REPORT TO THE SECRETARY OF TRANSPORTATION

Organ Transport Working Group Final Report

May 12, 2025

FAA Reauthorization Act of 2024 (Public Law 118-63) – Transportation of Organs (Section 1102)

EXECUTIVE SUMMARY

The Federal Aviation Administration (FAA) submits this Organ Transport Working Group Final Report to the Secretary of Transportation, on behalf of the members, in accordance with Section 1102 of the FAA Reauthorization Act of 2024. This report identifies best practices for transporting organs and biological material above wing (in the passenger cabin) on airplanes operating under part 121 of title 14, Code of Federal Regulations ("commercial airlines").

Section 1102 required the FAA to establish the Organ Transport Working Group (OT WG) to develop best practices and identify regulations that hinder the transportation of organs on commercial airlines. The FAA led the working group with support from the Department of Transportation (DOT); Department of Homeland Security (DHS), Transportation Security Administration (TSA); and Department of Health and Human Services (HHS), Health Resources & Services Administration (HRSA) (collectively referred to as the "interagency partners").

The membership was comprised of individuals representing the following transplant community and aviation industry stakeholder groups:

- Commercial Airlines
- Organ Procurement Organizations
- Organ Transplant Hospitals
- Unions representing flight attendants, pilots, dispatchers, and passenger service agents
- Couriers
- Patient Representatives

This report contains the history, methodology, and final recommendations of the OT WG.

The interagency partners concluded there are no statutory or regulatory barriers preventing the transportation of organs and biological material in the passenger cabin on commercial airlines. However, the current regulatory framework does not require airlines to allow above wing transport. Therefore, the decision to permit the transportation of organs and biological material in the passenger cabin and/or cargo compartment, along with any related policies or procedures, is left to the discretion of each individual airline.

The OT WG developed twenty (20) recommendations to improve the process of above wing transport of organs and biological material on commercial airlines. The recommendations are grouped into five categories corresponding to the overarching themes discussed by the members:

- Access
- Education
- Logistics
- Communication
- Reporting

This report also includes an addendum addressing recommendations to improve below wing organ transport (in the cargo compartment) on commercial airlines. While these recommendations fall outside the congressional mandate, the members concluded it was important to address specific concerns related to this process.

The OT WG final recommendations are advisory in nature and based on the participating transplant community and aviation industry stakeholder perspectives.

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INTRODUCTION

This report is submitted by the Organ Transport Working Group (OT WG) to the Secretary of Transportation pursuant to Section 1102 of the Federal Aviation Administration (FAA) Reauthorization Act of 2024 (Public Law 118-63). Section 1102 (Transportation of Organs) requires:

> *(a) In General.—Not later than 90 days after the date of enactment of this Act, the Secretary, in consultation with the Administrator, shall convene a working group (in this section referred to as the "working group") to assist in developing best practices for transportation of an organ in the cabin of an aircraft operating under part 121 of title 14, Code of Federal Regulations, and to identify regulations that hinder such transportation, if applicable.*
>
> *(b) Composition.—The working group shall be comprised of representatives from the following:*
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> > *(1) Air carriers operating under part 121 of title 14, Code of Federal Regulations.*
> >
> > *(2) Organ procurement organizations.*
> >
> > *(3) Organ transplant hospitals.*
> >
> > *(4) Flight attendants.*
> >
> > *(5) Other relevant Federal agencies involved in organ transportation or air travel.*
>
> *(c) Considerations.—In establishing the best practices described in subsection (a), the working group shall consider—*
>
> > *(1) a safe, standardized process for acceptance, handling, management, and transportation of an organ in the cabin of such aircraft; and*
> >
> > *(2) protocols to ensure the safe and timely transport of an organ in the cabin of such aircraft, including through connecting flights.*
>
> *(d) Recommendations.—Not later than 1 year after the convening of the working group, such working group shall submit to the Secretary a report containing recommendations for the best practices described in subsection (a).*
>
> *(e) Definition of Organ.—In this section, the term "organ"—*
>
> > *(1) has the meaning given such term in section 121.2 of title 42, Code of Federal Regulations; and*
> >
> > *(2) includes—*
> >
> > > *(A) organ-related tissue;*
> > >
> > > *(B) bone marrow; and*
> > >
> > > *(C) human cells, tissues, or cellular or tissue-based products (as such term is defined in section 1271.3(d) of title 21, Code of Federal Regulations).*

The content of this report fulfills the requirements of Section 1102.

BACKGROUND

Organs and biological material (e.g., bone marrow and peripheral blood stem cells) are transported via commercial airline virtually every day. Approximately 20% of the 21,042 kidneys procured and transplanted in 2023 were transported on commercial airlines, accounting for approximately 4,208 kidneys annually (or 11.5 per day).[1] Recent changes in organ allocation and distribution policies result in broader geographic sharing of donor organs, which means a higher percentage of organs will be transported over longer distances. There are two primary methods used to transport organs on commercial airlines.

1. **Below wing.** Currently, this is the most common method of transportation. Transporting below wing on an airline refers to the practice of placing the package/cargo (in this case, the container or vessel including an organ) in the cargo compartment of the airplane, rather than in the passenger cabin. The organ is typically in a secure, temperature-controlled container.
2. **Accompanied organ above wing transport.** This method utilizes a courier to accompany the organ above wing (in the passenger cabin), providing enhanced security and tracking.

The transplant community also expressed interest in the possibility of unaccompanied organ above wing transport. This method is like accompanied above wing transport, but the courier hands off the container or vessel to the airline for unaccompanied transport in the passenger cabin. This method is not currently in use due to logistical challenges and the difficulty of mitigating the associated risks. Such risks and challenges appear to unreasonably jeopardize the safety and security of unaccompanied organ transport. Some examples of the concerns raised by aviation industry stakeholders include:

- Commercial airlines are not resourced to safely and securely transport organs unaccompanied above the wing.
- Relevant staff (including pilots, flight attendants, and passenger service agents) are already task saturated with a multitude of required safety and security functions. Responsibility for organs could distract from existing mission-critical safety of flight responsibilities. Existing responsibilities also distract from their ability to secure organs for transport.
- In carrying out their core functions, relevant staff may be unable to maintain physical control or continuous monitoring of the unaccompanied organ, creating a substantial risk that an organ could be disturbed or tampered with.

To effectively mitigate these risks, organs are currently transported above wing accompanied by a dedicated courier. The organ courier has appropriate training and experience, and the courier can maintain physical custody of the organ to ensure its security, safety, and successful transport.

Under the regulatory frameworks of the FAA, Transportation Security Administration (TSA), and Health Resources & Services Administration (HRSA), the transportation of organs through security checkpoints and on airplanes is permitted. Furthermore, there are no specific restrictions (outside of standard size, weight, and securement) regarding the placement of an organ within the airplane.

[1] Projections based on a related 2018 study: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC9800715/.

Interagency Collaboration

In accordance with the Consolidated Appropriations Act of 2024 (Public Law 118 – 42), the FAA hosted meetings, with support from TSA and HRSA, to facilitate discussions across the transplant community and aviation industry stakeholder groups to better understand the challenges faced by Organ Procurement Organizations (OPO) and couriers during the transportation process.

> *The Committee notes impediments to secure and timely commercial aviation transport of lifesaving human organs for transplantation. Not later than 60 days after enactment of this Act, the Committee directs the FAA to convene a meeting of representatives of the Transportation Security Administration, domestic air carriers, members of Organ Procurement and Transplantation Network (OPTN) including Organ Procurement Organizations to discuss improving the transportation of organs for transplant on domestic commercial flights to reduce the transfer time of an organ between donor hospital and transplant center. Within 120 days of the meeting, the FAA is directed to issue a report with recommended actions to address the following identified challenges: the need for standardized processes and practices for commercial airline acceptance, handling and management of organs in transit above wing; development of a common definition of covered materials that includes organs and containers associated with their transfer; development of communication and tracking protocols to enhance the transparency of where an organ is on its travel plan and the responsible party to contact should the organ need to be rerouted; standard policies and protocols to permit Organ Procurement Organization staff to enter secure areas for the purpose of retrieving an organ in the event of a flight delay; consideration of protocols for air control outages that impact timeliness of flights transporting organs for transplant; consistent airline requirements allowing human person accompaniment of organs to and from the aircraft and between connecting flights; uniform use of flight notes to indicate organs on board to enable air traffic control to ensure priority takeoff and landing; and the creation of metrics regarding airline handling of organs and organ-related tissue to increase transparency and aid the development of best practices and improvement initiatives.*
>
> *– Consolidated Appropriations Act of 2024 (Report Language)*

The FAA, with TSA and HRSA support, began with community of interest discussions with OPOs, airline associations and airport associations, couriers, and unions (representing flight attendants, pilots, dispatchers, and passenger service agents). The FAA concluded this effort during a joint stakeholder discussion with over 150 participants across all communities of interest.

