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***2025-08701 Request for Information; Health Technology Ecosystem***

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## COVER LETTER

VIA ELECTRONIC FILING — <https://www.regulations.gov/>

June 16, 2025

The Honorable Dr. Mehmet Oz  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore MD 21244-8016

### **Re: Request for Information; Health Technology Ecosystem**

Dear Dr. Oz:

The United Network for Organ Sharing (UNOS) appreciates the opportunity to comment on the *Request for Information; Health Technology Ecosystem (RIN 0938-AV68)*, published in the Federal Register on May 16, 2025. UNOS is a leader in developing and advocating for innovative solutions to strengthen organ donation and transplantation in the United States.

UNOS is a nonprofit on a mission to save and transform lives through research, innovation, and collaboration. We help people live life without limits by developing new initiatives, conducting data-driven research and analysis, providing expert consulting services, and advocating for reforms to help patients. Our decades of experience as a federal contractor in the healthcare industry makes us a valuable partner for agencies aiming to improve the health of our nation.

For more than forty years, UNOS has helped operate the nation's Organ Procurement and Transplantation Network (OPTN) under contract with the Federal Government. As an OPTN contractor, we leverage data and advances in science and technology to continuously strengthen the system, increase the number of organs recovered and the number of transplants performed, and ensure patients across the nation have access to transplant.

UNOS supports CMS and ASTP/ONC's goal of creating a patient-centric digital healthcare system that is user friendly and provides real-world value for beneficiaries and their families.

Our response below includes several recommendations that would increase interoperability and secure access to health data throughout the donation and transplant system. Increasing interoperability will improve workflow efficiency and accuracy as well as reduce administrative burden for providers, granting them more time to focus on direct patient care. We look forward to working with you to strengthen the organ donation and transplantation system and save more lives.

## RESPONSE TO SOLICITATION OF PUBLIC COMMENTS

### B. Patients and Caregivers

#### 1. Patient Needs

**PC-1. What health management or care navigation apps would help you understand and manage your (or your loved ones) health needs, as well as the actions you should take?**

Please reference UNOS' response to Question PC-4.a.

**PC-1, a. What are the top things you would like to be able to do for your or your loved ones' health that can be enabled by digital health products?**

**Manage and track health, all in one place.** Patients and caregivers are tired of using multiple apps and portals to access their health information. A comprehensive digital health product that provides a unified view of vitals, labs, symptoms, medications, medical history and other information in one place would empower patients and caregivers to make informed decisions about their care and reduce the risk of errors or missed follow-up. Such a product should have the ability to sync a patient's health information across different providers, devices, and health systems. Potentially, this centralized product could also include the capability to track services not traditionally included, such as "health-related" factors like homeless shelters, food pantries, free lunches at schools, and subsidized housing.

**Coordinate and navigate care.** A product that allows caregivers to access health records, appointments, communications, notifications and other updates about those they are caring for would help them coordinate and navigate care for others more simply. This would be especially useful if it allowed a user to manage multiple profiles.

**Access Timely, Personalized Guidance.** When facing changes like new symptoms, diagnoses, and insurance issues, patients and caregivers seek direction. They need clarity and confidence about what to do next, and they often need this information in real time. Having access to digital tools that provide accurate and customized advice, and personalized and actionable next steps reduces confusion, delays, and potential poor outcomes.

**PC-4, a. What apps should exist but do not yet? Why do you believe they do not exist yet?**

To support patients in need of a transplant, UNOS recommends the following list of apps for future creation:

- A patient-facing app that both patients and caregivers can use to view waitlist status as well as other information regarding an individual's transplant journey including pre- and post-transplant. Currently patients do not have direct access to information about their listing status at transplant centers.
  - For example, patients awaiting a transplant do not fully understand how their lab values change their status on the waitlist. A patient facing app should be configured with features and functions to help patients maintain their active status on the waitlist. After their transplant procedures, a case management app that alerts patients' primary care physicians, home pharmacies, home health providers, and other providers of hospitalization and discharge could help ensure safe discharge planning.
- An app to support living donation, both for potential donors and recipients looking for a donor to provide education, process navigation, living donor program finder and mental health support before and after donation.
- Apps that can connect to credible information about health conditions and associated patient communities for support (e.g. PatientsLikeMe).

