declare their intent to donate their organs after death or serve as a living organ donor. Federal regulation authorizes TRICARE to cover certain organ donation costs when the donor or recipient is a TRICARE beneficiary.[39]

Intent to Donate After Death. Generally, DOD recognizes the "first person consent" or "donor designation" principle, which places an individual's desire to donate organs after death above the desire of the next of kin or designated power of attorney.[40] An individual with the capacity to provide informed consent may designate "an election to donate [their] organs" for transplantation or for the purposes of research and education.[41] DOD policies allow for TRICARE beneficiaries to declare their organ donor status at the time of DOD identification card issuance.[42] This policy also requires DOD to record an individual's organ donor status in the Defense Enrollment Eligibility System.[43]

Servicemembers as Living Organ Donors. All TRICARE beneficiaries may choose to be living organ donors. DOD policies outline specific requirements for a servicemember intending to serve as a living donor if the donation (1) requires an "absence from duty for more than one day" or (2) may potentially impact the servicemember's fitness for duty or deployability.[44] These requirements include

- a servicemember's written request to be a living donor;
- written counseling and endorsement by the servicemember's chain of command;
- a medical examination by the servicemember's primary care manager;[45] and

[37] For more on TRICARE's cost-sharing features, see CRS Report R45399, *Military Medical Care: Frequently Asked Questions* ("Question 7. What are the Different TRICARE Plans?"). A *sponsor* refers to a servicemember or retired servicemember. For more on sponsors and family members, see TRICARE, "Plans and Eligibility," https://www.tricare.mil/Plans/Eligibility.

[38] Department of Defense (DOD) Instruction 6465.03, *Anatomic Gifts and Tissue Donation*, June 8, 2016, p. 3, https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/646503p.pdf.

[39] 32 C.F.R. §199.4(e)(5)(i)(A)(3).

[40] DOD Instruction 6465.03, *Anatomic Gifts and Tissue Donation*, June 8, 2016, p. 6.

[41] Ibid. For more on informed consent, see U.S. Department of Health and Human Services (HHS), "Office for Human Research Protections," https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/informed-consent/index.html.

[42] Ibid; and Defense Health Agency (DHA) Procedural Instruction 6465.01, *Anatomic Gifts and Tissue Donation*, February 17, 2023, p. 12, https://www.health.mil/Reference-Center/DHA-Publications/2023/02/17/DHA-PI-6465-01.

[43] DHA Procedural Instruction 6465.01, *Anatomic Gifts and Tissue Donation*, February 17, 2023, p. 12, https://www.health.mil/Reference-Center/DHA-Publications/2023/02/17/DHA-PI-6465-01. The Defense Enrollment Eligibility Reporting System (DEERS) is a "database of information on uniformed services members (sponsors), U.S.-sponsored foreign military, DoD and uniformed services civilians, other personnel as directed by the DoD, and their family members." For more on DEERS, see milConnect, "About DEERS," https://milconnect.dmdc.osd.mil/milconnect/public/faq/DEERS-About_DEERS.

[44] DOD Instruction 6465.03, *Anatomic Gifts and Tissue Donation*, June 8, 2016, pp. 6-9; and DHA Procedural Instruction 6465.01, *Anatomic Gifts and Tissue Donation*, February 17, 2023, pp. 12-20.

[45] DHA Procedural Instruction 6465.01 requires the medical examination to include completion of Defense Department (DD) Form 2807-1, *Report of Medical History*; DD Form 2808, *Report of Medical Examination*; and appropriate diagnostic testing.

- a statement from the transplant facility's attending physician that verifies the recipient's diagnosis, prognosis, and that no other donor is available.[46]

The surgeon general of the respective military service is the approval authority for servicemember requests to be a living organ donor.[47]

Does DOD Provide for Organ Transplants?

Federal regulation requires DOD to cover "services or supplies in connection with an organ transplant procedure, provided such transplant procedure is in accordance with accepted professional medical standards and is not considered unproven."[48] In addition to the transplant procedure, covered services and supplies can include

- evaluation of a potential candidate's suitability for an organ transplant,
- pre- and posttransplant inpatient hospital and outpatient services,
- pre- and postoperative services of the transplant team,
- blood and blood products,
- Food and Drug Administration (FDA)-approved immunosuppression medications,
- care to treat or mitigate complications of the transplant procedure,
- periodic evaluation and follow-up assessments,
- donor acquisition services and organ transportation, and
- maintenance of the viability of the donor organ.[49]

TRICARE policies stipulate that beneficiaries who require a medically necessary organ transplant obtain a preauthorization.[50] TRICARE covers organ transplant procedures performed only in TRICARE- or Medicare-certified transplantation centers.[51] Beneficiaries also may be subject to certain cost-sharing requirements for an organ transplant procedure and related services or supplies.[52] DOD policy requires the MHS to participate in the Organ Procurement and Transplantation Network (OPTN); as such, organ transplant procedures may be performed in certain MTFs with appropriate capabilities.[53]

[46] For more on the requirements of servicemembers intending to be a living organ donor, see DHA Procedural Instruction 6465.01, *Anatomic Gifts and Tissue Donation*, February 17, 2023, p. 35.

[47] DHA Procedural Instruction 6465.01, *Anatomic Gifts and Tissue Donation*, February 17, 2023, p. 10.

[48] 32 C.F.R. §199.4(e)(5)(i).

[49] 32 C.F.R. §199.4(e)(5) and CRS analysis of Chapter 4 of the *TRICARE Policy Manual 6010.60-M*, April 2015 (Change 125), https://manuals.health.mil/pages/ManualToc.aspx?Manual=TP15&Change=107. While outside the purview of this report, these regulatory and policy authorities also allow DOD to cover stem cell transplantation under certain conditions.

[50] Chapter 1, Section 6.1 of the *TRICARE Policy Manual 6010.60-M*, updated June 12, 2023, https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-03-18/AsOf/TP15/C1S6_1.html.

[51] 2 C.F.R. §199.6(b)(4)(ii) and Chapter 11, §7.1 of the *TRICARE Policy Manual 6010.60-M*, April 2015 (Change 125), https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-03-18/AsOf/TP15/C11S7_1.html.

[52] For more on TRICARE cost-sharing requirements, see TRICARE, "TRICARE Costs and Fees 2024," March 2024, https://tricare.mil/-/media/Files/TRICARE/Publications/FactSheets/TRICARE_Costs_Fees_FS_FINAL_032624.pdf.

[53] DOD Instruction 6465.03, *Anatomic Gifts and Tissue Donation*, June 8, 2016, pp. 6-9; and DHA Procedural Instruction 6465.01, *Anatomic Gifts and Tissue Donation*, February 17, 2023, pp. 12-20.

Does DOD Provide for Posttransplant Care?

Federal regulation requires DOD to cover posttransplant care when the organ transplant procedure is "in accordance with accepted professional medical standards and is not considered unproven."[54] Posttransplant care may include related inpatient hospital services, outpatient services, and pharmacy services. For posttransplant care of living donors who are not TRICARE beneficiaries, federal regulation and TRICARE policy limit the coverage of costs to services and supplies "directly related to the transplant procedure itself and do not include medical care costs related to the treatment of the donor, including complications."[55]

Does DOD Provide for Immunosuppressive Drugs Posttransplant?

Federal regulation requires DOD to cover FDA-approved immunosuppressive drugs when the organ transplant procedure is "in accordance with accepted professional medical standards and is not considered unproven."[56] The regulation also authorizes TRICARE coverage of these drugs for "off-label uses when determined to be medically necessary for the treatment of the condition for which it is administered, according to accepted standards of medical practice."[57]

U.S. Immigration and Customs Enforcement Noncitizen Detention

Within the Department of Homeland Security (DHS), Immigration and Customs Enforcement's (ICE's) mission "is to protect America from the cross-border crime and illegal immigration that threaten national security and public safety."[58] ICE's Enforcement and Removal Operations component is responsible for immigration enforcement in the interior of the United States, including managing and overseeing the immigrant detention system.[59]

ICE detention standards were originally developed in 2000 and have been updated several times. Rather than there being one set of standards, there are currently various sets of standards that incorporate different laws and regulations and vary in terms of scope and rigor. Although there are different sets of standards, all facilities housing noncitizen detainees generally must comply with one of the sets of ICE detention standards, including health care standards.[60] Contracts or agreements between ICE and detention facilities specify which set of standards facilities are required to follow.[61]

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[54] 32 C.F.R. §199.4(e)(5)(i).

[55] 32 C.F.R. §199.4(e)(5)(i)(A)(4); and Chapter 4, §24.9, of the *TRICARE Policy Manual 6010.60-M*, April 2015 (Change 125), https://manuals.health.mil/pages/DisplayManualHtmlFile/2024-03-18/AsOf/TP15/C4S24_9.html.