Stakeholders highlighted the need for consistent processes, education, and training to improve the organ transport process. They identified that ongoing communication among OPOs, couriers, airlines, and TSA would be essential to resolving the issues raised during the discussions. The primary concern cited by the transplant community centered on the need to standardize and enhance existing processes, given the variability in how screening personnel or crewmembers may respond due to their limited exposure to couriers. While programs and solutions do exist, stakeholders in the transplant community highlighted the importance of improving consistency to ensure more predictable and seamless interactions. The discussions

did not focus on unaccompanied above wing transport, but rather on improving the accompanied transport process. Couriers expressed concerns with the chain of custody, liability, and flight interruptions. Aviation industry stakeholders shared those concerns. Coming out of the initial effort, the interagency partners identified the need for education and better communication across the communities of interest.

The FAA, with TSA and HRSA support, briefed Congress on the feedback from these discussions. The individual community of interest and joint stakeholder discussions served as a framework for the organ transport working group scope of work.

Statutory Authority

The interagency partners concluded there are no statutory or regulatory barriers preventing the transportation of organs and biological material in the passenger cabin on commercial airlines. However, the current regulatory framework does not require airlines to allow such above wing transport. Therefore, the decision to permit the transportation of organs and biological material in the passenger cabin and/or cargo compartment, along with any related policies or procedures, is left to the discretion of each individual airline.

Federal Aviation Administration

The FAA derives its statutory authority primarily from the Federal Aviation Act of 1958 49 U.S.C. § 40101 et seq.) and subsequent amendments, including the FAA Reauthorization Act of 2024 (Public Law 118-63). These laws provide the FAA with broad authority to regulate safe flight of civil aircraft and establish policies for the use of the navigable airspace, ensuring the safety of aircraft and the efficient use of airspace.

Department of Transportation

The DOT derives its statutory authority from the Department of Transportation Act of 1966 (49 U.S.C. § 101 et seq.) and other related legislation. This includes broad authority to oversee and regulate all aspects of transportation in the United States, including roadways, airways, railways, and waterways, and to ensure the safe and efficient movement of people and goods.

Transportation Security Administration

TSA derives its statutory authority primarily from the Aviation and Transportation Security Act (ATSA) (49 U.S.C. § 114 et seq.), which was enacted following the September 11 attacks. The TSA Administrator has broad statutory authority to carry out security-related responsibilities for all modes of transportation.[2] The Administrator may prescribe or rescind regulations and issue orders.[3] ATSA grants TSA the responsibility to secure the nation's transportation systems, including aviation, rail, transit, and pipelines, as well as to develop and implement policies and procedures to safeguard passengers, crewmembers, and critical infrastructure.

[2] *See* 49 U.S.C. § 114(d).
[3] *See* 49 U.S.C. §§ 114(l)(1), 40113(a), and 44903(b).

Health Resources & Services Administration

HRSA derives its overall statutory authority primarily from the Public Health Service Act (42 U.S.C. § 201 et seq.), as well as the Health Centers Consolidation Act of 1996 (Public Law 104-299). HRSA is responsible for improving access to health care services for underserved populations, overseeing the national organ and blood stem cell transplant systems, and promoting health workforce development, among other duties aimed at enhancing public health and well-being. Specific to organ transplantation, including organ transportation, the National Organ Transplant Act (NOTA) of 1988 grants the Secretary of the Department of Health and Human Services (HHS) with delegated authority to HRSA, to provide for the operation of the Organ Procurement and Transplantation Network (OPTN). NOTA includes broad authority for HRSA to provide oversight of the OPTN and administer and oversee contracts necessary for the function of the national system for organ donation, procurement, and transplantation, ensuring that donated organs are allocated fairly and efficiently across the United States.

Stakeholder Perspectives

Transplant community and aviation industry stakeholder groups are most interested in standardization and consistency in the organ transport process:

- Accompanied organ above wing transport: Under this scenario, the courier accompanies the organ or biological material when transported above wing. The courier often purchases a second seat for the organ. This method provides enhanced security and tracking; however, transplant community stakeholders noted flight availability can be a challenge.
- Unaccompanied organ above wing transport: Under this scenario, the courier hands off the organ to a crewmember for placement in the passenger cabin. There are currently no FAA, TSA, or HRSA regulatory barriers to accompanied or unaccompanied above wing transport of organs and biological material. However, transplant community stakeholders do not currently transport organs and biological material unaccompanied due to chain of custody concerns and airline policies. All stakeholders noted that unaccompanied transport requires close coordination between OPOs, couriers, TSA, and airlines. This method introduces additional complexity and resource concerns en route (e.g., organ handoff, connecting flights, delays).

Commercial Airlines

In accordance with Section 1102 of the FAA Reauthorization Act of 2024, the FAA invited airlines operating under part 121 of title 14, Code of Federal Regulations and their associations to serve on the working group. The FAA included air carrier associations and individual airlines to ensure that broader industry perspectives were considered, including major airlines, regional airlines, low-cost carriers, and ultra low-cost carriers.

It is important to note that regional airlines primarily partner with major airlines under codeshare services. In a codeshare arrangement, a regional airline partners with a major airline to operate flights under the major airline's branding. Regional airlines are responsible for the operation of flights (e.g., logistics, airplanes, crewmembers, and operation of the flight). Due to their position connecting smaller airports to larger hubs, regional airlines are essential for maintaining connectivity within the organ transplantation system. Regional airlines often operate with a more streamlined workforce, meaning they typically do not have dedicated ticket agents, passenger service agents, or a large customer service team at smaller airports. Instead, these above wing functions are often performed by their mainline partners. This means that communication and coordination between a major airline and a regional partner will be critical when an organ is on board to ensure awareness by the regional airline dispatcher and crewmembers.

For example, if a major airline is flying a passenger connecting to a regional flight, and there is an organ on board that requires special handling or attention, the regional airline's dispatch center needs to be aware. This awareness is best accomplished by earlier check-in with the major airline to allow for that coordination. OPOs and couriers need to notify the major airline as soon as possible, and as early as possible, to allow time for the coordination and notification process.

The OT WG worked with passenger airlines directly, and through their industry associations, to determine which airlines permit organ transport. The OT WG inquired about documented policies and procedures, as well as training and education. The responses to the questionnaire suggest several areas where the organ transport process can be enhanced:

- Eight (8) airlines allow organ transport without restrictions:
  - Seven (7) airlines allow both above and below wing transport.
  - One (1) airline allows below wing transport only.
- Almost all major airlines and low-cost carriers permit organ transport, while most ultra low-cost carriers do not permit organ transport.[4]
- A few airlines that permit transport have a designated point of contact for OPOs couriers. A small number of airlines also publish specialized handling instructions for organ transport.
- Airlines that permit transport have policies and procedures for organ below wing transport. Most of these airlines also have some policies and procedures for above wing transport. Such policies address handling instructions during flight delays/disruptions, purchase of multiple seats, and use of the MEDEVAC call sign when pilots are made aware that an organ is on board.
- Approximately half of the airlines that permit organ transport include training for their personnel, including flight attendants, pilots, dispatchers, and passenger services agents.
- Airlines do not currently coordinate with TSA regarding the transport of organs.

[4] The OT WG recognizes that regional airlines involved in codeshare agreements with major airlines that facilitate organ transport also permit organ transport.

Organ Procurement Organizations

In accordance with Section 1102 of the FAA Reauthorization Act of 2024, the FAA invited OPOs to serve on the working group. OPOs are federally designated and certified entities responsible for coordinating the organ procurement process within their designated geographic regions, from hospital notification of a potential organ donor to surgical organ recovery to allocation and delivery of donated organs. OPOs contract organ couriers to transport organs to and from transplant hospitals or research institutions.

OPOs are regulated by the Centers for Medicare and Medicaid Services (CMS). OPOs are required to be OPTN members. The OPTN is a public-private partnership overseen by HRSA that links all professionals involved in the U.S. donation, procurement, and transplantation system, aiming to fairly distribute organs donated to people awaiting transplants. OPOs, as OPTN members, are subject to federal regulations (the OPTN Final Rule), and OPTN bylaws and policies, which define transparency, fairness, and compliance in organ donation, procurement, and transplantation processes.

Anecdotally, OPOs in high population areas may transport organs a lower percentage of the time by commercial air, while OPOs in more geographically dispersed areas are more likely to transport organs by commercial air. OPOs share similar organ transport concerns as couriers and organ transplant hospitals.

Organ Transplant Hospitals

In accordance with Section 1102 of the FAA Reauthorization Act of 2024, the FAA invited organ transplant hospitals to serve on the working group. Organ transplant hospitals, also referred to as transplant centers, are required to be OPTN members. Organ transplant hospitals perform surgical procedures to transplant organs and biological material, relying on efficient logistics and seamless communication to ensure viability of the organ.

Organ transplant hospitals are concerned about the ischemic time (time period the organ is without a blood supply) and viability of the organ after transport. The length of time for viability varies from organ to organ, and transplant centers are interested in all possibilities to reduce the total transportation time.