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**PC-4, b. What set of workflows do you believe CMS is uniquely positioned to offer?**

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CMS is uniquely positioned to offer several different workflows for the complex pre- and post-organ transplant journey. Implementing longitudinal health data access would enable providers and patients to view and manage health information over time, supporting more informed decision-making. Seamless care transitions and care coordination would ensure that individuals experience smooth handoffs between different care settings or providers, reducing gaps in care. Benefits navigation would assist patients in understanding and utilizing their health coverage and available resources. Chronic disease care and prevention workflows are designed to support ongoing management of long-term conditions and preventive health measures. Advance care planning could facilitate discussions and documentation of patient preferences for future healthcare, ensuring that care aligns with their values and wishes.

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**PC-5. What can CMS and its partners do to encourage patient and caregiver interest in these digital health products?**

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To foster patient and caregiver interest in digital health products, CMS and its partners should move beyond providing these tools. They must ensure the tools are accessible, trustworthy, relevant, and user-friendly

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**PC-5, a. What role, if any, should CMS have in reviewing or approving digital health products on the basis of their efficacy, quality or impact or both on health outcomes (not approving in the sense of a coverage determination)? What criteria should be used if there is a review process? What technology solutions, policy changes, or program design changes can increase patient and caregiver adoption of digital health products (for example, enhancements to data access, reimbursement adjustments, or new beneficiary communications)?**

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CMS should play a pivotal role in fostering trust and transparency, and in establishing standards for digital health products within the Medicare, Medicaid, and CHIP ecosystems. By addressing provider reimbursement to reflect the investments necessary for digital health solutions, CMS can help ensure these products are both accessible and sustainable. As a uniquely positioned agency, CMS can signal the trustworthiness of digital health products through the development of frameworks or scorecards, incentivize and promote equity, safety, and impact using policy levers and partnerships, and encourage widespread adoption by supporting quality, interoperability, and usability.

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**PC-5, b. What changes would enable timely access to high quality CMS and provider generated data on patients?**

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UNOS believes the following changes would enable timely access to high quality CMS and provider generated patient data:

Enabling Change	Impact
Real-time API infrastructure	Timely, up-to-date access to care data, high data integrity
National data standards enforcement	Consistency across providers and systems
Unified patient access via CMS portals	Simplified experience for patients/families
Proxy and patient matching infrastructure	Trusted, secure access for caregivers
Provider incentives for data sharing	Increased data flow and accountability
Tools to make data interpretable	Empowered decisions and self-management

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**PC-7. If CMS were to collect real-world data on digital health products' impact on health outcomes and related costs once they are released into the market, what would be the best means of doing so?**

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CMS can utilize its national reach to gather data on the impact of digital health products on health outcomes and costs by using claims data, clinical data, patient-reported outcomes, and app usage.

When it comes to donation and transplant, UNOS believes that this data collection should include an evaluation of cost reduction across the entire value chain, including reductions in costs due to preventative care (such as a decreased need for organ transplants), transplant effectiveness, and post-transplant care costs. UNOS is an expert in this space and would like to collaborate with CMS to support these products without duplicating the existing OPTN infrastructure.

## **2. Data Access and Integration**

***PC-12. What are the most valuable operational health data use cases for patients and caregivers that, if addressed, would create more efficient care navigation or eliminate barriers to competition among providers or both?***

The main patient and caregiver-facing use cases in organ transplant focus on understanding the listing process. This includes determining which transplant center to list at, what requirements are mandated by the OPTN versus specific to a particular transplant program, understanding where they stand in the listing process (with the transplant center's own pre-Waitlist review process or within the OPTN Waitlist itself), and potentially gaining visibility into organ offers made on their behalf.

UNOS recommends the development of a patient-facing application that could help improve the care navigation process for transplant patients and caregivers. Such an app could allow both patients and caregivers to view waitlist status and access information about the entire transplant journey, including pre- and post-transplant stages. Having this information readily available would empower patients and caregivers to be active participants in their care and reduce the risk of errors going unnoticed.

A frequently raised question is why a separate patient portal is necessary in addition to the electronic health record (EHR). The primary advantage of a dedicated portal is that it can ensure transparency and consistent access to transplant information for patients, regardless of their hospital affiliation. Achieving this level of transparency and accessibility is only possible through a standalone application, unless all existing patient portals are mandated to integrate transplant-specific data.