[56] 32 C.F.R. §199.4(e)(5)(i).

[57] 32 C.F.R. §199.4(e)(5)(i)(A)(1)(v).

[58] Department of Homeland Security (DHS), "Immigration and Customs Enforcement" (ICE), https://www.dhs.gov/topic/immigration-and-customs-enforcement.

[59] The law provides ICE with broad authority to detain noncitizens while awaiting a determination of whether they should be removed from the United States and mandates that certain categories of noncitizens are subject to mandatory detention (e.g., when the noncitizen is removable on account of certain criminal or terrorist activity). See 8 U.S.C. §§1225, 1226, 1226a, 1231, and 1357.

[60] For more information, see CRS In Focus IF12623, *Medical Care Standards in Immigrant Detention Facilities*.

[61] ICE owns and operates some of its own facilities, and it has arrangements through contracts with private companies that operate immigration detention facilities. In addition, immigrant detention facilities owned by state or local governments or private entities operate through intergovernmental agreements. (GAO, *ICE Should Enhance Its Use of Facility Oversight Data and Management of Detainee Complaints*, GAO-20-596, August 2020, pp. 6-7; hereinafter, GAO-20-596.)

Two sets of detention standards are applied at facilities that house the majority of the adult detained population: the 2011 Performance-Based National Detention Standards (PBNDS) and the 2000/2019 National Detention Standards (NDS).[62] The 2011 PBNDS and 2019 NDS provide identical guidance on certain standards. Multiple DHS Office of Inspector General (OIG) and Government Accountability Office reports indicate inadequate compliance with these standards in many ICE detention facilities.[63] For more information, see CRS In Focus IF12623, *Medical Care Standards in Immigrant Detention Facilities*.

Does ICE Provide for Organ Donation or Transplantation?

The PBNDS addresses detainees' ability to donate organs. It states that detainees may donate organs to immediate family members; the donation shall be at the detainees' expense, involving no government funds; and the government is not responsible for any associated medical complications.[64] The PBNDs does not reference detainees' ability to receive organ transplantations. The NDS does not address organ donation or transplantation.[65] CRS contacted ICE for more specifics and had not heard back by the date of publication.

Indian Health Service

American Indians and Alaska Natives who are members of federally recognized tribes are eligible to receive health care through IHS within HHS. IHS provides health care directly or provides funds for Indian tribes or tribal organizations to operate health care facilities.[66] It provides limited

[62] The 2011 Performance-Based National Detention Standards (PBNDS) was revised in 2016 to meet detention standards consistent with federal legal and regulatory requirements, as well as prior ICE policies and policy statements. The 2011 PBNDS is an updated version of the 2008 PBNDS; some facilities have contracts agreeing to adhere to the 2008 version (GAO-20-596). The 2019 National Detention Standards (NDS) is a modified version of the 2000 NDS. The data provided by GAO do not distinguish between the facilities using 2000 and 2019 NDS (GAO-20-596).

[63] For example, see DHS, Office of the Inspector General (OIG), *Concerns About ICE Detainee Treatment and Care at Detention Facilities*, OIG-18-32, December 11, 2017; DHS OIG, *ICE Does Not Fully Use Contracting Tools to Hold Detention Facility Contractors Accountable for Failing to Meet Performance Standards*, OIG-19-18, January 29, 2018; DHS OIG, *Management Alert—Issues Requiring Action at the Adelanto ICE Processing Center in Adelanto, California*, OIG-18-87, September 27, 2018; DHS OIG, *Concerns About ICE Detainee Treatment and Care at Four Detention Facilities*, OIG-19-57, June 3, 2019; DHS OIG, *Capping Report: Observations of Unannounced Inspections of ICE Facilities in 2019*, OIG-20-45, July 1, 2020; GAO, *Immigrant Detention: Additional Actions Needed to Strengthen Management and Oversight of Detainee Medical Care*, GAO-16-321, February 2016; GAO, *Immigrant Detention: Care of Pregnant Women in DHS Facilities*, GAO-20-330, March 2020; GAO, *Immigrant Detention: ICE Should Enhance Its Use of Facility Oversight Data and Management of Detainee Complaints*, GAO-20-956, August 2020. DHS OIG, *Medical Processes and Communication Protocols Need Improvement at Irwin County Detention Center*, OIG-22-14, January 3, 2022; GAO, *Immigrant Detention: ICE Needs to Strengthen Oversight of Informed Consent for Medical Care*, GAO -23-105196, October 2022; GAO, *Immigration Detention: ICE Can Improve Oversight and Management*, GAO-23-106350, January 2023; and DHS OIG, *ICE and CBP Deaths in Custody During FY2021*, OIG-23-12, February 1, 2023.

[64] ICE, "4.7 Terminal Illness, Advance Directives and Death," D. Organ Donation by Detainees," in *Performance-Based National Detention Standards 2011,* revised 2016, p. 341, https://www.ice.gov/doclib/detention-standards/2011/4-7.pdf. Note that while the section on "organ donation by detainees" is included in the chapter on "Terminal Illness, Advance Directives and Death," the guidelines do not specify that only dying or terminally ill detainees may donate organs to immediate family members.

[65] ICE, "4.3 Medical Care" and "4.6 Terminal Illness and Death," in *National Detention Standards for Non-Dedicated Facilities*, revised 2019, https://www.ice.gov/detain/detention-management/2019.

[66] The Indian Health Service (IHS) also provides grants to Urban Indian Organizations (UIOs) that operate smaller health facilities in urban areas. These facilities vary in terms of the services available; some provide comprehensive services, whereas others provide information and referral services. UIOs do not provide inpatient services. As such, they would not be directly providing transplant services. Outside of the grants they receive, UIOs generally are not (continued...)

services free of charge to approximately 2.8 million eligible American Indians and Alaska Natives in 37 states.[67] IHS is organized into 12 geographic areas, which cover one or more states. Areas are then subdivided into service units that may consist of multiple facilities. Service units may cover a number of small reservations, or a larger reservation may be covered by multiple service units.

Not all individuals who are eligible to receive services will use IHS, and not all individuals who self-identify as American Indian and Alaska Native are eligible for IHS.[68] American Indians and Alaska Natives experience high rates of chronic conditions that may lead to organ failure (e.g., liver disease). Despite this, these individuals account for less than 1% of patients on the organ transplant waiting list. In 2020, 30% of American Indian/Alaska Native patients waiting for a transplant received one, compared with 49% of White patients that year.[69]

IHS does not have a standard medical benefit that includes or excludes certain services. The agency generally focuses on primary and preventive services through a network of nearly 700 facilities, which include hospitals (43), health centers (383), and small health stations (101). Other facility types include school health centers, youth regional treatment centers, and Alaska village clinics.[70] In general, IHS has limited funding and some facilities serve small populations. Most IHS hospitals are small and do not directly provide transplant services. IHS will pay for some services, potentially including transplant services, outside its system in non-IHS or non-tribally-owned or operated facilities (i.e., community health care facilities), through its Purchased/Referred Care (PRC) system as will be discussed further below.[71]

Does IHS Provide for Individuals to Donate Organs?

IHS's facilities are small and do not provide transplantation services directly. As such, IHS facilities would not retrieve organs for donation from IHS beneficiaries, nor would IHS facilitate the donation of organs that would be received by an IHS beneficiary. As discussed in the question below, IHS may pay for transplant services provided to IHS beneficiaries outside of IHS health facilities through the PRC program.[72] PRC information is not specific enough to determine whether IHS would pay for organ donation. IHS policy requires that a procedure be "medically necessary" but does not define that term.[73] Providing an organ to another individual would not be "medically necessary" for the donor; as such, it is unlikely that IHS funds would be available to pay for donor services.

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eligible to receive funds from the overall IHS budget; this includes purchased/referred care, which is the source of payment for IHS system transplant services. For more information on the IHS system and UIOs, see CRS Report R43330, *The Indian Health Service (IHS): An Overview*.

[67] HHS, IHS, *Fiscal Year 2025 Indian Health Service Justification of Estimates*, Justification of Estimates for Appropriations Committees (ihs.gov) https://www.ihs.gov/sites/budgetformulation/themes/responsive2017/display_objects/documents/FY-2025-IHS-CJ030824.pdf, see CJ.2.

[68] For discussion of issues related to measuring the American Indian and Alaska Native population, see Appendix A in CRS Report R43330, *The Indian Health Service (IHS): An Overview*.

[69] HHS, Office of Minority Health, "Organ Donation and American Indians/Alaska Natives," https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=42.

[70] HHS, IHS, *Fiscal Year 2024 Indian Health Service Justification of Estimates*, https://www.ihs.gov/sites/budgetformulation/themes/responsive2017/display_objects/documents/FY-2025-IHS-CJ030824.pdf, p. 41-42.