Unions

In accordance with Section 1102 of the FAA 2024 Reauthorization Bill, the FAA invited unions for flight attendants to serve on the working group. The FAA also included unions representing pilots, dispatchers, and passenger service agents. Many pilots and flight attendants only experience organ transport a few times in their career but are generally familiar with the procedures.

Pilots and flight attendants need to be aware that the organ is onboard and that there is no dry ice in the packaging. OPOs and couriers need to engage with passenger service agents at the check-in counter and gate to ensure crewmembers are made aware of the organ transport. Proper coordination and communication with dispatchers, who file the flight plan, needs to occur in advance of the flight to ensure priority handling of organs during flight. The dispatcher in the airline operations center can annotate the flight plan and notify the pilots so they can use the MEDEVAC call sign.

Airport and airline counters are often minimally staffed, and passenger service agents are generally unable to assist in moving the organ. If the organ is unaccompanied, risk increases in the event of a crewmember change on the flight or if a courier is not there to pick up the organ.

Unions note that a courier credentialling system could make identification and handoff smoother for couriers.

Couriers

The FAA invited third-party couriers who operate under agreement with OPOs to serve on the working group since this community of interest specializes in the safe and efficient transportation of donor organs. Some OPOs have their own in-house courier systems, and they raised issues on behalf of their couriers as well. Couriers are responsible for logistics, by coordinating with OPOs, transplant hospitals, research institutions, and airlines to maintain an unbroken chain of custody during the organ transport process.

Couriers are responsible for the transportation of human organs from the OPO or donor hospital to the organ transplant hospital, where the organ will be transplanted into a recipient (or to a research institution). The OPO first ensures that the organ is properly packed and stored for transport in a way that preserves its viability and minimizes ischemic time. Courier transport can involve both air and ground transportation, and couriers often work under strict time constraints and protocols to ensure the organ arrives safely and in optimal condition for transplant or research purposes.

The courier experience during organ transport is inconsistent from airport to airport and from airline to airline. When attempting to notify the airline that they will be carrying an organ, couriers often have difficulty talking to a knowledgeable person within a timely manner. Couriers often purchase an additional ticket—one for themselves and one for the organ—and attempt to provide information indicating that one of the tickets is for transporting an organ. However, communication with the airlines can be challenging and the information rarely makes it to the crewmembers in advance. When advance notice is not provided to the airline, and/or the crewmembers are not informed in advance of the flight, the pilots cannot confirm proper protocols were followed. This may inadvertently result in barring the package from the flight due to the airline's inability to confirm contents and/or security screening. In other cases, the airline might cancel the extra ticket (not realizing an organ was intended to be secured in the seat). By the time communication occurs at the gate, the flight may be fully booked.

While couriers transporting bone marrow and peripheral blood stem cells (PBSC) do not report challenges with above wing transport (primarily due to the smaller size of the container which can be opened while going through security), couriers transporting organs cited numerous examples when the courier encountered difficulties during above wing transport. Couriers are interested in preserving as many options as possible for organ transport.

Patient Representatives

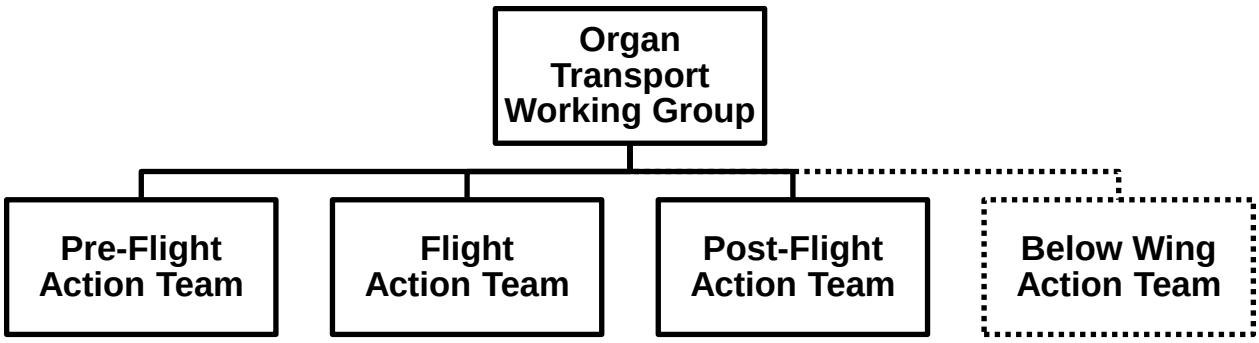
The FAA invited patient representatives to serve on the working group since this community of interest advocates for the needs and interests of transplant recipients and their families, providing valuable perspectives to guide decision-making and improve the system's effectiveness.

Patient representatives recognize that, in the context of organ transportation, *every second counts*. They advocate enhanced transparency, ensuring clear visibility of an organ's location and status throughout transit, and increased urgency by prioritizing organs in commercial transport systems.

Patient representatives are interested in more people receiving the lifesaving gift of an organ donation. They support any process that facilitates easier and more frequent organ transport.

METHODOLOGY

The OT WG held its first meeting on August 9, 2024, and initially divided the scope of work across three action teams. These action teams reported to the OT WG and were assigned a specific workstream. Based on stakeholder interest, the Below Wing Action Team was added to discuss the issues with below wing transport. While the Below Wing Action Team is outside of the scope of the Congressional mandate, the OT WG wanted to address some of the outstanding issues (see Addendum) since this is currently the most common method of organ transport on commercial airlines.



The OT WG held monthly plenary meetings where they tasked and reviewed proposed recommendations from the action teams.

The action teams met independently to request information and additional briefings from interagency partners and other OT WG members, discuss specific issues in their assigned workstream, and propose recommendations to the OT WG for consideration.

Scope of Work

The Pre-Flight Action Team developed recommendations about the transportation process starting from identification of the transplant center through courier involvement and passage through airport security. The Pre-Flight Action Team addressed stakeholder interest in the following topics:

- Standardization of authorization forms and responsibility for completion (e.g., TSA screening clearance, required airline documentation) when transporting organs.
- Standardization of the types of Courier identification/courier letters presented to TSA and airlines.
- Standardization of any pre-notification process for TSA.
- Consideration of developing facility-specific airport emergency contact lists in the event of complications or questions.
- Standardization of the security process experience for couriers accompanying organs and biological material.
- Consideration of alternatives for screening in the event the organ or biological material should not be x-rayed.
- Education for stakeholders and TSA officers about the organ transport process.

The Flight Action Team developed recommendations about the transportation process after the courier and organ or biological material clear security until the transportation process is complete (including tracking). The Flight Action Team addressed stakeholder interest in the following topics:

- Education on the use of the MEDEVAC call sign.
- Ensuring notification of dispatchers and crewmembers when an organ or biological material is on board.
- Standardization of container material and size limitations for above wing transport.
- Education regarding storage options for organs and biological material (seat, closet, etc.).
- Possibility of priority pre-boarding and deplaning for couriers accompanying organs and biological material.
- Ensuring timely notification of flight changes, delays, or cancellation.
- Possibility of voluntarily “bumping” other passengers to prioritize organ transport.
- Feasibility of unaccompanied organ above wing transport.

The Post-Flight Action Team developed recommendations around reporting and data collection after the organ transportation process is complete. The Post-Flight Action Team addressed stakeholder interest in the following topics:

- The collection of specific data regarding methods of transportation (e.g., above, below wing), including comprehensive data for success/failure rates and the reason(s) for failure.
- Additional granularity in reporting (e.g., detailed codes, time it takes to deplane organs and biological material, etc.)
- Standardized universal data reporting/monitoring system.
- Creating a central repository for all data collected during the organ transport process.
- Developing an error mitigation program to prevent future challenges.
- Consideration of a safety management system construct and safety reporting system(s).

Considerations

In establishing best practices for above wing organ transport, the working group considered a safe, standardized process for acceptance, handling, management, and transportation of an organ above wing on a commercial airplane, as well as protocols to ensure the safe and timely transport of the organ. The OT WG final recommendations are also informed by the considerations highlighted in this section.

Organs for Transplantation

While organs are transported for multiple reasons, including research, the OT WG focused on organs for transplantation. All OT WG discussions and recommendations assume that the organ is being transported for transplantation purposes. When OPOs transport an organ for transplantation, they use a standardized, OPTN regulated, label on the container. FAA and TSA subject matter experts (SME) reviewed the label and believe that, in conjunction with the accompanying courier letter, this provides sufficient information to standardize a process for acceptance, handling, management, and transportation of an organ. While each organ transport

is different, a standardized process ensures safe and timely transport by enhancing awareness and communication across all transplant community and aviation industry stakeholder groups.

Organs as Category B without being Hazardous Material

Organs, when transported by air, are not generally considered hazardous material (or dangerous goods). However, there are specific guidelines for organ transport due to their biological nature.

