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WHAT IS THE LLPR?

The Limb Loss and Preservation Registry is the first hospital systems and prosthetic/orthotic facilities collaborative database to focus on the acquired and congenital limb difference, as well as, limb preservation, populations.

HOW WILL THE REGISTRY IMPACT THE COMMUNITY?

- The Registry addresses a substantial public health knowledge gap for a population that has no current reliable data repository.

- The information housed in the Registry will help to prevent limb loss, influence clinical practice guidelines, refine rehabilitation approaches, and guide development of more optimal care plans for people living with limb loss.

- As a collaborative data hub, the Registry collects data from hospital and O&P EHR systems and other outcomes measuring systems, to create a longitudinal view of a patient's care journey.

- This dataset will be made available to researchers studying medical conditions that contribute to limb loss, such as diabetes and vascular disease, enhance their functionality and quality of life.

WHO WE SERVE

- Patients
- Clinicians
- Manufacturers
- Hospitals
- Researchers
- Payers
Since the LLPR received Authority to Operate in February 2022, the LLPR has ingested data from participating sites.

The LLPR receives data from its participating sites on a quarterly basis. Therefore, the numbers below and on the following pages will continue to change over time.*

**SNAPSHOT OF DATA IN THE LLPR DATABASE**

- Visits: 11,579,020
- Patients: 435,979
- States: Patients in all 50 States, DC, Canada, Mexico, Virgin Islands, and Puerto Rico

*Data as of 4/22/2024.

**HOW SECURE ARE THE DATA?**

The LLPR environment is compliant with FedRAMP moderate, HIPAA, and NIST 800-53 requirements. Because the LLPR is funded by the NIH and DOD, the LLPR is obligated to meet NIH and DOD security requirements. That means your data is as protected as US military data.
SNAPSHOT OF DATA
IN THE LLPR DATABASE

Data as of 2/21/2024.
SNAPSHOT OF DATA
IN THE LLPR DATABASE

Data as of 2/21/2024.
Since the LLPR received Authority to Operate in February 2022, hospitals and O&P practices have participated in this national initiative.

23 O&P practice systems participating.

10 Hospital systems participating.

**PARTICIPATING HOSPITALS**

- Atlantic Health System
- Atrium Health
- Mayo Clinic
- Shirley Ryan AbilityLab
- University of Alabama at Birmingham Medicine
- University of Colorado Health
- University of Michigan Health
- University of Texas Health Houston
- University of Washington Medicine
- The Johns Hopkins University Health System Corporation
WHAT KIND OF DATA ARE AVAILABLE FOR ME?

SEE HOW YOU COMPARE

PATIENT POPULATION

With the data from the LLPR, O&P providers are able to critically evaluate the types of patients their facility is treating in comparison to others regionally and nationally.

The below shows where your hospital system or site compares to others.
WHAT KIND OF DATA ARE AVAILABLE FOR ME?

SEE HOW YOU COMPARE

PATIENT JOURNEY

With the data from the LLPR, O&P providers are able to critically evaluate their patients' journey post amputation and how their facility is performing in comparison to others regionally and nationally.
WHAT DATA ARE COLLECTED?

patients

Address
Alcohol Use
Allergies
Date of Birth
Date of Death
Deceased Indicator
Education Level
Ethnicity
Marital Status
Name
Occupation
Patient ID
Race
Sex
Tobacco Use
Veteran Status

patient visit

Assistive Device Type & Use
Discharge Location
DX Codes
Encounter Date & Time
Function Level
Height
ICPC Codes
Pain Level
Patient Goals
PT/OT Therapy
Residual Limb Characteristics
SDOH Codes
Socket Comfort Score
Weight

lower limb prosthesis

Capability
Delivery Date
Fabrication Location
Foot*
Knee*
Hip*
Laterality
Liner Material
Liner Size
Prosthetic Avg Hours of Use
Prosthetic Description
Prosthetic Use
Sock**
Socket***
Structural Design
Suspension
Suspension Type
Suspension Type Additional

patient reported outcome

Category
Lower Extremity
Upper Extremity

Mobility & Functional Status

PLUS-M
PROMIS
ABC Scale
OPUS-UEFS
PROMIS UE - Custom

Quality of Life

PROMIS-PROPr

Safety

Fall History

Prosthesis Use

Day per week
Hours per day
TAPES-RR LL SAT

Orthosis*

Manufacturer
Manufacturer Year
Orthosis Experience
Orthosis Type & Use
Hours of Use
Suspension Type

orthosis

Comorbidity
Date of Presentation
DX Code

comorbidity

Facility Address
Facility ID
Facility Name
Facility Phone Number

facility

Credential Number & Type
Credentialing State
Organization Name
Provider Name
Provider NPI
Provider Specialty
Taxonomy Code

provider

*Brand, Lot Number, Manufacturer, Serial Number, SKU UPC Code
**Ply, Size, Use
***Design, Composition, & Manufacturer
****Shoulder, Elbow, & Wrist

payer

Cardinality
Payer Type
Payer Status
Payer Status Effective Date
**HOW LONG WILL IT TAKE TO SEE MY DATA?**

40–55 business days. After your practice signs a Participation Agreement, we are ready to receive your data!