[71] HHS, IHS, "Purchased/Referred Care," https://www.ihs.gov/prc/. In FY2024, the program received an appropriation of approximately $996.8 million in P.L. 118-42.

[72] Ibid.

[73] HHS, IHS, "Can PRC Pay for Your Referral Medical Care? Find Out in 3 Stages," https://www.ihs.gov/sites/prc/themes/responsive2017/display_objects/documents/PRC-ProcessHandout.pdf.

Does IHS Provide for Organ Transplants?

IHS's facilities are small and do not provide transplantation services directly. IHS, however, may pay for transplant services provided to IHS beneficiaries outside of IHS health facilities through the PRC program.[74] IHS's PRC funds may be used to pay for an individual's transplant, subject to PRC program requirements. Only a subset of IHS beneficiaries are eligible for PRC, because eligibility is restricted to individuals who live in certain geographic areas.[75] PRC funds are authorized only for services in instances when the PRC-eligible individual does not have an alternate source of coverage or payment (e.g., Medicaid). In instances where the IHS beneficiary has alternate sources of coverage or payment, the program or plan rules of the alternate source apply.

For individuals without alternate sources, PRC referrals may be authorized and PRC funds would pay for services, to the extent that funds are available, based on medical priority rankings. These priorities range from Medical Priority Level I (emergency care services necessary to save life, limb, or senses, which are almost always paid) to Medical Priority Level V (excluded services, including those considered elective or experimental, which are not paid).[76] PRC programs are managed locally, and these local programs determine what priority level will be paid and may add or remove services within specific priority levels. In FY2022, 90% of IHS-operated PRC programs were able to pay for services beyond Medical Priority Level II services.[77] IHS's budget for PRC is limited, and funds may not be available toward the end of any given fiscal year. IHS reports that it denied or deferred 119,938 services for eligible IHS beneficiaries in FY2022 because of these funding limitations.[78]

Transplant services generally are considered Medical Priority Level IV (chronic tertiary care services). These treatments are not considered essential to treat an initial or emergent diagnosis, have less of an impact on mortality or morbidity, and are high cost. Transplant PRC referrals are subject to additional authorization than are PRC requests at higher priority levels. Specifically, for a transplant to be authorized, the service unit level PRC committee must concur with the referral. The area level Chief Medical Officer or a designee also must monitor and, depending on cost, concur with the referral.[79]

Does IHS Provide Posttransplant Care?

IHS policies do not explicitly address posttransplant care. To the extent that a facility has the appropriate services that someone who has donated an organ or received a transplant requires,

[74] HHS, IHS, "Purchased/Referred Care," https://www.ihs.gov/prc/.

[75] These are called *purchased/referred care delivery areas*. Each individual PRC program has its own purchased/referred care delivery area and in statute, some areas comprise entire states (e.g., Arizona under 25 U.S.C. §1678). The Purchased/Referred Care program was previously named the Contract Health Services program. In statute, these areas are referred to by the prior program name (i.e., *contract health service delivery areas*).

[76] For more information, see HHS, IHS, "Purchased/Referred Care: Requirements: Priorities of Care," https://www.ihs.gov/prc/eligibility/requirements-priorities-of-care/, see "Indian Health Service Medical Priority Levels" Word document.

[77] HHS, IHS, *Fiscal Year 2025 Indian Health Service Justification of Estimates*, Justification of Estimates for Appropriations Committees, https://www.ihs.gov/sites/budgetformulation/themes/responsive2017/display_objects/documents/FY-2025-IHS-CJ030824.pdf. See CJ-97.

[78] Ibid.

[79] HHS, IHS, "Purchased/Referred Care—Requirements: Priorities of Care," https://www.ihs.gov/prc/eligibility/requirements-priorities-of-care/, see "Indian Health Service Medical Priorities Levels," https://www.ihs.gov/prc/eligibility/requirements-priorities-of-care/(linked Word document).

IHS would provide these services. In addition, to the extent that such services meet PRC medical priority levels (discussed above), PRC funds could be used to provide these services.

Does IHS Provide Immunosuppressive Drugs Posttransplant?

IHS does provide pharmaceutical benefits, and most facilities offer such services. IHS uses a National Core Formulary, which individual facilities can supplement with additional drugs, depending on facility needs. The formulary provides limited access to immunosuppressive drugs, based on CRS's search of the formulary as of April 2024. Some facilities may offer additional types of pharmaceuticals as part of supplementing the core formulary; in such cases, a facility could be providing immunosuppressive drugs.[80] As with other IHS services, pharmaceuticals are provided to eligible American Indians and Alaska Natives free of charge.

Department of Veterans Affairs

The Veterans Health Administration (VHA) of the Department of Veterans Affairs (VA) operates the nation's largest public integrated direct health care delivery system.[81] VHA's primary mission is to provide health care services to eligible veterans.[82] VHA provides care to approximately 6.4 million unique veteran patients on an annual basis.[83] VHA generally provides care directly through over 1,300 sites of care, including hospitals, clinics, and health care facilities.[84]

VHA is primarily a direct provider of care. It directly operates associated facilities and employs clinicians.[85] This model differs from the predominant health care financing and delivery model in the United States, in which there is a payer for health care services (e.g., Medicare, private health insurance plan), a provider (e.g., hospital, physician), and a recipient of care (patient). VHA is not a health insurance financing program that provides reimbursement to providers for all or a portion of a patient's health care costs.

VA has established, through regulation, a medical benefits package to standardize care provided to patients enrolled in the system.[86] The medical benefits package includes, among other things, inpatient care, outpatient care, and prescription drugs.[87]

VHA also provides health care to dependents, spouses, and caregivers of veterans who meet certain eligibility criteria through the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA).[88] Unlike the provision of health care for veterans, which follows the standard medical benefits package, CHAMPVA is required to provide benefits similar to

[80] HHS, IHS, "National Core Formulary," https://www.ihs.gov/nptc/formularysearch/.

[81] Department of Veterans Affairs, *FY2025 Congressional Submission, Medical Programs*, vol. 2 of 4, March 2024, p. VHA-362.

[82] 38 U.S.C. §7301.

[83] Ibid., p. VHA-41.

[84] Department of Veterans Affairs, *FY2025 Congressional Submission, Medical Programs*, vol. 2 of 4, March 2024, p. VHA-17.

[85] The Veterans Health Administration (VHA) does pay for care in the community (i.e., non-Veterans Affairs [VA] providers) under certain circumstances. The VA Maintaining Internal Systems and Strengthening Integrated Outside Networks Act of 2018 (VA MISSION Act; P.L. 115-182) established the Veterans Community Care Program (VCCP), which requires VHA to provide for care in the community to all enrolled veterans who meet specified criteria.

[86] 38 C.F.R. §17.38.

[87] For more information on VA health care in general, see CRS Report R42747, *Health Care for Veterans: Answers to Frequently Asked Questions*.

[88] For more information on the Civilian Health and Medical Program of the Department of Veterans Affairs (CHAMPVA), see CRS Report RS22483, *Health Care for Dependents and Survivors of Veterans*.

DOD's TRICARE Standard plan.[89] Furthermore, CHAMPVA is primarily a health insurance program in which enrollees receive care from private sector health care providers and CHAMPVA pays for a portion of the cost of care; this is in contrast to the provision of health care for veterans, which is generally provided by VA clinicians.

Does VA Have Protocols in Place for Individuals to Donate Organs?

VA has protocols in place to allow patients to donate organs upon death and for living donors to donate organs to patients in need.

VA policy requires that each VA medical center enter into an agreement with the local Organ Procurement Organization (OPO) to identify potential donors and to facilitate the donation-after-death process.[90] VA has established protocols for procession of donation after death, which includes conforming policy with specific state UAGAs and notifying OPOs of all hospital deaths, among other activities.

Subject to the availability of appropriations, the Secretary of Veterans Affairs is required to furnish any care or services that may be required in connection with a living donation for an eligible veteran's transplant procedure to any live donor, regardless of whether the donor is a veteran themselves.[91] The Secretary can furnish such services at a VA or non-VA facility.[92]

VA will provide the following for live donors pertaining to solid organ donation.[93]

- Any examinations, tests, and studies necessary to qualify a prospective live donor to donate.
- The surgical procedure to remove a solid organ or part of a solid organ.
- All hospital care, medical services, and other services that are necessary and appropriate to live donor follow-up for a period not less than that which the OPTN prescribes or recommends or for a period of two years, whichever is greater.

Under certain circumstances, VA will also reimburse living donors for the cost of travel for hospital care or medical services as well as for temporary lodging.[94]

Does VA Provide Organ Transplants?