Under the U.S. Hazardous Materials Regulations (HMR), certain materials are classified as hazardous based on their potential risks to health, safety, or the environment during transport. Human organs, however, are not considered hazardous materials. According to the Pipeline and Hazardous Materials Safety Administration, hazardous materials are substances that pose significant risks, such as being explosive, flammable, or corrosive.[5] Human organs do not fall under these categories.[6]

Although human organs are classified under Category B infectious substances during transport, they are not classified as hazardous materials.[7] Organs are transported as biological substances unless they are suspected of containing pathogens that could cause disease.

DOT enforces packaging and labeling requirements for the transport of human organs to ensure biosecurity and safety. These requirements are separate from those governing hazardous materials under the HMR and focus specifically on biological risks.[8]

- Non-infectious organs (e.g., healthy organs from a donor who does not have infectious diseases) do not require hazardous material classification and are typically treated as biological materials that need to be transported under the appropriate guidelines for medical specimens.
- Infectious organs (e.g., organs from a donor with a known or suspected infectious disease) might be treated as Category B Infectious Substances (under International Air Transport Association (IATA) regulations) and must be packed and transported according to guidelines to prevent the spread of infection. These would then be considered dangerous goods for transport purposes.

So, while organs themselves are not automatically classified as hazardous materials, they may be subject to additional regulations to ensure safety during transport if there is any risk of infection or contamination. The goal is to balance the safe delivery of vital organs with the protection of public health and safety.

- Packaging: Organs are typically transported in specially designed containers that maintain a controlled temperature and prevent leakage.
- Documentation: There may be specific medical documentation and labels required, especially if the organ could be considered a biological substance.

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[5] *See* 49 CFR § 171.8.
[6] Specifically, 49 CFR § 173.196 exempts human organs intended for transplant from hazardous material classification, as they do not present immediate physical risks during transport when properly packaged.
[7] This distinction is outlined in 49 CFR § 173.134, with guidance from the World Health Organization.
[8] *See* 49 CFR § 173.199. These regulations fall under IATA Dangerous Goods Regulations and require packaging that meets certain standards to prevent leakage and contamination.

- Regulatory compliance: Transporters need to comply with IATA, International Civil Aviation Organization, and other relevant regulations that govern the safe transport of biological materials and potentially infectious substances.

A biohazard in the context of organ transportation refers to any biological material (such as human organs) that may pose a risk of infection or contamination to people or the environment. However, organ transportation is generally not classified as hazardous material because organs are not typically considered dangerous goods unless they are contaminated with infectious diseases. While biohazards need special handling and packaging, they are not automatically classified as hazardous materials under FAA rules unless they meet specific criteria, such as being infectious substances.

Organs as Cargo under FAA and TSA Regulatory Frameworks

Under FAA regulations, "cargo in the cabin" refers to any goods, materials, or items that are stored or transported in the passenger cabin of an airplane rather than in the cargo compartment. Typically, cargo is stored in the hold or belly of the airplane, where it is secured and separated from the passengers. However, there are certain instances where cargo might be placed in the cabin.[9]

- The term generally applies to items that are transported in passenger areas (not in the cargo compartment), which can include luggage, special items, or even live animals.
- This can occur when there is no room in the cargo compartment, or if there is special handling required for certain items (e.g., valuable or fragile goods, or when transporting certain dangerous goods that must be placed in the cabin for safety reasons).

Under the FAA regulatory framework, any cargo placed in the cabin must adhere to specific safety standards.[10]

- Cargo in the cabin must be properly secured to prevent movement during flight, which could be a safety hazard in the event of turbulence or an emergency.
- The placement of cargo in the cabin must not obstruct emergency exits, interfere with the evacuation process, or pose a risk to passenger safety.
- Time-sensitive materials (e.g., organs for transplant) might be transported in the cabin for more direct access and to ensure they are handled with extra care.

FAA regulations specify how much and what type of cargo can be transported in the cabin to ensure the safety and security of all passengers and crewmembers onboard.

- Weight and Size: Items transported in the cabin cannot exceed the weight and size restrictions for the airplane's cabin storage.[11]
- Securement: Cargo must be securely fastened to prevent shifting or movement that could create a hazard.[12]

[9] *See* 14 CFR § 25.857.
[10] *See* 14 CFR § 25.787.
[11] *See* 14 CFR § 25.857.
[12] *See* 14 CFR § 25.857.

- Packaging: Items may need to be in approved containers depending on their nature, especially if they are fragile or require special conditions (e.g., temperature-sensitive).[13]
- Labeling: Cargo that requires special handling, including hazardous materials, must be clearly labeled and documented according to the appropriate regulations.[14]

It is important to note that, while the term cargo is applicable for both above and below wing transport, cargo accepted for below wing transport may not be transported above wing.

Existing Programs with Efficient and Effective Transport

Unlike the commercial transport of most organs, bone marrow and PBSC already have a standardized transportation process, authorized by the C.W. Bill Young Cell Transplantation Program.[15] The current processes and procedures of using trained couriers for above wing transport of bone marrow and PBSC products are efficient and effective. Stakeholders should consult with the operator of the C.W. Bill Young Cell Transplantation Program before applying the final recommendations to the above wing transport of bone marrow and PBSC products to avoid introducing unnecessary complications for these couriers.

[13] *See* 14 CFR § 175.10.
[14] *See* 49 CFR § 172.400.
[15] *See* 42 U.S.C. § 274k.

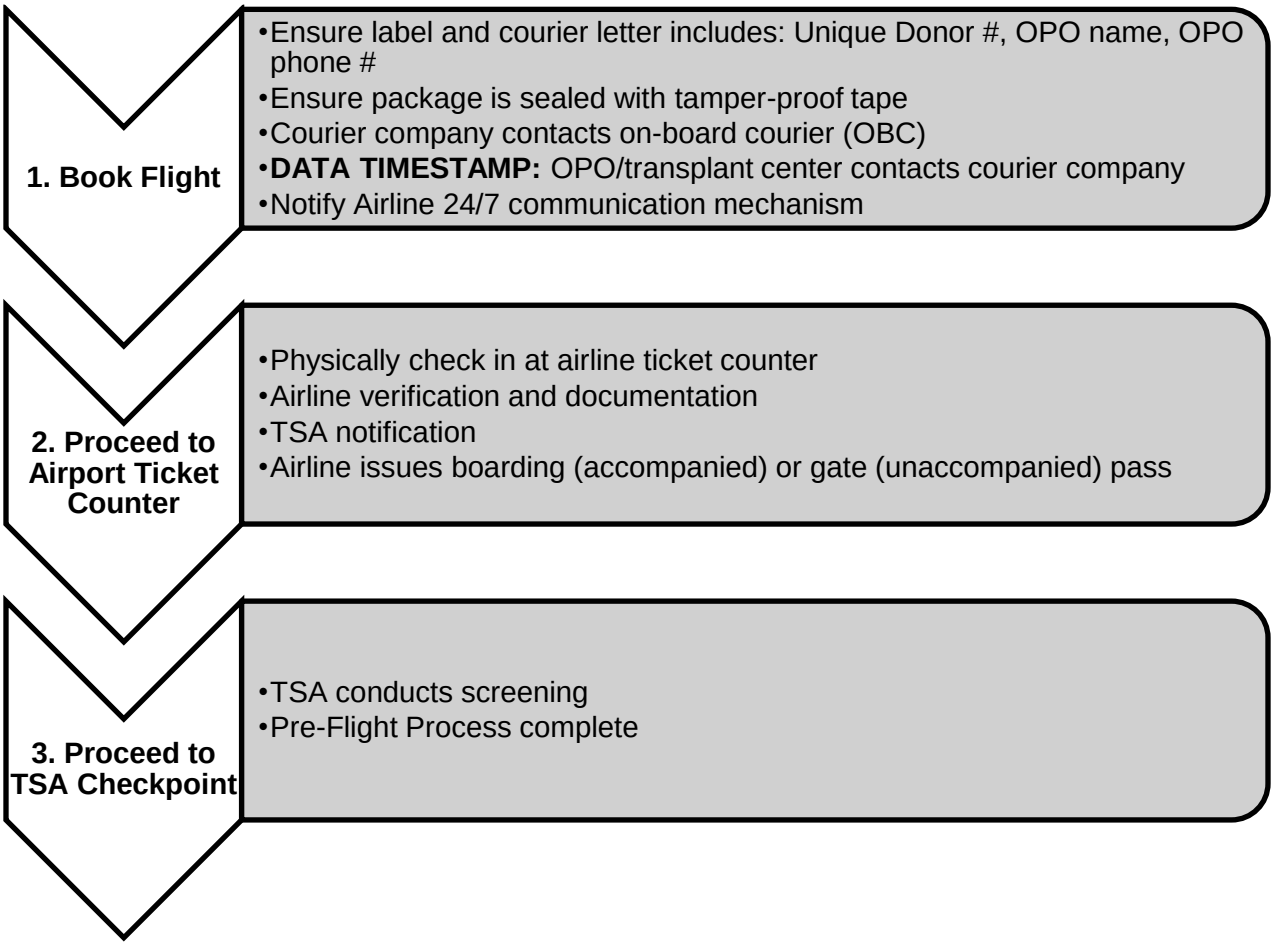
ORGAN TRANSPORT PROCESS

To address the workstream identified for each action team, the leads and facilitators engaged participants in interactive discussion to map current state processes and envision possible future state processes with a specific set of assumptions. Each action team developed a step-by-step process of the necessary actions to successfully complete their assigned phase of the transportation process. This exercise was instrumental in identifying gaps in the current process and serving as the initial step in formulating actionable recommendations. The diagrams below reflect the ideal future state processes captured for each phase of the transport process.