Please note the timeline below is an estimate and may vary by institution.

---

<table>
<thead>
<tr>
<th>Participation Agreement**</th>
<th>EHR Onboarding</th>
<th>Data Validation</th>
<th>Dashboard Access</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Review</td>
<td>• Your EHR vendor will contact you to confirm your participation&lt;br&gt;• Your EHR vendor may require you to sign a separate agreement to share your data&lt;br&gt;• Depending on your EHR vendor, an onboarding call with you, the LLPR, and your EHR may be scheduled</td>
<td>• After onboarding, we receive and validate your data (depending on your EHR, your EHR will send your data or you may send it to us via private upload location the LLPR sets up)</td>
<td>• Additional user IDs setup by the LLPR&lt;br&gt;• Dashboard access to registered users</td>
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*Actual duration varies per O&P practice’s EHR system. Current EHR APIs are established with Nymbi, OPIC, & OP Solutions with MediYeti and eClinicalWorks underway.**AOPA President of the Board of Directors Teri Kuffel completed a legal review of the Participation Agreement for O&P practices. We can send this to you upon request.
## O&P Patient Care Providers Subscription Pricing

<table>
<thead>
<tr>
<th>Service</th>
<th>Base Reporting Organization</th>
<th>Each Additional Organization (up to 9 additional organizations)</th>
<th>Each Additional Organization (more than 9 additional organizations)</th>
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<tbody>
<tr>
<td><strong>Base Subscription</strong></td>
<td>$1,500</td>
<td>$1,350</td>
<td>$1,200</td>
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<tr>
<td><strong>Analytic Dashboards</strong></td>
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<td><strong>Expanded Population</strong></td>
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<tr>
<td><strong>Analysis Add-On</strong></td>
<td>$1,000</td>
<td>$850</td>
<td>$750</td>
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<tr>
<td><strong>What’s included:</strong></td>
<td>Data Quality dashboards sum</td>
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<td></td>
<td>marize data for completeness</td>
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<td></td>
<td>and accuracy. Case Mix</td>
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<td>dashboards give descriptive</td>
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<td>summaries and unadjusted</td>
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<td>benchmarks about patient</td>
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<td>demographics and healthcare</td>
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<td>experiences of the limb</td>
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<td>loss and preservation</td>
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<td>patient population.</td>
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<td><strong>Subpopulation</strong></td>
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<tr>
<td><strong>Analysis Add-On</strong></td>
<td>$1,000</td>
<td>$850</td>
<td>$750</td>
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<tr>
<td><strong>What’s included:</strong></td>
<td>These enhanced dashboards</td>
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<td>enable deeper delivery of</td>
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<td>care insights along with</td>
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<td></td>
<td>unadjusted benchmarks</td>
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<td>through added global filters.</td>
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<td>Individual provider–specific</td>
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<tr>
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<td>insights are included as</td>
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<td>well.</td>
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<tr>
<td><strong>Risk-Adjusted</strong></td>
<td>$1,200</td>
<td>$960</td>
<td>$900</td>
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<tr>
<td><strong>Benchmarking Add-On</strong></td>
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<tr>
<td><strong>What’s included:</strong></td>
<td>Advanced risk modeling</td>
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<td>methodology applied to</td>
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<td>contributor data to support</td>
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<td>comparisons across entities</td>
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<td>of similar size and type to</td>
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<td>yours.</td>
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</table>

- New participants are invoiced for the annual subscription fee at the time of their first data transmission; subscription renewals are processed annually
- Each organization includes 2 user licenses, additional licenses are available for $250 each, per subscription cycle
- Organization is defined by you; it can be one or all of your locations, or somewhere in–between
- There is a 3-month lag for report availability from the time of data transmission to the Registry
- You do not need to subscribe to contribute data, non–subscribing data contributors will receive 2 reports annually; one is aggregated data for the entire Registry population, and one specifically generated from your organization’s data
BENEFITS OF PARTICIPATING

DISCOUNT ON LIABILITY INSURANCE

Cailor Fleming is proud to offer new and existing customers a discount on premiums (5-15%) to O&P Providers who participate in the LLPR. Discounts to be applied at renewal or at the beginning of the policy year.

PROUD PARTNER OF THE LLPR

BENEFIT

Cailor Fleming is proud to offer new and existing customers a discount on premiums (5-15%) to O&P Providers who participate in the LLPR. Discounts to be applied at renewal or at the beginning of the policy year.

https://www.cailorfleming.com/

INTERESTED?