VA operates a national transplant program for veterans enrolled in the VA health care system. As shown in **Figure 1**, VA operates its own transplant centers, which generally focus on a specific organ or organs for transplantation. Veterans generally travel to the nearest VA transplant center to receive transplant care. The veterans' care team at their VA medical center makes a referral to the VA transplant center when medically appropriate.[95]

Under the Veterans Community Care Program (VCCP), veterans can receive organ transplant care at a non-VA transplant center if the procedure is medically necessary and the veteran's primary care provider provides a medically compelling reason for the veteran to travel to a different

[89] 38 U.S.C. §1781(b).

[90] VA, VHA, "Solid Organ, Tissue, and Eye Donation," VHA Directive 1101.3, August 23, 2021.

[91] 38 U.S.C. §1788.

[92] 38 C.F.R. §17.395(e).

[93] 38 C.F.R. §17.395(c).

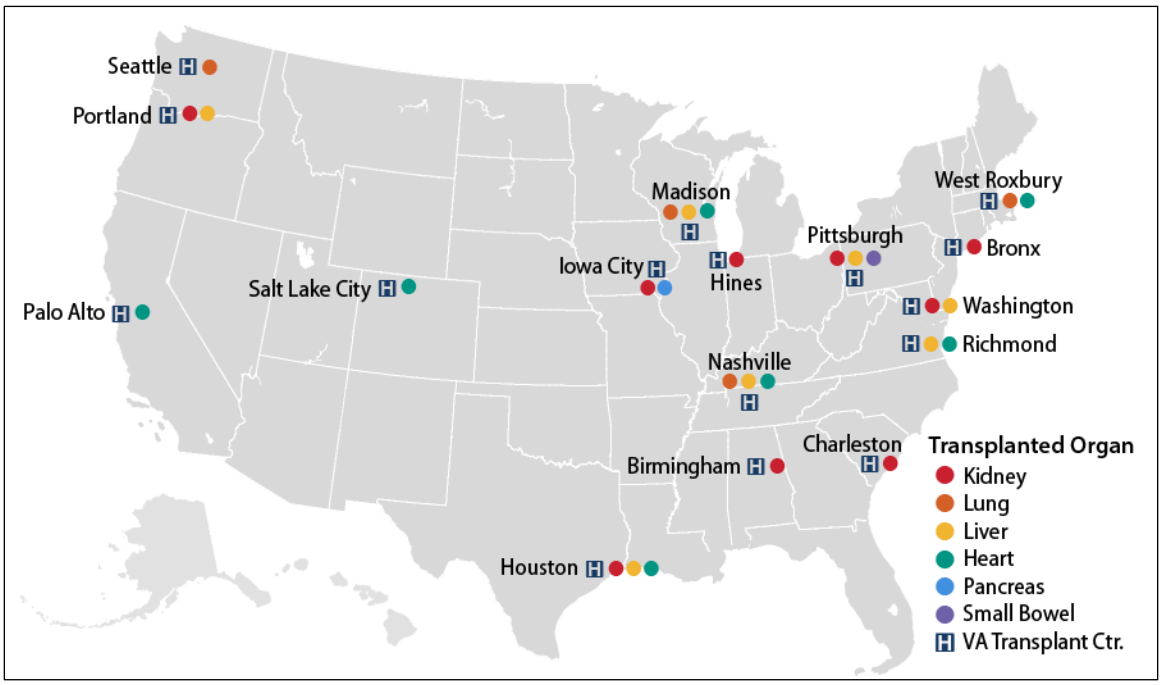
[94] 38 C.F.R. §17.395(d).

[95] VA, VHA, "Solid Organ and Bone Marrow Transplantation," VHA Directive 2012-018(1), July 9, 2012.

OPTN region than where the veteran resides.[96] This differs from other types of care authorized under the VCCP, which can be authorized based on specified eligibility criteria or access standards.[97]

VA also pays for transplant services for certain spouses, dependents, and caregivers of veterans through the CHAMPVA program.[98] CHAMPVA beneficiaries generally do not need prior authorization (i.e., advanced approval) to receive care paid for by CHAMPVA. However, beneficiaries do require prior authorization for organ transplant care.

Figure 1. VA Transplant Centers



Source: Adapted by CRS from VA, https://www.va.gov/health/services/transplant/ (accessed on 02/07/2023).

Does VA Provide Posttransplant Care?

VA provides enrolled veterans all medically necessary inpatient and outpatient care as part of the medical benefits package.[99] This includes any posttransplant care. VA generally does not pay for nonmedical expenses; however, under certain circumstances, it will reimburse veterans for certain travel costs.[100]

[96] 38 C.F.R. §17.4020(d).

[97] For more information on the VCCP, see CRS Report R42747, *Health Care for Veterans: Answers to Frequently Asked Questions*.

[98] CHAMPVA, *CHAMPVA Program Guide*, p.57, https://www.va.gov/COMMUNITYCARE/docs/pubfiles/programguides/CHAMPVA-Guide.pdf.

[99] 38 C.F.R. 17.38(a)(1).

[100] 38 C.F.R. Part 70.

VA provides CHAMPVA beneficiaries postoperative services as well as any costs associated with complications of a transplant procedure.[101] CHAMPVA does not cover posttransplant nonmedical expenses, such as out-of-hospital living expenses.

Does VA Provide Immunosuppressive Drugs Posttransplant?

VA provides all medically necessary medications to enrolled veterans as required by the standard medical benefit package.[102] Veterans are generally required to pay copayments for medication. However, copayments are not required if the organ transplant is related to a service-connected disability, among other potential reasons.[103]

CHAMPVA beneficiaries also are provided appropriate and FDA-approved immunosuppression therapy.[104] Beneficiaries are required to pay a specified cost sharing for pharmacy services unless they utilize the CHAMPVA *meds by mail* program. Under this program, beneficiaries pay no cost sharing for pharmacy services.[105]

Coverage of Organ Transplantation Services

Medicaid

Medicaid, authorized in Social Security Act (SSA) Title XIX, is a federal-state program that jointly finances primary and acute medical services, as well as long-term services and supports, to a diverse low-income population, including eligible children, pregnant women, adults, individuals with disabilities, and people aged 65 and older.[106] Participation in Medicaid is voluntary for states; all states, the District of Columbia, and U.S. territories choose to participate.

In general, states must follow federal rules to receive federal matching funds, but states have the flexibility to design their own versions of Medicaid within the federal statute's framework. For example, the federal government requires states to cover certain mandatory populations and benefits but allows states to cover other optional populations and benefits. In another example, states can require certain enrollees to share in the cost of certain Medicaid services, but there are limits on (1) the amounts that states can impose (subject to a maximum allowable amount), (2) the beneficiary groups that can be required to pay, and (3) the services for which cost sharing can be charged. Due to this flexibility, there is substantial state variation in factors such as Medicaid eligibility, covered benefits, and enrollee cost-sharing requirements. In FY2023, Medicaid provided health care services to an estimated 97 million individuals at a total cost of approximately $894 billion (including federal and state expenditures).[107]

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[101] *CHAMPVA Operational Policy Manual*, CHAMPVA, Chapter 2, Section 31.4, "Kidney Transplantation," in *CHAMPVA Operational Policy Manual*.

[102] 38 C.F.R. 17.38(a)(1)(iii).

[103] For more information see, CRS Report R42747, *Health Care for Veterans: Answers to Frequently Asked Questions*.

[104] CHAMPVA, Chapter 2, Section 30.8, "Immunosuppression Therapy," in *CHAMPVA Operational Policy Manual*.

[105] CHAMPVA, *CHAMPVA Program Guide*, p.45, https://www.va.gov/COMMUNITYCARE/docs/pubfiles/programguides/CHAMPVA-Guide.pdf.

[106] For more information about the Medicaid program, see CRS Report R43357, *Medicaid: An Overview*

[107] This enrollment figure is measured according to average monthly enrollment and represents the number of enrollees with full and partial benefits who are enrolled on an average monthly basis. This enrollment measure differs from *person-year equivalents*, which represent the average program enrollment over the course of a year, and from *ever-enrolled counts*, which measure the number of people covered by Medicaid for any period of time during the year. (continued...)

Does Medicaid Cover Organ Donation?