While developing these process diagrams, the OT WG assumed the organ was a kidney in industry-standard cardboard packaging, with no pump and/or power unit, and accompanied by a courier. Kidneys represent the largest percentage of organs transported on commercial airlines, so they were used as the test case example. The OT WG believes these process diagrams generally apply to organs and biological material, as well as container types for above wing transport.

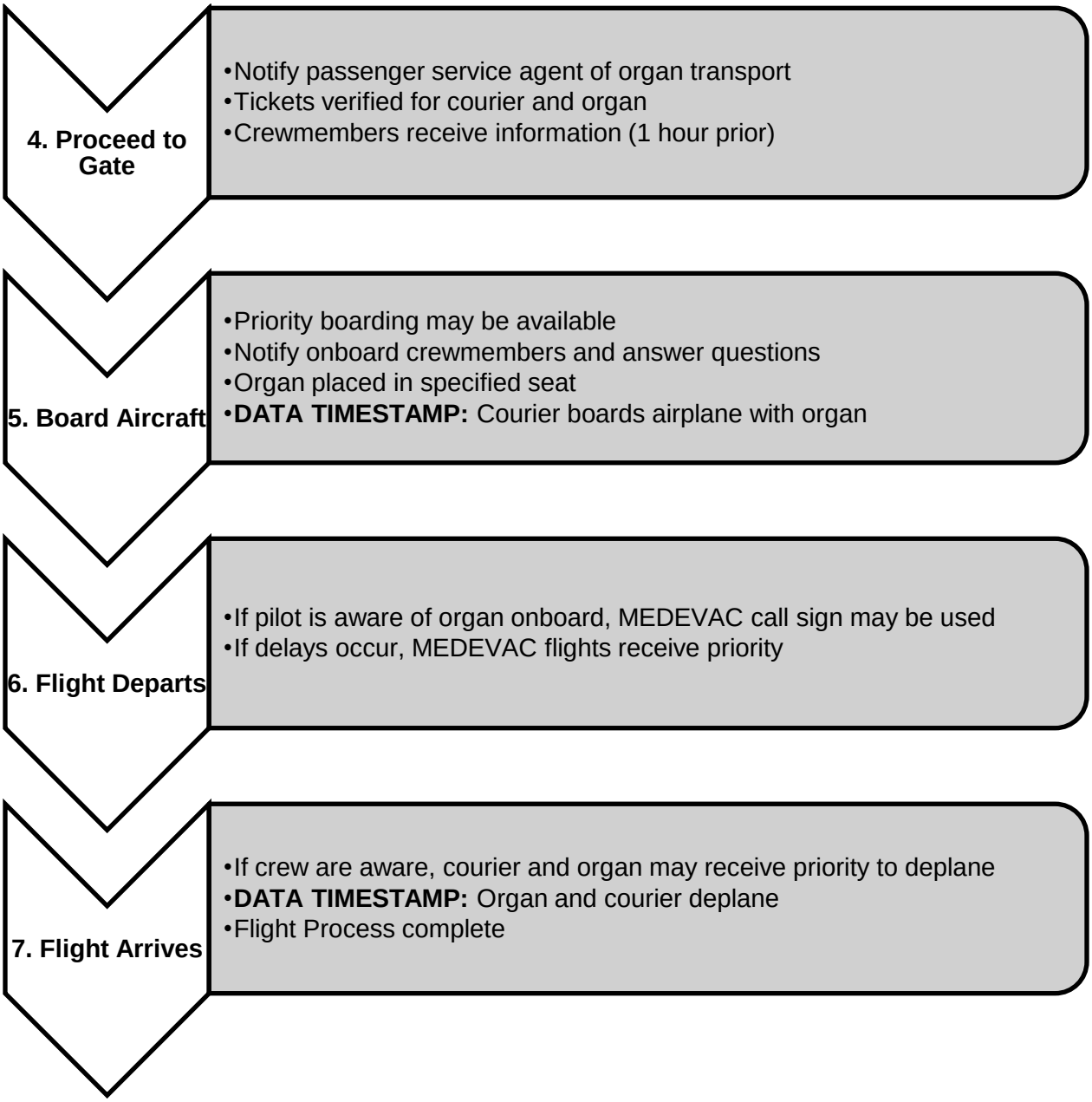
Pre-Flight Process

Accompanied & Unaccompanied Organ



Flight Process

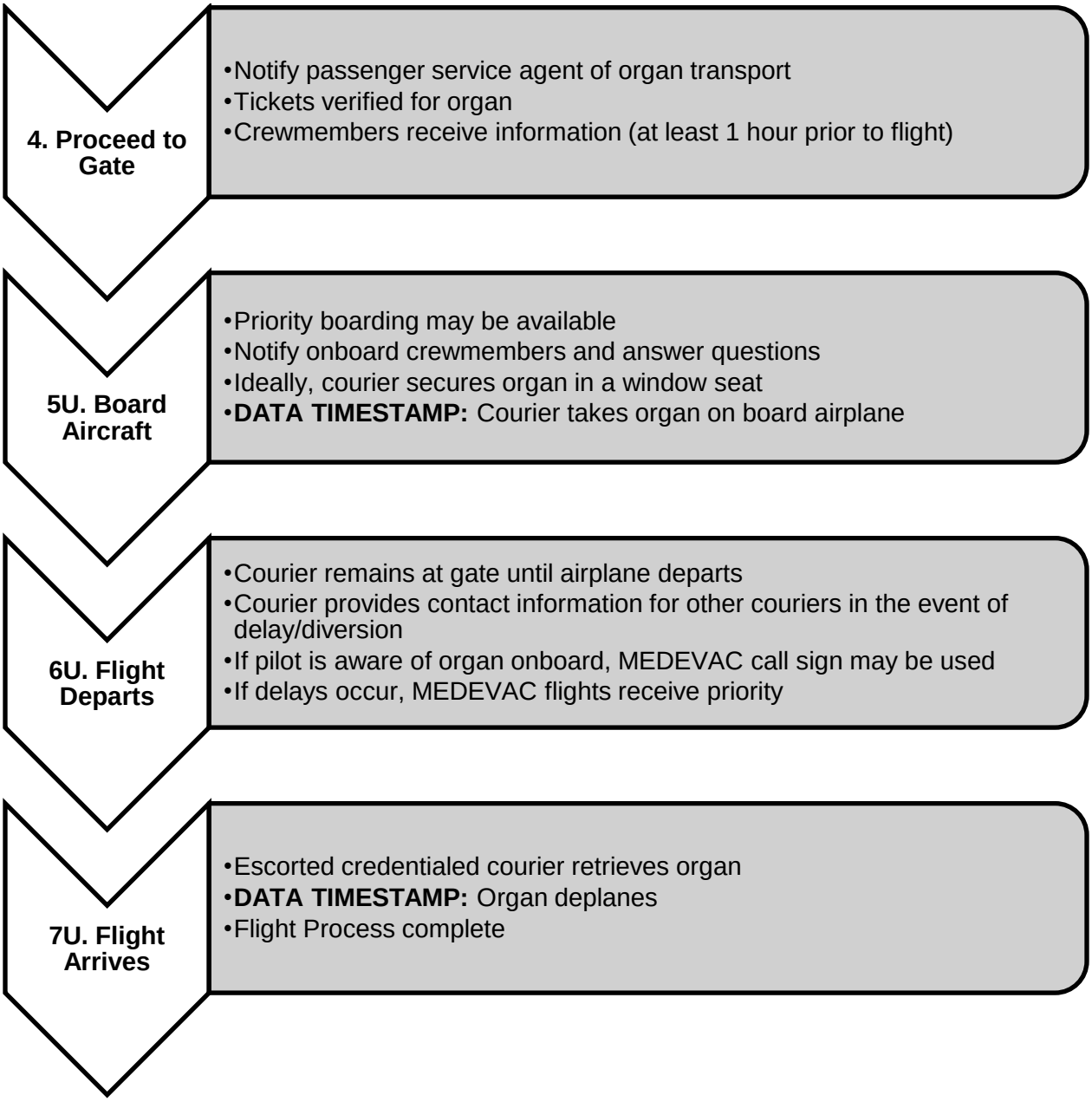
Accompanied Organ



Unaccompanied Organ

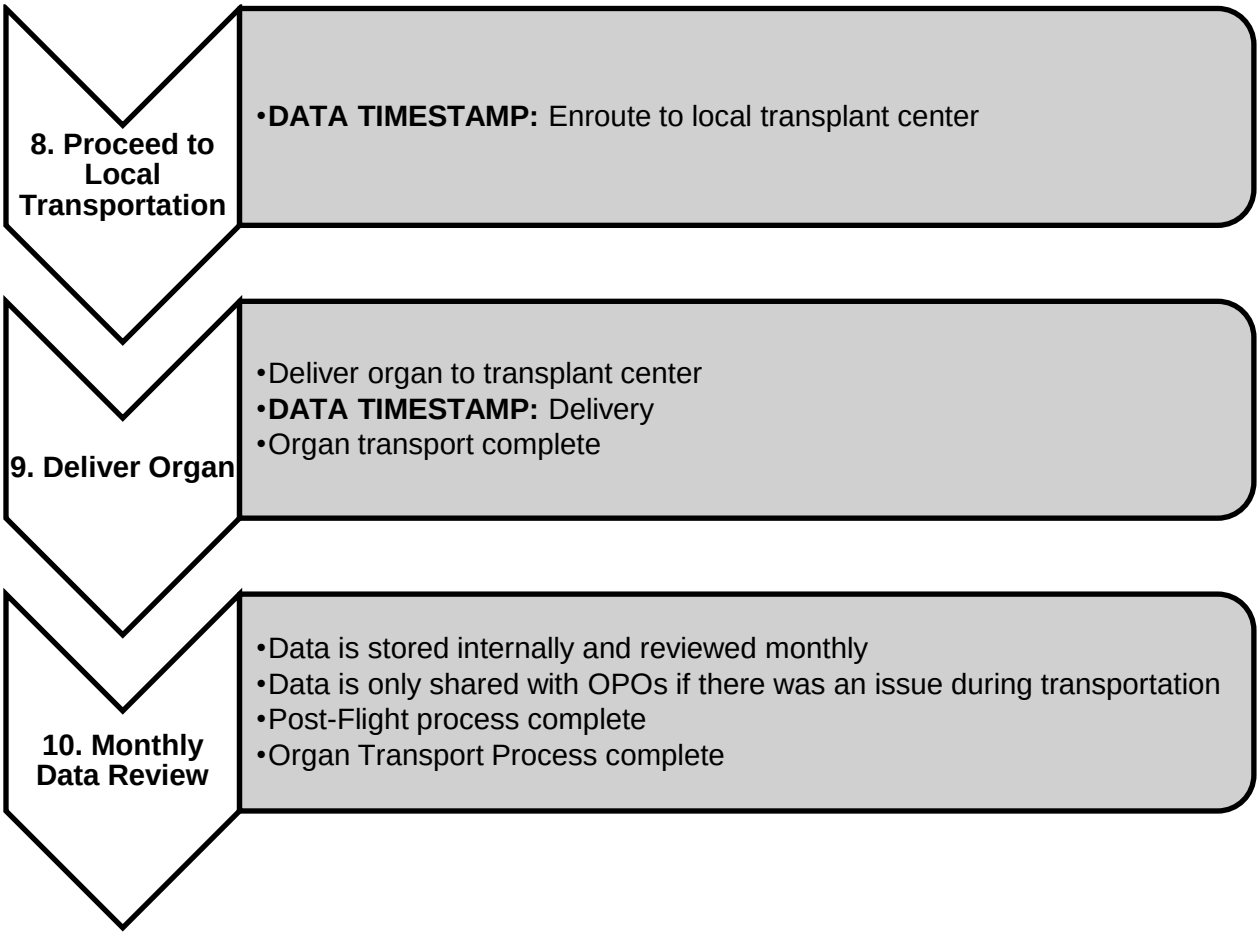
Airlines have the discretion to decide whether they will allow organs to be transported unaccompanied above wing. While there are no regulatory barriers preventing the transportation of unaccompanied organs above wing, OT WG members acknowledge concerns associated with chain of custody and liability.

This process diagram assumes that the unaccompanied organ above wing transport is a direct flight. Step 4 remains the same as the accompanied organs process, and steps 5U – 7U represent the process if the organs are unaccompanied.



Post-Flight Process

Accompanied & Unaccompanied Organ



FINAL RECOMMENDATIONS

The OT WG developed twenty (20) recommendations to improve the process of above wing transport of organs and biological material on commercial airlines. The recommendations are grouped into five categories:

- Access
- Education
- Logistics
- Communication
- Reporting

Each recommendation includes the intent and objective of the recommendation, which provides further context to subject matter experts implementing the recommendation. The OT WG does not consider this additional information to be part of the recommendation.

Access

Access recommendations address stakeholder interest for organ transport to receive priority consideration during the transportation process.

Recommendation 1: Priority Airline Access

Airlines should develop procedures to ensure couriers can access priority/expedited check-in at the ticket counter and boarding/deplaning at the gate (when available).

Intent of Recommendation:

- To ensure that organs are appropriately prioritized during transport and arrive at transplant centers in a timely manner for use in transplantation while avoiding any detriment to patients in need.

Recommendation 2: Designated Seating

Airlines should develop policies and procedures to designate specific seating arrangements (e.g., window seats) for organs, as appropriate, traveling above wing.

Intent of Recommendation:

- To ensure that organs are handled and transported in a safe and appropriate manner, free from obstruction or damage, for use in transplantation while avoiding any detriment to patients in need.

Recommendation 3: Access to Full Flights

Airlines should develop policies and procedures to prioritize organ transportation on full flights, by considering bumping revenue passengers when necessary.

Intent of Recommendation:

- To ensure that organs are provided appropriate seating prioritization during transport.

Outstanding Concerns:

- Existing reporting and regulatory requirements penalize airlines for involuntary denied boarding. DOT involvement would ensure that such bumping would not trigger enforcement activity against the airline, would not be reported as involuntary denied boarding, and would not trigger compensation requirements that would be borne by the airlines.

Education

Education recommendations address stakeholder interest in ensuring everyone involved in the organ transport process is properly educated and/or trained.

Recommendation 4: Publish FAA Guidance

The FAA should publish guidance material highlighting the regulatory framework that permits the transport of organs above wing on commercial flights, as well as suggested crewmember training.