## **C. Providers**

### **1. Digital Health Apps**

***PR-1, b. What information should providers share with patients when using digital products in the provision of their care?***

Healthcare providers should ensure that pre- and post-transplant patients receive clear and comprehensive information when digital products are used in their care.

Patients should be informed about how they can access their EHRs, what data is available to them, how that data is relevant to their care to encourage patient engagement, and the importance of privacy and security measures.

***PR-1, c. What responsibilities do providers have when recommending use of a digital product by a patient?***

It is critical that providers give recommendations that are aligned with each patient's treatment plan and needs. From that point, it is important that providers give recommendations that align to the correct compliance and accessibility requirements for patients while being able to ensure they are generating better outcomes that keep their patients engaged.

***PR-2. What are obstacles that prevent development, deployment, or effective utilization of the most useful and innovative applications for physician workflows, such as quality measurement reporting, clinical documentation, and billing tasks? How could these obstacles be mitigated?***

There are several overarching factors that contribute to the development, deployment, and effective utilization of physician workflow innovations. Changes to workflows can be expensive, with a lack of existing capabilities or technology, and with several gaps in how the workflows are intended to work. This is why it is imperative to acknowledge these challenges while focusing on a clear mitigation strategy that:

- Ensures there is financial and incentive support from the innovators.
- Creates a gradual implementation using human centered design to demonstrate the value through each iteration.
- Factors in the costs associated with training the workforce on using and implementing new technologies.
- Ensures interoperability through a solution that securely builds off the necessary requirements while training key staff on what this means for them in adoption.

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***PR-3. How important is it for healthcare delivery and interoperability in urban and rural areas that all data in an EHR system be accessible for exchange, regardless of storage format (for example, scanned documents, faxed records, lab results, free text notes, structured data fields)? Please address all of the following:***

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Although advanced hospital systems and technologies are increasingly prevalent in healthcare, both urban and rural areas can face challenges in accessing the most cutting-edge solutions. To address this, it is essential to develop technological solutions that are agnostic to the methods of information and data exchange between systems. Supporting multiple formats enables improved care coordination, enhanced data interoperability, deeper health insights, and reduced administrative burden. This underscores the importance of frameworks that ensure consistency across various storage formats, allowing information to be shared reliably when integrated into different systems.

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***PR-3, a. Current challenges in accessing different data formats.***

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Rural areas may struggle with adoption of electronic data formats due to antiquated paper-based systems and operational workflows, or a lack of internet service. Adoption of new technologies and standard electronic data formats, mixed with modern and reliable internet connections, can reduce the barriers to accessing large data formats and data ingestion using standard data formats.

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***PR-3, b. Impact on patient care quality.***

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Facilitating the exchange of information is essential for delivering optimal patient care. This concept is particularly relevant for donation and transplantation. Deceased organ donation is dependent on accurate and timely data sharing between hospitals and organ procurement organizations, the nonprofits responsible for procuring deceased donor organs.

Medicare Conditions of Participation require hospitals to notify OPOs of all patients indicating imminent death in a timely manner to maximize potential donation. This referral is usually done manually with a phone call by busy hospital staff. The manual nature of potential donor referral increases the risk of human error and therefore increases the risk of missed opportunities for donation. Up to 28% of potential donors are lost due to a missed or late referral, according to the National Academies of Medicine. One donor can save up to eight lives.

Automated systems exist today that replace manual reporting by integrating with hospital electronic health records systems, but standards do not yet exist to support broad national adoption. Automated donor referral systems increase interoperability between providers, reduce burden on busy hospital staff, equip OPOs with accurate patient information, and streamline the potential organ donor referral process.



Ensuring information about potential donors is exchanged between hospitals and OPOs accurately is critical. An efficient process to maximize donation helps us honor this and prevent donor families from the pain of knowing their loved one's final wishes could not be realized due to process failures.

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***PR-3, d. Cost or privacy implications of making all data formats interoperable.***

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While there are inherent financial and privacy risks associated with making all data formats interoperable, it is important to consider the broader outcomes. Failing to implement interoperability can also result in increased costs and privacy concerns, particularly when information is shared through more manual or cumbersome processes. Balancing these risks is essential to achieve more efficient and secure data exchange.