States are permitted to tailor their organ transplantation benefit coverage through what are referred to as *written standards* included in the Medicaid state plan as approved by Centers for Medicare & Medicaid Services (CMS).[108] (For more information, see "Does Medicaid Cover Organ Transplants?") This results in variability in the types of coverage available across states. CRS could not identify a consolidated summary of organ donation coverage policies across states. However, the following are examples of state variation in organ donation policies.[109]

- **District of Columbia**: Covers procedures and medical care required to retrieve an organ from a living donor for use by a Medicaid enrollee, regardless of the donor's Medicaid eligibility status.[110]
- **California**: Covers donor *and* recipient organ transplant surgeries, as specified.[111]
- **Kentucky**: Covers donor expenses, including physician services, facility costs, and lodging and transportation incurred in connection to the transplant surgery, as long as Medicaid is payer of last resort before all other possible insurance sources.[112]
- **Michigan**: Allows Medicaid enrollees to be an organ donor for a non-Medicaid enrolled recipient, but the acquisition of the organ must be paid for by the organ recipient's health insurance.[113]
- **Mississippi**: Covers all facility and physician charges related to the procurement of an organ, whether from a living donor or from a cadaver. Examples of other charges allowable in this state include fees related to searching for matching tissue, bone marrow, or organ; the donor's transportation and hospitalization costs; and fees associated with the removal, withdrawal, and preservation/storage of the organ or tissue. The state also covers medically necessary follow-up care

Congressional Budget Office Baseline Projections, *Medicaid*, June 2024, https://www.cbo.gov/system/files/2024-06/51301-2024-06-medicaid.pdf. Centers for Medicare & Medicaid (CMS), Form CMS-64 data as of May 29, 2024, https://www.medicaid.gov/medicaid/financial-management/state-expenditure-reporting-for-medicaid-chip/expenditure-reports-mbescbes/index.html.

[108] The Medicaid state plan is an agreement between the state and the federal government that details how the state will administer its program (e.g., eligibility requirements, benefit coverage, provider reimbursement, delivery systems) and certifies that the state has met program requirements set forth in federal statute and regulations. If a state wants to change how its program operates (e.g., by adjusting eligibility levels or benefit coverage) or if Congress modifies a requirement (e.g., adds a new state plan option), the state must submit a state plan amendment describing the change to CMS for approval.

[109] The state organ donation policies listed here are not comprehensive or complete. They are intended to provide an illustration of the range of policies that states have adopted through CMS-approved written standards. For more complete information on a given state's coverage, see the source materials associated with each state.

[110] For example, see CMS, Letter to State, "District of Columbia State Plan Amendment (SPA) 20-0008," June 2, 2021, available at DC SPA 20-0008 APPROVAL.pdf (medicaid.gov). Also see CMS, Letter to State, "South Dakota's State Plan Amendment (SPA) Transmittal #22-0005," July 12, 2022, https://www.medicaid.gov/medicaid/spa/downloads/SD-22-0005.pdf.

[111] California State Statues of 2022, Chapter 47, §126, https://heinonline.org/HOL/P?h=hein.ssl/ssca0412&i=222.

[112] Kentucky Law, Title 907, Chapter 010, Regulation 830, https://apps.legislature.ky.gov/law/kar/titles/907/010/830/.

[113] Michigan Department of Health and Human Services, Behavioral and Physical Health and Aging Services Administration, "Organ and Tissue Transplant Services," Bulletin Number MMP 22-44, December 1, 2022, p. 7, https://www.michigan.gov/mdhhs/-/media/Project/Websites/mdhhs/Assistance-Programs/Medicaid-BPHASA/2022-Bulletins/Final-Bulletin-MMP-22-44-Hospital.pdf?rev=f09538bf929b44bc873b6177d2bdc81f&hash=6C2BA9EF7AC66E621E5E472A283FD972.

beyond the transplant hospital admission for the living donor, but only in the case that the donor is a Medicaid enrollee.[114]

- **North Dakota**: Covers medically necessary transplants and related services, including "cadaveric or living donor expenses; organ procurement costs, tissue typing, and searches and matches."[115]

Does Medicaid Cover Organ Transplants?

Federal Medicaid funds may be used to pay for "services furnished in connection with organ transplant procedures." States that offer this coverage are required to include written standards defining such coverage in the Medicaid state plan. The Medicaid statute requires that these written standards provide that similar individuals are treated alike and that any restrictions on facilities or practitioners that provide organ transplant procedures are consistent with the accessibility of high-quality care under Medicaid.[116]

The federal Medicaid statute explicitly excludes coverage of organ transplantation services for unauthorized aliens (i.e., noncitizens in Medicaid statute) who are entitled to limited benefit coverage under emergency Medicaid.[117] In general, benefit coverage under emergency Medicaid comprises "medical assistance under Title XIX of the Social Security Act ... for care and emergency services that are necessary for the treatment of an emergency medical condition (as defined in Section 1903(v)(3) of such Act) of the alien involved and are not related to an organ transplant procedure."[118]

States are permitted to tailor their organ transplantation benefit coverage through the written standards included in the Medicaid state plan, as approved by CMS. This flexibility results in variability across state Medicaid programs in terms of state coverage of organ transplantation services. For example, states may limit coverage to specified Medicaid enrolled subgroups (e.g., children under the age of 21, adults with an absence of specified comorbidities), specify the coverage that will be available (e.g., types of organs that can be transplanted, full coverage for some groups and limited coverage for others, limited coverage of experimental or investigative services or multi-organ transplants), specify utilization controls (e.g., prior authorization requirements, requirements that the procedure must be performed at a Medicare-approved transplantation center), among other criteria. The type of coverage available and the level of detail included in the written standards vary across states.

Does Medicaid Cover Posttransplant Care?

States are permitted to tailor their organ transplantation benefit coverage through the written standards included in the Medicaid state plan, as approved by CMS, resulting in variability across state Medicaid programs in terms of state coverage of posttransplant care. Examples of state

[114] Mississippi Division of Medicaid, "Title 23: Medicaid Part 202 Hospital Services," in *Administrative Code*, p. 33, https://medicaid.ms.gov/wp-content/uploads/2021/07/Title-23-Part-202-Hospital-Services-07.01.21.pdf#page=37.

[115] CMS, Letter to State, "RE: North Dakota State Plan Amendment (SPA) 20-0022," August 26, 2020, https://www.medicaid.gov/medicaid/spa/downloads/ND-20-0022.pdf.

[116] Social Security Act (SSA) §1903(i)1 [42 U.S.C. 1396b(i)]; 42 C.F.R. §441.35.

[117] Under emergency Medicaid, states are required to cover limited Medicaid services for the treatment of an emergency medical condition to otherwise eligible aliens (i.e., those who meet Medicaid's other eligibility requirements such as financial, categorical, and state residency requirements), regardless of immigration status or lack of immigration status. See SSA §1903(v)(3) [42 U.S.C. §1396b(v)(3) and 8 U.S.C. §1611(b)(1)(A)].

[118] P.L. 104-193; Personal Responsibility and Work Opportunity Act, §401(a)(1)(A).

coverage for posttransplant care include the following:[119] all postoperative surgical follow-up care services for liver transplants, including treatment for acute rejection; re-harvesting and/or re-transplantation for up to 120 days following the surgical procedure;[120] transplant services (including evaluations and assessments) after a transplant and follow-up services, as well as medically necessary inpatient services following the discharge for the transplant stay to manage complications from the transplant;[121] and follow-up care for the Medicaid enrollee and live donor.[122]

CMS guidance explicitly addresses requirements regarding federal Medicaid payment for follow-up services (e.g., immunosuppressive drugs, medically necessary care that may be required as a result of the transplant) for a Medicaid-enrolled adult who received an organ transplant that was *not* paid for by the Medicaid program.[123] The guidance specifies that states are permitted (but not required) to cover such services, as long as the services are coverable under Medicaid, meet applicable Medicaid coverage requirements (e.g., are sufficient in amount, duration, and scope to reasonably achieve its purpose),[124] and are included in that state's Medicaid state plan.

Does Medicaid Cover Immunosuppressive Drugs Posttransplant?

States are permitted to tailor their organ transplantation benefit coverage through the written standards included in the Medicaid state plan as approved by CMS, resulting in variability across state Medicaid programs in terms of state coverage of posttransplant immunosuppressive drugs. (For more information, see "Does Medicaid Cover Organ Transplants?") With regard to coverage for immunosuppressive drugs administered after the transplant procedure, CRS found evidence that at least some states offer this coverage.[125] As with the other coverage categories discussed above, coverage of immunosuppressive drugs posttransplant varies by criteria including enrollee group or transplantation procedure type within and across states.

[119] The posttransplant care policies listed here are not comprehensive or complete. They are intended to provide a range of the types of policies that states have adopted through CMS-approved written standards. For more complete information on the specific coverage included in these examples, see the source materials.

[120] Medi-Cal, *Provider Manual*, June 2021, https://mcweb.apps.prd.cammis.medi-cal.ca.gov/assets/8B313A4A-3B84-49DB-B98B-6A51BECCF01C/transplant.pdf?access_token=6UyVkRRfByXTZEWIh8j8QaYylPyP5ULO.

[121] MoHealth Net, *State of Missouri Transplant Manual*, p. 28, https://mydss.mo.gov/media/pdf/transplant-provider-manual.

[122] Minnesota, "Transplant Services," in *Provider Manual*, https://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=ID_008926#transplant.