Intent of Recommendation:

- To clarify applicable policies and regulations as well as reinforce that there are no FAA regulatory barriers to organ transportation.

Recommendation 5: Clarify Airline Security Requirements

TSA should ensure clarity of airline security requirements pertaining to organ transport and revise the Aircraft Operator Standard Security Program as needed.

Intent of Recommendation:

- To expedite the security screening process by ensuring the Airline fully understands and completes its security requirements when accepting an organ as cargo for transport, before the organ arrives at the TSA security checkpoint.
- To ensure airlines understand existing TSA security requirements for cargo, including organs, even when carried above wing.

Recommendation 6: Airline Education

Airlines should ensure all appropriate employee groups are educated about the organ transport process and the airline's applicable policies and procedures to ensure that they are knowledgeable about the process and their responsibilities.

Intent of Recommendation:

- To ensure all relevant airline personnel are equipped with the knowledge to facilitate organ transport safely and effectively.

Recommendation 7: Clarify TSA Screening Procedures

TSA should clarify internal screening procedures and ensure personnel are appropriately trained.

Intent of Recommendation:

- To expedite the security process by ensuring TSA personnel understand all security requirements for each stage of the organ screening process, as well as the screening procedures for the organ and courier at the checkpoint.
- To ensure that TSA officers at security checkpoints are aware of the alternative screening measures for special cargo currently utilized in below wing transport.

Recommendation 8: Catalog Packaging Information

The OPTN should develop and maintain a catalog of common packaging types to be used in TSA and airline training. This catalog should document the various sizes, colors, and sealing techniques for conventional containers. The catalog should document the make/model and battery size/type (if applicable) for perfusion devices. The catalog should also mandate the use of tamper proof tape for sealing the packaging.

Intent of Recommendation:

- To clarify and expedite the security screening process by ensuring that TSA officers are familiar with the various types of containers they might encounter.
- To ensure crewmembers are also familiar with the various types of containers they might encounter to ensure acceptance and proper handling.

Logistics

Logistics recommendations address stakeholder interest in making the organ transport process as efficient as possible by ensuring that everyone involved is aware of a pending organ transport.

Recommendation 9: Organ Labeling and Courier Letter

OPOs should ensure that the labeling on the container matches the information in the courier letter. Both the label and the letter should include the OPTN #, the OPO name, and the OPO contact number. The container should be sealed with tamper proof tape. The courier letter should include additional information about organ packaging, such as the container type, if the container or tracking device uses an FAA-approved power source, and whether the package contains any hazardous materials/dangerous goods.

Intent of Recommendation:

- To ensure that both the courier and container are always properly identified.
- To ensure contact information is readily available if the courier and container are prematurely separated.

Recommendation 10: Airline 24/7 Notification

Airlines should make available a 24/7 communication mechanism (e.g., customer service line, e-mail box) that can adequately support organ transport inquiries and facilitate such transportation.

Intent of Recommendation:

- To ensure continuous communications access is available as a means of immediate support for stakeholders involved in organ transport.