Contact your broker today or email us at support@llpregistry.org with questions.
**LEGAL SUMMARY**

AOPA President of the Board of Directors Teri Kuffel, JD wrote a legal summary of the LLPR Participation Agreement.

| PARTIES | Mayo Clinic (“Mayo”) and O&P Provider (“Participant”) |
| TERM | One year from date of execution with auto one-year renewals, unless written notice of termination at least 30 days prior to anniversary of effective date. |
| WHEREAS | 1. Mayo and National Institute of Health (“NIH”) have contracted to develop and operate LLPR.  
2. Participant desires to participate in LLPR and Mayo desires to receive data from Participant. |
| CONSIDERATION | Exchange of data through web-based portal to result in reports. LLPR requirements include compliance, record management, privacy, and information security. |
| COST | Initial participation is without charge. Subscription fees may be charged in the future with 60 days advance written notice. |
| CONFIDENTIALITY | Both parties will take all reasonable and professional steps to maintain confidentiality of protected health information (“PHI”) and electronic protected health information (“E PHI”) under the Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) and the Health Information Technology for Economic and Clinical Health Act (“HITECH”) regulations. |
| DATA OWNERSHIP | Remains with Participant. Provided to Mayo to fulfill NIH Contract for LLPR. |
| LIABILITY | Neither party liable to the other for any specified damages. |
| LIMITATION OF LIABILITY | Each party to agreement is responsible for own acts and omissions. |
| DISCLAIMER OF WARRANTY | All reports provided by Mayo are “as-is”, disclaimers provided. |
| INSURANCE | Each party shall maintain general and professional liability insurance. |
| BOILERPLATE CONTRACT TERMS | Include equitable relief, independent contractors, notice requirements, assignment, waiver, choice of law, severability, survival, access to records, etc. |
APPENDIX I, NIH CONTRACT – CERTIFICATE OF CONFIDENTIALTY (“CoC”)

Mayo, as Contractor with NIH, “shall protect the privacy of the individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service Act as a term and condition of contract.”

The CoC defines the research, provides permitted disclosures, and requires Contractor maintain effective internal controls that provide reasonable assurance that the award is managed in compliance with Federal Statutes and regulations.

APPENDIX II, BUSINESS ASSOCIATE AGREEMENT (“BAA”)

PARTIES

Mayo Clinic (“Mayo”) and O&P Provider (“Participant”)

WHEREAS

BAA is connected to LLPR Participation Agreement and sets forth desire to submit and receive PHI, and comply with all applicable requirements of HIPAA and HITECH.

CONSIDERATION

Exchange of mutual promises, conditions and other good and valuable considerations, parties agree to do business as described in following sections:

1.DEFINITIONS;
2.APPLICABILITY OF TERMS;
3.BUSINESS ASSOCIATE OBLIGATIONS;
4.PERMITTED USE AND DISCLOSURES BY MAYO;
5.BUSINESS ASSOCIATE REPORTING OBLIGATIONS;
6.GENERAL OBLIGATIONS OF PARTICIPANT;
7.TERM AND TERMINATION;
8.INDEMNIFICATION;
9.MISCELLANEOUS.

For more information on the Participation Agreement and/or to schedule a call with the LLPR team to learn more about the registry, please email us at info@llpregistry.org.
**WHAT IS THE FUTURE OF THE REGISTRY?**

**2022**
- **Hospital** Collection of **Lower** and **Upper** Limb Amputation and Preservation Clinical Procedure Data Begins
- **Hospital** Focus Group

**Q1 2023**
- **O&P Provider** Market Analysis
- **Hospital** Market Analysis

**Q2 2023**
- **O&P Dashboard Subscription Model**
- **O&P Subscription Model Limited Release**
- **Patient** Self-Reported Outcomes Finalized

**Q3 2023**
- **Hospital** Dashboard Subscription Model & Limited Release
- **Manufacturer** Market Analysis
- **O&P** EHR Data Collection of All Visits Begins
- **O&P** Dashboard Focus Group and Ongoing Development

**Q4 2023**
- **Manufacturer** Dashboard Subscription Model
- **Manufacturer** Focus Group
- **O&P Full Subscription Model Release**
- **Hospital** Dashboard Development & Full Release of Subscription Model

**Q1 2024**
- **Manufacturer** Dashboard Subscription Model Release
- Engagement with **Accrediting and Credentialing Organizations**

**Q2 2024**
- **Researcher** Market Analysis & Data Requests Pricing Model
- **Manufacturer** Dashboard Development & Full Release of Subscription Model

**Q3 2024**
- **Patient** Engagement Platform Design
- **Researcher** Focus Group Kickoff
- **Researcher** Dashboard Development & Full Pricing Release

**Q4 2024**
- **Payer** Market Analysis & Focus Group Kickoff
- **Government** Policy Engagement