[123] HHS, Region V Health Care Financing Administration, Chicago Regional State Letter #52-93, "Coverage of Follow-Up Services for Organ Transplants Not Provided Under Medicaid—Information," December 1993, https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/1993%2520-%2520organ%2520transplants%2520not%2520provided%2520under%2520medicaid_221.pdf.

[124] For more information on Medicaid benefit coverage requirements, see CRS Report R43357, *Medicaid: An Overview*.

[125] For example, see Nevada, Medicaid Services Manual Transmittal Letter, "Medicaid Services Manual Changes Chapter 3600—Managed Care Organization," January 28, 2022, https://dhcfp.nv.gov/uploadedFiles/dhcfpnvgov/content/Resources/AdminSupport/Manuals/MSM/C3600/MSM_3600_01_29_22_ADA.pdf#page=28. See also Michigan Department of Health and Human Services, Behavioral and Physical Health and Aging Services Administration, "Michigan Medicaid Policy Bulletin Number MMP 22-44," December 1, 2022, https://www.michigan.gov/mdhhs/-/media/Project/Websites/mdhhs/Assistance-Programs/Medicaid-BPHASA/2022-Bulletins/Final-Bulletin-MMP-22-44-Hospital.pdf?rev=f09538bf929b44bc873b6177d2bdc81f&hash=6C2BA9EF7AC66E621E5E472A283FD972.

Medicare

Medicare is a federal program that pays for covered health care services of qualified beneficiaries. It was established in 1965 under Title XVIII of SSA to provide selected health care items and services to individuals aged 65 and older, permanently disabled individuals under the age of 65, and persons with end-stage renal disease (ESRD; permanent kidney failure requiring dialysis or an organ transplant), or amyotrophic lateral sclerosis (also known as Lou Gehrig's disease).[126] In 2023, Medicare covered 66.7 million beneficiaries and spent $1.037 trillion.[127] The program is administered by CMS, within HHS.

Medicare consists of four distinct parts:

- Part A (Hospital Insurance) covers inpatient hospital services, skilled nursing care, hospice care, and some home health services.
- Part B (Supplementary Medical Insurance) covers various items and services including physician services, outpatient hospital services, some home health and preventive services, and certain durable medical equipment for home use.
- Part C (Medicare Advantage, or MA) is a private plan option that covers all Medicare Parts A and B services, except hospice.[128] Private insurers (organizations) may offer one or more MA plans, where a plan is a set of benefits and cost-sharing obligations offered for a specific premium in a specific geographic area. Most MA plans provide care through a contracted network of providers. In 2023, approximately 48% (over 32 million) of beneficiaries received their Medicare services through MA.[129]
- Part D is optional and covers outpatient prescription drug benefits. Part D benefits are offered only through private organizations, which offer prescription drugs only or offer drugs through an MA plan.

Services provided under Parts A and B (also referred to as *original* or *traditional* Medicare) generally are paid directly by the government on a *fee-for-service* basis, using different prospective payment systems or fee schedules.[130] Under Parts C and D, Medicare pays private insurers a monthly *capitated* amount to provide enrollees with required benefits; the insurers then contract with and pay providers to furnish covered health care services and pharmacies to pay for outpatient prescription drugs for enrollees. Payments to contracted providers may vary across providers and may differ from rates paid under traditional Medicare.

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[126] HHS, "Who's Eligible for Medicare?," https://www.hhs.gov/answers/medicare-and-medicaid/who-is-eligible-for-medicare/index.html.

[127] The Board of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, Table II.B1: "Medicare Data for Calendar Year 2023," in *2024 Annual Report*, March 2024, p. 11, https://www.cms.gov/oact/tr/2024. Some Medicare beneficiaries are also eligible for and receive Medicaid coverage—dual-eligible individuals. Medicare is the primary payer for these individuals, and Medicaid coverage for dual-eligible individuals can include Medicare cost sharing and/or coverage of services not covered by Medicare.

[128] Medicare Advantage (MA) enrollees may choose hospice, but the hospice benefit is paid for through Medicare Part A and not through the MA plan's capitated monthly payment.

[129] The Board of Trustees, Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, *2024 Annual Report*, March 2024, p. 7.

[130] A *prospective payment system* 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. A *fee schedule* is a comprehensive list of maximum payment amounts that Medicare uses to reimburse physicians and other entities; fee schedule payment amounts are based on statutory and regulatory requirements.

Does Medicare Cover Organ Donation?

Medicare, traditional and MA, typically does not pay for health care services furnished to non-Medicare beneficiaries. However, traditional Medicare pays transplant hospitals or OPOs for the costs of acquiring organs, such as excising an organ(s) from a non-Medicare beneficiary who is a living or deceased donor when the organ recipient is a Medicare beneficiary. In addition, traditional Medicare pays for organ acquisition costs related to kidney transplants regardless of whether the recipient is enrolled in traditional Medicare or MA.[131]

The aforementioned Medicare payments are made to health care providers—hospitals, physicians, laboratories, and so on—not to organ donors or recipients. For example, Medicare pays for a hospital's or OPO's organ acquisition costs but does not pay the costs incurred by a donor or donor's family.

Does Medicare Cover Organ Transplants?

In general, Medicare covers reasonable and necessary health care services associated with certain organ transplants, including heart, lung, kidney, pancreas, intestine, and liver organ transplants.[132]

Medicare pays transplant hospitals for the implantation surgery and related preoperative services furnished to an organ recipient who is a Medicare beneficiary, similar to the way Medicare pays for other inpatient hospital services.[133] Specifically, traditional Medicare pays the transplant hospital the Medicare inpatient prospective payment system (IPPS) rate for the inpatient stay and related preoperative outpatient services.[134] Except in limited circumstances, each MA organization pays its network hospitals the rate that was negotiated between each organization and each hospital.[135] Under MA, in-network and out-of-network rules regarding coverage, cost sharing, and payment rates to hospitals may apply.[136]

In addition to the IPPS or MA plan payment for the inpatient hospital services, Medicare pays for other health care services associated with an organ transplant. For example, traditional Medicare pays for physician (e.g., anesthesiologist, surgeon) and laboratory tests separately under two Medicare payment systems—the physician fee schedule and the clinical lab fee schedule, respectively. MA plans pay the negotiated rates to network providers.

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[131] The costs of organ acquisition for kidney transplants, including the Medicare-covered costs related to the care of a living kidney donor, are covered by original Medicare, even for beneficiaries enrolled in MA. SSA §1852(a)(1)(B)(i).

[132] Medicare.gov, "Organ Transplants," https://www.medicare.gov/coverage/organ-transplants. See also CMS, , Internet-Only Manuals, *Medicare National Coverage Determinations (NCD) Manual*, publication no. 100-03, https://www.cms.gov/regulations-and-guidance/guidance/manuals/internet-only-manuals-ioms-items/cms014961. MA plans are required to cover all Medicare required services, except hospice and the organ acquisition costs for kidney transplants, consistent with Medicare statutory and regulatory requirements, as well as national and local coverage determinations.

[133] For more detail about traditional Medicare and MA, see CRS Report R40425, *Medicare Primer*.

[134] For further information about the Medicare inpatient prospective payment system, see Medicare Payment Advisory Commission (MedPAC), "Hospital Acute Inpatient Services Payment System," https://www.medpac.gov/document-type/payment-basic/.

[135] In general, MA organizations are required to provide all items and services for which benefits are available under Parts A and B to beneficiaries who are eligible for Part A and enrolled in Part B. SSA §1852(a)(1)(B).

[136] An MA organization and a hospital or hospital system decide whether the hospital is in-network or out-of-network, which may determine the payment rates/amounts an MA organization pays a hospital for inpatient and outpatient services.

All services furnished to the Medicare beneficiary organ recipient are subject to applicable Medicare cost sharing—deductible, co-payment, or coinsurance.[137] Beneficiaries enrolled in MA may be subject to different cost sharing based on the MA plan's requirements.

Does Medicare Cover Posttransplant Care?

Medicare pays for postoperative surgical care for 60 days for organ transplant recipients.[138] Postoperative services furnished to a Medicare beneficiary recipient are subject to Medicare deductible and coinsurance requirements.

For living donors, Medicare pays for postoperative services directly related to the organ donation. Medicare also covers routine follow-up care for organ donors until the donor "no longer exhibits symptoms related to the organ donation." However, Medicare may review claims for services rendered more than three months after the organ donation surgery; follow-up examinations may continue to be covered up to six months after the donation surgery to monitor for complications. Donors do not pay Medicare coinsurance or deductible for the aforementioned services.[139]

Does Medicare Cover Immunosuppressive Drugs Posttransplant?