Recommendation 11: Enhance Airport Coordination

Couriers should check in at the airline ticket counter so airlines may finalize their security requirements, direct couriers to the front of the screening checkpoint, and notify the TSA coordination center of the organ transport.

Intent of Recommendation:

- To ensure the airline is aware of the organ transport to complete TSA security requirements and accept the cargo for transport.
- To help with ensuring that the crewmembers are aware of the organ transport, preparing them to accept the cargo onboard. Depending on the airline's procedures, more notice may be required to achieve the intent of this recommendation.
- To expedite the security process by providing TSA advance notice of the courier's arrival.

Recommendation 12: MEDEVAC Call Sign

Airlines should develop policies and procedures to ensure dispatchers annotate the flight plan and notify pilots so they can use the MEDEVAC call sign.

Intent of Recommendation:

- To ensure that organs are transported in a timely manner so they can be transplanted, avoiding any detriment to patients in need.

Outstanding Concerns:

- In the event of organ transport on a regional airline, the ticketing airline does not notify the regional airline that an organ is onboard. For the regional airline to use the MEDEVAC call sign, the courier will need to check in with the ticketing airline as soon as possible so that the regional airline operations center can be notified that an organ is on board.

Communication

Communication recommendations address stakeholder interest for clear and up to date communication of stakeholders' policies and procedures for the organ transport process.

Recommendation 13: FAA Public Information Hub

The FAA should create and maintain a public-facing website to serve as an information hub for stakeholders involved in transporting organs on commercial airlines.

Intent of Recommendation:

- To provide a central source of information that includes this final report, regulatory information from the FAA and pertinent HHS/HRSA and TSA information.

Recommendation 14: TSA Public Information Hub

TSA should create and maintain a public-facing website to serve as an information hub for stakeholders involved in transporting organs on commercial airlines.

Intent of Recommendation:

- To provide a central source of information that includes regulatory information from TSA and pertinent FAA and HHS/HRSA information.

Recommendation 15: Airline Public Information Hubs

Airlines should communicate organ transport policies and procedures clearly on their public-facing websites.

Intent of Recommendation:

- To ensure that all stakeholders (including OPOs, couriers and passengers), have easy access to important information regarding organ transport policies, promoting transparency and efficient coordination.

Recommendation 16: Organ Transport Incident Reports

HHS/HRSA should share relevant incident reports with TSA and airlines (through their industry associations) to support existing aviation safety culture of continuous improvement.

Intent of Recommendation:

- To ensure that there is a continuous improvement process that enhances the safety, security and efficiency of organ transportation by fostering collaboration and communication between HHS/HRSA, TSA, and airlines.

Recommendation 17: Organ Transport Committee

HHS/HRSA should establish a forum for continuous discussion and communication across transplant community and aviation industry stakeholder groups. TSA and FAA should support these efforts with subject matter expertise when needed.

Intent of Recommendation:

- To ensure a platform for continuous dialogue and collaboration exists so that stakeholders can address emerging issues and enhance the efficiency of the organ transportation process.

Reporting

Reporting recommendations address stakeholder interest in improved data collection to better enable data-driven decisions about the transportation process.

Recommendation 18: Centralize Data Collection

HHS/HRSA should develop a centralized data management system to collect data from OPTN members, couriers, and other relevant stakeholders.

Intent of Recommendation:

- To streamline data collection, storage, and analysis for data designed to improve the organ transport process and increase communication across the organ transport community.

- To eliminate data silos, improve data accessibility, and support more data-driven decision-making, leading to better-coordinated and more effective organ transport processes.

Recommendation 19: Standardize Data Collection

HHS/HRSA should establish standardization of data definitions, data types, and reporting protocols for data collection in the organ transport community.

Intent of Recommendation:

- To ensure consistency and reliability in data definitions and reporting across the OPTN stakeholder community.
- To guarantee that all data collected is uniform and comparable, eliminating discrepancies and enhancing data integrity.

Recommendation 20: Additional Granularity in Data Reporting

HHS/HRSA should add additional granularity in data reporting by collecting transportation methods and success/failure rates, in addition to timing and scheduling.

Intent of Recommendation:

- To Improve the accuracy, consistency and granularity of data collected on organ transportation, ensuring that all relevant information is systematically gathered, shared, and analyzed to enhance organ transport efficiency and safety.

CONCLUSION

The OT WG appreciated the opportunity to discuss challenges the transplant community and aviation industry face when organs and biological material are transported in the passenger cabin on commercial airlines, while focusing on ways to improve the existing process.

Moving forward, sustained collaboration across these groups will be essential to implement these recommendations and drive measurable improvements. While there are no statutory or regulatory barriers to above wing organ transport, there are perceived barriers and identified logistical challenges associated with the process. The following efforts will help ensure that every donated organ has the best chance to reach the patient who needs it—safely, timely, and reliably:

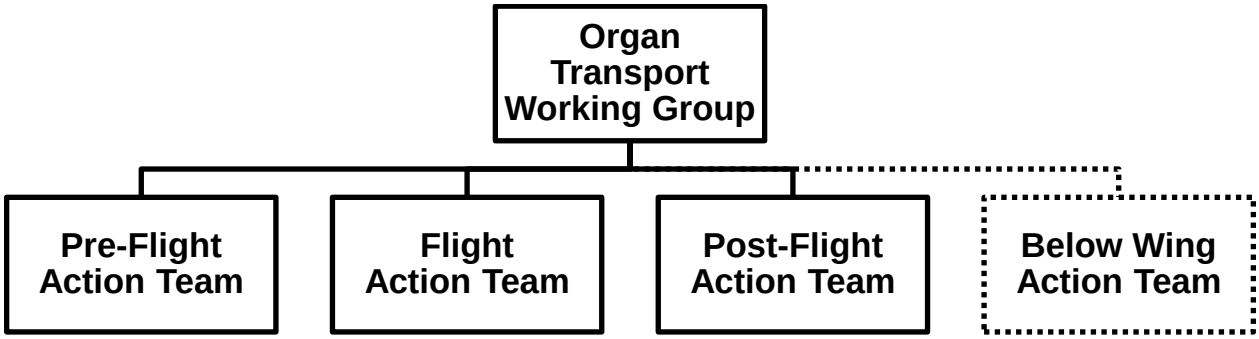
- Standardized and consistent processes;
- Increased communication before and during transport; and
- Education for all participants involved in the transport process.

This body of work identifies several best practices, with recommendations directed at the FAA, TSA, HRSA, OPOs, couriers, and airlines. The members believe that implementing these recommendations will improve the organ transport process, as well as address perceived barriers, to ensure better and continuous communication among transplant community and aviation industry stakeholder groups. The OT WG anticipates the expected efficiencies gained from these recommendations will encourage more airlines to voluntarily participate in organ transport.

The OT WG recommendations represent an excellent first step toward a more efficient and effective life-saving organ transport system, reinforcing our shared commitment to honoring the gift of donation and improving outcomes for transplant recipients nationwide.

ADDENDUM: BELOW WING ACTION TEAM

Based on stakeholder interest, the OT WG established the Below Wing Action Team to discuss the issues with below wing organ transport in the cargo compartment on cargo airlines. While the Below Wing Action Team is outside of the scope of the FAA Reauthorization Act of 2024 mandate, the OT WG wanted to address some of the outstanding issues since this is currently the most common method of organ transport on commercial airlines.



The Below Wing Action Team met independently to request information and additional briefings from interagency partners and other OT WG members, discuss issues specific to below wing organ transport, and propose recommendations to the OT WG for consideration.

Below Wing Scope of Work

The Below Wing Action Team developed recommendations about the transportation process after the organ is received at the cargo desk until the organ is received by the designated courier (including tracking). The Below Wing Action Team addressed stakeholder interest in the following topics:

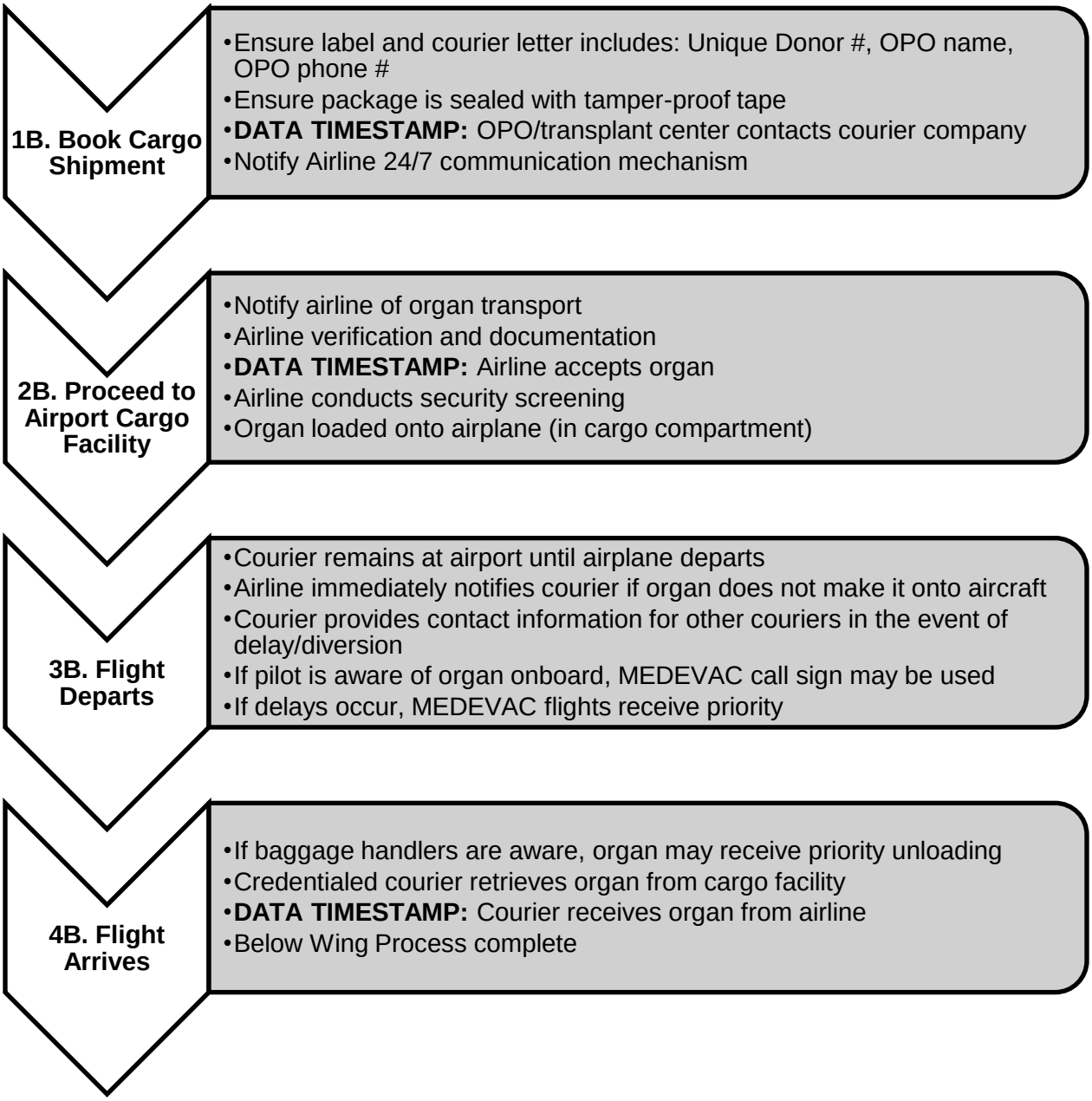
- Improve cargo facility organ recovery times and claims approval processes.
- Possibility of extending cargo desk hours or other “after hours” organ pickup solutions.
- Possibility of giving couriers priority at the cargo desk to tender and retrieve an organ.
- Possibility of allowing organs to be placed on a plane after cargo closes if they tender before the facility closes.
- Guidelines for where organs should be placed in the cargo compartment for quick access.
- Realistic cut-off time for loading.

Below Wing Organ Transport Process

While developing this process diagram, the Below Wing Action Team assumed the organ was a kidney in industry-standard cardboard packaging with no pump and/or power unit. Kidneys represent the largest percentage of organs transported by commercial airlines, so they were used as the test case example. The Below Wing Action Team believes this process diagram applies to all organs and FAA-approved container types for below wing transport.

Unaccompanied Organ

Steps 1B – 4B specifically address the process for below wing organ transport.



Below Wing Recommendations

The Below Wing Action Team did not propose new recommendations to the OT WG. Instead, they proposed supplemental language to eight existing recommendations to address issues specific to below wing organ transport in the cargo compartment on commercial airlines.

The supplemental language for the Final Recommendations is below:

Recommendation #	Supplement
1: Priority Airline Access	This access priority should also apply at cargo facilities.
6: Airline Education	This education should also apply to safe handling of organs transported below wing.
8: Catalog Packaging Information	Catalog should be shared with baggage handlers for awareness/education.
9: Organ Labeling and Courier Letter	Label and/or letter should be visible and note that organ transport is for transplant purposes.
10: Airline 24/7 Notification	This communication mechanism should also apply at cargo facilities.
15: Airline Public Information Hubs	Hub should provide guidance on the booking process for below wing organ transport.
16: Organ Transport Incident Reports	These reports should also include incidents that occur at cargo facilities.
20: Additional Granularity in Data Reporting	Data should report if organ transport is above or below wing.

APPENDIX A: ACRONYMS AND DEFINITIONS

Acronyms

Acronyms	
ATSA	Aviation and Transportation Security Act
CMS	Centers for Medicare and Medicaid Services
CFR	Code of Federal Regulations
DHS	Department of Homeland Security
DOT	Department of Transportation
FAA	Federal Aviation Administration
HHS	Department of Health and Human Services
HMR	Hazardous Materials Regulations
HRSA	Health Resources & Services Administration
IATA	International Air Transport Association
NOTA	National Organ Transplant Act
OPO	Organ Procurement Organization
OPTN	Organ Procurement and Transplantation Network
OT WG	Organ Transport Working Group
PBSC	Peripheral Blood Stem Cells
SME	Subject Matter Expert
TSA	Transportation Security Administration
U.S.C.	United States Code

Definitions

Term	Definition
Above Wing	As used in this report, the passenger cabin of the airplane.
Below Wing	As used in this report, the cargo compartment of the airplane.
Biohazard	Any biological material, including human organs, tissues, or other biological substances, that can potentially pose a risk of harm to living organisms, particularly through infection, contamination, or disease transmission. This can include pathogens, viruses, bacteria, or other biological agents that can affect human health, the environment, or animals. In the context of organ transportation, biohazards involve risks associated with the potential for transmitting infectious diseases from the donor organ to others.
Cargo[16]	Medical shipments including organ-related tissue, bone marrow, or peripheral blood stem cells, are considered cargo (not checked luggage/baggage or carry-on baggage) regardless of whether they are transported above wing or below wing.
Cargo Facility	The location at the airport where airlines receive, handle, and sort cargo for below wing transport.

[16] *See* TSA and FAA definitions in 49 CFR § 1540.5 and 14 CFR § 121.285. This narrowly focused definition is for the purposes of the working group only. It clarifies how organs and other tissue, or medical shipments, should be treated with regard to TSA security policies, processes, and exceptions.

Term	Definition
Cold Ischemic Time	The time period during which the organ is preserved in a cooled state to slow down metabolic processes and reduce damage.
Courier	Anyone carrying the organ through the transport process. The term is not specific to an OPO or courier organization/entity. The courier may be directly affiliated with the OPO or with a third-party company that handles the transport of organs.
Hazardous Materials/ Dangerous Goods[17]	Substances or materials that pose an unreasonable risk to health, safety, or property when transported by air. These materials can be solids, liquids, or gases, and include a wide range of items such as flammable liquids, toxic substances, and explosives. The HMR provides the regulatory framework for the safe transportation of hazardous materials. Based on the OT WG test case (kidney in industry-standard cardboard packaging with no pump and/or power unit), there are no hazardous materials limitations applicable for this type of organ transport.
Ischemic Time	The time period during which an organ (typically a transplant organ) is without a blood supply, causing a lack of oxygen and nutrients to the tissue. This time begins when the organ is removed from the donor and ends when it is reconnected to the recipient's blood supply during transplantation. In the context of organ transplantation, minimizing ischemic time is crucial because prolonged periods without blood flow can lead to organ damage or dysfunction, reducing the chances of a successful transplant. There are two types of ischemic time: cold ischemic time and warm ischemic time.
Organ Procurement Organization	A federally designated and certified entity responsible for coordinating the procurement and distribution of donated human organs within its designated geographic region for transplant or research. OPOs coordinate care and operations with donor hospitals, donor families, transplant centers, and medical professionals to ensure the safe and efficient procurement of organs, as well as the matching of donated organs with recipients in need under statutory, regulatory, and OPTN policy requirements. OPOs are responsible for ensuring that organs are properly preserved and transported to transplant centers or research institutions in a timely and safe manner. OPOs are regulated by the CMS with joint oversight shared between CMS and HRSA in the United States.
Warm Ischemic Time	The time period the organ is without blood supply, but still at body temperature (typically after removal from the donor but before preservation).

[17] *See* 49 CFR Part 173. Hazardous materials are known internationally as dangerous goods.

APPENDIX B: WORKING GROUP MEMBERS & ACTION TEAM PARTICIPANTS

Organ Transport Working Group

Name	Organization
Randa Hayes, Chair	Federal Aviation Administration
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Zarah Sheikh, Support Team	Federal Aviation Administration
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Andy Uribe	Air Line Pilots Association, International
Molly White	Southwest Airlines
Katey Wilson	Transportation Trades Department, AFL–CIO

Post-Flight Action Team

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Below Wing Action Team

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