Medicare coverage for immunosuppressive drugs depends on the type of organ transplant and how the recipient initially qualified for Medicare. This is specifically relevant for kidney recipients who are under the age of 65 and become eligible for Medicare because they have ESRD.[140]

ESRD Medicare beneficiaries who receive a successful kidney transplant no longer have ESRD, and thus their Medicare coverage ends after the 36th month post-hospital discharge.[141] However, beginning January 1, 2023, these individuals may enroll in a new Medicare Part B benefit that covers immunosuppressive drugs (PBID), as long as they do not have other health insurance coverage such as group health plans, Medicaid, or VA coverage.[142] The PBID benefit covers only immunosuppressive drugs and only when an ESRD Medicare beneficiary loses Medicare coverage due to no longer having ESRD and does not otherwise qualify for Medicare. Individuals enrolled in the PBID benefit pay a monthly premium, and the covered drugs are subject to an annual deductible and 20% coinsurance.[143]

Medicare Part B covers immunosuppressive drugs for non-kidney organ transplant recipients as long as the recipient was entitled to Medicare Part A and is enrolled in Part B and the organ

[137] For further information about Medicare coverage of, payment for, services and applicable beneficiary cost sharing, see CRS Report R40425, *Medicare Primer*.

[138] CMS, Part I, Chapter 31, §3103 in *Medicare Provider Reimbursement Manual*.

[139] Ibid, §3105.

[140] End-stage renal disease is one of the Medicare eligibility categories,[140] as well as persons aged 65 and older, permanently disabled individuals under the age of 65, and individuals who have amyotrophic lateral sclerosis (also known as Lou Gehrig's disease).

[141] Medicare General Information, Chapter 2, §10.4.4, in *Eligibility and Entitlement Manual*.

[142] Consolidated Appropriations Act, 2021 (P.L. 116-260), §402. See also Medicare General Information, Chapter 2, §40.9.3, in *Eligibility and Entitlement Manual*; and Chapter 15, §50.5.1, in *Medicare Benefit Policy Manual*.

[143] GAO, *Kidney Transplants: Medicare Coverage of Immunosuppressive Drugs*, GAO-24-107230, August 8, 2024, p. 4.

transplant was covered by Medicare (i.e., not by another health insurance plan or program).[144] This coverage is subject to the Part B deductible and coinsurance.[145]

Private Health Insurance

Private health insurance is the predominant source of health insurance coverage in the United States.[146] Nearly 190 million individuals in the United States had private health insurance as of the first quarter of 2022.

Covered benefits (e.g., office visits, surgical procedures, prescription drugs) may differ by plan, subject to applicable federal and state requirements. Common variations include what cost-sharing requirements apply to a given benefit and whether a benefit is covered both *in network* and *out of network.* In addition, a plan's coverage of a benefit generally depends on the benefit being deemed *medically necessary* for an enrollee.

Private health insurance plans are subject to federal and/or state requirements, including certain benefit coverage requirements. Federal requirements on private health coverage may apply to *large-group*, *small-group*, *self-insured group*, and/or *nongroup* plans.[147] Requirements for nongroup and small-group plans apply to plans sold on and off the health insurance exchanges.[148] State-level private health insurance requirements also may apply to large-group, small-group, and nongroup plans but generally do not apply to self-insured group plans.[149] Federal and state private health insurance requirements may vary by type of plan. For example, as discussed below, the federal requirement on coverage of *essential health benefits* is applicable only to small-group and nongroup plans.

Plans may voluntarily cover benefits, including providing coverage that exceeds any applicable federal or state requirements or providing coverage where there is no requirement to do so, as long as there is no applicable prohibition on such coverage.[150]

[144] 42 U.S.C. §1395x(s)(2)(J).

[145] CMS, Chapter 17, §80.3, in *Medicare Claims Processing Manual.*

[146] See CRS Report R47507, *Private Health Insurance: A Primer*, for more information on private health insurance, including data on private health insurance enrollment. As further explained (and broken down) in that primer, the enrollment estimate cited above in this report includes large-group, small-group, and self-insured group plans offered by private sector employers, as well as nongroup plans. The primer also explains plan features such as covered benefits (including medical necessity and other considerations, such as medical management requirements), cost sharing, and provider networks.

[147] Broadly, private health insurance includes group plans (largely made up of employer-sponsored insurance) and nongroup plans (i.e., plans a consumer purchases directly from an insurer). See CRS Report R45146, *Federal Requirements on Private Health Insurance Plans*, for more information on large-group, small-group, self-insured group, and nongroup plans; background on federal and state regulation of private health insurance; and summaries of current federal requirements on different types of plans.

[148] The individual exchanges and small business health options program (SHOP) exchanges are virtual marketplaces in which consumers and small businesses, respectively, can shop for and purchase private health insurance coverage. Plans sold in the individual and SHOP exchanges have to meet all the requirements applicable to the nongroup and small-group markets, respectively. Additional requirements apply only to exchange plans. For more information, see CRS Report R44065, *Overview of Health Insurance Exchanges*.

[149] State-level private health insurance requirements are beyond the scope of this report.

[150] This report section focuses on federal requirements relevant to private health insurance coverage of organ transplants. CRS is not aware of data on frequency or scope of such private health insurance coverage (including where it may otherwise be required by states or where plans may voluntarily provide it).

Does Federal Law Require Private Health Insurance to Cover Organ Donation?

There is no federal law that specifically requires private health insurance coverage of benefits related to organ donation—for organ donors or recipients.

However, certain federal private health insurance requirements are, or may be, relevant to such coverage, depending on state implementation, plan variation, and/or individual circumstances. This primarily includes the requirement that certain plans cover a set of *essential health benefits* (EHB), as discussed in the next section regarding organ transplants for recipients.

To the extent that a plan covers benefits for an *enrollee's receipt* of an organ donation, the plan also may cover the costs of the enrollee's organ *donor*. This would likely depend on the terms and conditions of the enrollee's (organ recipient's) plan, any applicable requirements on that plan (EHB or state requirements), and whether the organ donor has another source of coverage.

If a private health insurance enrollee decides to *donate* an organ to someone, similar considerations may determine whether the enrollee's plan will cover the costs of his or her donation. In general, private health insurance plans cover benefits that are medically necessary for their enrollees' health, so this may be another consideration regarding coverage of the donor's costs, especially if the recipient is not also an enrollee of that plan. See, for example, the coverage exclusion discussed in the next section.

Does Federal Law Require Private Health Insurance to Cover Organ Transplants?

There is no federal law that specifically requires private health insurance coverage of benefits related to organ donation. However, certain federal private health insurance requirements (particularly as related to coverage of the EHB) are, or may be, relevant to coverage of an enrollee's *receipt* of an organ transplant, depending on state implementation, plan variation, and/or individual circumstances.

Coverage of the Essential Health Benefits

Small-group and nongroup plans are required cover a core package of 10 categories of essential health benefits.[151] The categories of EHB are ambulatory patient services; emergency services; hospitalization; maternity and newborn care; mental health and substance use disorder services, including behavioral health treatment; prescription drugs; rehabilitative and habilitative services and devices; laboratory services; preventive and wellness services and chronic disease management; and pediatric services, including oral and vision care.

The benefits to be covered within each EHB category generally are not defined in federal law; rather, the law requires the HHS Secretary to further define the EHB to include items and services in at least those 10 categories and to be "equal in scope to the benefits provided under a typical employer plan." To date, the HHS Secretary has directed each state to select an EHB *benchmark plan*, within certain parameters, to serve as the basis for the state's EHB.[152] Applicable plans in each state must provide EHB coverage that is "substantially equal" to such coverage in their state's benchmark plan, as specified in regulations.[153] For example, if a state selects a benchmark

[151] 42 U.S.C. §300gg-6; 42 U.S.C. §18022.

[152] For more information on the process for defining the essential health benefits (EHB) in each state, see CMS, Center for Consumer Information and Insurance Oversight (CCIIO), "Information on Essential Health Benefits (EHB) Benchmark Plans," https://www.cms.gov/cciio/resources/data-resources/ehb.

[153] 45 C.F.R. §156.115(a)(1).

plan that includes organ transplant benefits in one or more EHB categories, the applicable plans in that state would have to provide substantially equal coverage, including in terms of any coverage limitations.

Because states select their own EHB benchmark plans, EHB coverage requirements may vary considerably from state to state. Per CRS review of publicly available EHB summary documents, "transplant" is listed as a covered essential health benefit in all 51 EHB benchmark plans.[154] Some of the benchmark plan summaries provide additional detail about transplant coverage and/or exclusions.

For example, Arizona's EHB benchmark plan summary includes explanations on its transplant coverage such as, "organ transplant services include the recipient's medical, surgical and hospital services; inpatient immunosuppressive medications; and costs for organ procurement." It also details certain exclusions such as, "these benefits are available when the Member is the recipient of an organ transplant. No coverage if Member is an organ donor for a recipient other than a Member enrolled under this plan."[155]

Iowa's EHB benchmark plan summary indicates that transplant coverage exclusions do apply and that transplant coverage is subject to case management but does not provide further detail. Some of the EHB benchmark plan summaries do not detail any transplant coverage or exclusions (e.g., Florida, Massachusetts, Washington).[156] In all cases, the full EHB benchmark plan documents may provide more detail than the summary documents discussed here.

In short, as currently implemented, the requirement to cover the EHB *effectively* includes transplant coverage in all states and the District of Columbia, although the details of this coverage requirement vary across the states. Plans required to cover the EHB—those in the small-group and nongroup markets—must provide transplant coverage according to their state's EHB benchmark plan.

Cost sharing (including deductibles, coinsurance, and co-payments) is possible for most categories of EHB, although certain federal requirements limit enrollees' total cost sharing on the EHB.[157] For example, plans must have annual limits on enrollee out-of-pocket costs that are no higher than federally set amounts ($9,450 for self-only coverage and $18,900 for coverage other

[154] See current benchmark plan documents for each state and the District of Columbia at CMS, CCIIO, "Information on Essential Health Benefits (EHB) Benchmark Plans," https://www.cms.gov/marketplace/resources/data/essential-health-benefits#ehb. For each state and DC, see the "EHB Benchmark Plan Information" ZIP file, which generally includes the full benchmark plan and a benchmark plan summary document and also may include other documents. For the analysis and examples in this report, CRS extracted and reviewed the benchmark plan summaries, which list certain benefits (i.e., "transplant") and indicate whether they are covered as EHB, otherwise covered, or not covered. As indicated in the discussion above, additional coverage details may or may not be provided for the listed benefits.

[155] Ibid. See Arizona's 2017-2025 EHB Benchmark Plan Information ZIP file, which includes its summary document, "AZ-BMP-Summary-PY2025-2027.pdf," https://www.cms.gov/marketplace/resources/data/essential-health-benefits#Arizona.

[156] Ibid. See the EHB Benchmark Plan Information ZIP files for Iowa, Florida, Massachusetts, and Washington at https://www.cms.gov/marketplace/resources/data/essential-health-benefits#ehb. For these and most other states, the current EHB benchmark plans are dated 2017-2025. Prior-year files are listed separately. For states that have made changes to their EHB benchmark plans in certain years, current and prior files are dated accordingly. See the top of the webpage cited here for further discussion.

[157] See the "Enrollee Cost Sharing and Plan Payment for Benefits" section in CRS Report R45146, *Federal Requirements on Private Health Insurance Plans*.

than self-only, in plan year 2024).[158] This generally applies to most private health insurance plans and only to in-network coverage of the EHB.[159]

Other Potentially Relevant Federal Requirements

Other federal requirements on private health insurance also could be relevant for enrollees seeking coverage of organ transplants. This may depend on the circumstances and/or other factors.

For example, most plans are prohibited from excluding coverage based on an enrollee's preexisting health conditions. This does not mandate a plan to cover particular benefits (such as organ transplants), but with respect to the benefits a plan does cover, a plan may not deny coverage of those benefits based on an enrollee's health condition. In other words, if a plan covers organ transplant benefits, the plan cannot exclude that coverage for an enrollee because the enrollee had a related health condition before enrolling in the plan.[160] Large-group, small-group, self-insured, and nongroup plans are subject to this requirement.

Does Federal Law Require Private Health Insurance to Cover Posttransplant Care?

There is no federal law that specifically requires private health insurance coverage of benefits related to organ donation, but the EHB and other requirements may be applicable. This includes benefits related to posttransplant care.

For example, to the extent that benefits for posttransplant care are included as EHB in a state's EHB benchmark plan, applicable plans in the state would be required to provide substantially equal coverage. See next question regarding coverage of immunosuppressant drugs in particular.

Does Federal Law Require Private Health Insurance to Cover Immunosuppressive Drugs Posttransplant?

There is no federal law that specifically requires private health insurance coverage of immunosuppressive drugs posttransplant. However, the EHB requirement described above is effectively applicable.[161] Although states, rather than the federal government, generally specify the benefits to be covered as EHB, federal regulations have provided specific requirements regarding some EHB categories—including the prescription drugs category.[162]

Current regulation provides that an applicable health plan meets the EHB requirements for the prescription drugs category of EHB if it covers at least one drug in every U.S. Pharmacopeia (USP) category and class, or the same number of prescription drugs in each category and class as the state-selected EHB benchmark plan. Under the USP, *immune suppressants* are a class within the category of *immunological agents,* which effectively means that all plans subject to EHB requirements must cover at least one immunosuppressant drug.

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[158] Ibid.

[159] Ibid. Although large-group and self-insured plans are not required to cover the EHB, they are subject to certain cost-sharing and plan-payment requirements that are related to the EHB.

[160] For more information on this requirement and others related to private health insurance premiums, benefits, cost sharing, provider networks, and other topics, see CRS Report R45146, *Federal Requirements on Private Health Insurance Plans*.

[161] See "Coverage of the Essential Health Benefits" in this report.

[162] See, for example, 45 C.F.R. §156.115 and 45 C.F.R. §156.122.

Federal rulemaking finalized in April 2024 also codified the existing agency stance that "to the extent that a health plan covers prescription drugs in excess of the benchmark, these drugs will be considered EHB and are subject to requirements including the annual limitation on cost sharing and the restriction on annual and lifetime dollar limits."[163] In general, this means that if a plan covers immunosuppressant drugs beyond what is required as EHB, these drugs also are subject to certain cost-sharing protections applicable to the EHB, such as an annual out-of-pocket maximum.[164]

[163] Departments of the Treasury and HHS, "Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2025; Updating Section 1332 Waiver Public Notice Procedures; Medicaid; Consumer Operated and Oriented Plan (CO-OP) Program; and Basic Health Program," Final Rule, April 15, 2024, 89 *Federal Register* 26218. See this preamble discussion for additional information, including on the interaction of state benefit mandates: https://www.federalregister.gov/d/2024-07274/p-1998.

[164] See "Coverage of the Essential Health Benefits" in this report. Though large-group and self-insured group plans are not subject to EHB coverage requirements, they generally are subject to the cost-sharing requirements that are based on the EHB. However, in guidance released concurrent to the above-mentioned rulemaking, the agencies indicated that future rulemaking will "address the applicability of this policy to those plans." See Departments of Labor, HHS, and the Treasury, "FAQ About Affordable Care Act Implementation Part 66," April 2, 2024, https://www.dol.gov/agencies/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-66.

Appendix. Policy Experts and Acronyms

Table A-1. Congressional Research Service Policy Experts

Issue Area	CRS Contact
Organ Transplantation (General); Organ Procurement and Transplantation Network	Jared Sussman
Organ Transplantation, Legal Issues	Wen Shen
Medicare Oversight of Organ Procurement Organization (OPO) and Transplant Hospitals/Programs	Marco Villagrana
Bureau of Prisons	Nathan James
Department of Defense	Bryce Mendez
Immigration and Customs Enforcement	Abigail Kolker
Indian Health Service	Elayne Heisler
Department of Veterans Affairs	Jared Sussman
Medicaid	Evelyne Baumrucker
Medicare Part A Coverage of and Payments to Hospitals and OPOs for Organ Implantation Surgeries and the Costs of Organ Acquisition	Marco Villagrana
Medicare Part B Coverage of Immunosuppressive Drugs	Cliff Binder
Medicare Advantage	Paulette Morgan
Private Health Insurance	Vanessa Forsberg

Table A-2. Acronyms Used in This Report

Acronym	Definition
BOP	Bureau of Prisons
CCIIO	Center for Consumer Information and Insurance Oversight
CD	Clinical Director
CHAMPVA	Civilian Health and Medical Program of the Department of Veterans Affairs
CMS	Centers for Medicare & Medicaid Services
DHS	Department of Homeland Security
DOD	Department of Defense
EHB	Essential Health Benefits
ESRD	End-Stage Renal Disease
FDA	Food and Drug Administration
FMC	Federal Medical Center
GAO	Government Accountability Office

Acronym	Definition
HHS	Health and Human Services
ICE	Immigration and Customs Enforcement
IHS	Indian Health Service
IPPS	Inpatient Prospective Payment System
MA	Medicare Advantage
MHS	Military Health System
MTF	Military Treatment Facility
NDS	National Detention Standards
NOTA	National Organ Transplant Act
OIG	Office of Inspector General
OPO	Organ Procurement Organization
OPTN	Organ Procurement and Transplantation Network
PBNDS	Performance-Based National Detention Standards
PRC	Purchased/Referred Care Program
SHOP	Small business health options program
SSA	Social Security Act
UAGA	Uniform Anatomical Gift Act
UNOS	United Network for Organ Sharing
VA	Department of Veterans Affairs
VCCP	Veterans Community Care Program
VHA	Veterans Health Administration

Source: Compiled by the Congressional Research Service.

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