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***PR-3, e. Priority level compared to other interoperability needs.***

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In the realm of donation and transplantation, achieving full data interoperability between the OPTN Computer System and electronic medical records (EMR) systems should be a top priority. By utilizing shared frameworks for information, we can maximize data accessibility. Doing so would eliminate the need for individual integration with each health system and instead provide aggregated data in a centralized location for efficient use. For example, lab interoperability and integration into the OPTN Computer System would ensure that accurate values are stored and the integrity of transplant waitlist data is maintained. Implementing the electronic referral process, which should be directly integrated into the OPTN Computer System, would further streamline operations.

Interoperability should be approached with short-term solutions that support more formats upfront to get better interoperability outcomes long-term. Supporting a wider range of data formats may be necessary to facilitate seamless data exchange, and as interoperability improves, the reliance on multiple formats can be reduced. Prioritizing seamless data transfer—such as from trauma hospitals to transplant organizations—will streamline processes and ultimately minimize the need to support additional data formats.

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***PR-4. What changes or improvements to standards or policies might be needed for patients' third-party digital products to have access to administrative workflows, such as auto-populating intake forms, viewing provider information and schedules, and making and modifying an appointment?***

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Greater clarity and standardized access to information are essential for ensuring consistency, scalability, and adaptability in the ever-evolving healthcare environment. While healthcare organizations retain autonomy over data collection methods, implementing a uniform framework for sharing and pre-populating information is critical. This approach minimizes data quality gaps and reduces redundant data collection, thereby decreasing operational burden and costs while streamlining processes. As these improvements are adopted, the overall administrative workflow will be more efficient.

## ***2. Data Exchange***

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***PR-5. Which of the following FHIR APIs and capabilities do you already support or utilize in your provider organization's systems, directly or through an intermediary? For each, describe the transaction model, use case, whether you use individual queries or bulk transactions, and any constraints:***

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UNOS' system features direct connectivity through RESTful APIs and file-based integrations, enabling healthcare and OPO organizations to efficiently support data exchanges within their operational models. This approach enhances timely coordination in transplantation by establishing robust data SLAs and connections, which facilitate more consistent and proactive intake of information. By expanding this program to include data obtained at trauma hospitals where donor activity or hospitals where kidney or heart disease can occur, we can better understand patient needs earlier through a shift-left mindset—



whether before a transplant is required or at the outset of the donation process—ultimately improving outcomes and saving more lives.

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***PR-5, h. SMART on FHIR—Do you support both EHR-launched and standalone app access? What does the process for application deployment entail?***

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We have consistently supported seamless integrations with healthcare systems through our robust API platform and work directly with EHR vendors to ensure accessible and efficient integrations for providers. We maintain a proactive deployment schedule, regularly updating our integration partner environment to enable vendors to align their solutions with any new updates and features prior to production release. This collaborative approach allows us to rapidly adapt to evolving requirements and ensures that our solutions are well-positioned for direct EHR launches in the future, maximizing accessibility and positive outcomes for all stakeholders.

#### **4. Information Blocking**

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***PR-12. Should ASTP/ONC consider removing or revising any of the information blocking exceptions or conditions within the exceptions (45 CFR part 171, subparts B through D) to further the access, exchange, and use of electronic health information (EHI) and to promote market competition?***

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This approach should prioritize the clear definition of rules and regulations, while establishing exception protocols that are reserved for truly exceptional circumstances rather than routine activities. Enhancing standardization will help ensure that privacy and security requirements are consistently met, even as exception processes are expanded.

### **E. Technology Vendors, Data Providers, and Networks**

#### **1. Ecosystem**

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***TD-1. What short term (in the next 2 years) and longer-term steps can CMS take to stimulate developer interest in building digital health products for Medicare beneficiaries and caregivers?***

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CMS should act on its role as a convener within the next two years to stimulate developer interest with multiple avenues for participating to capture the most interest:

UNOS recommends 3 options:

1. CMS should establish a task force dedicated to identifying targeted use cases for digital health products and developing a structured framework for the submission and subsidization of these products in partnership with Medicare caregivers. This framework should include clear guidelines for reporting progress and outcomes related to the development and implementation of these technologies. Potential use cases in the transplant space could include patient-centered applications that educate individuals on their transplant options, such as:
  - a. Tools for patients on long-term dialysis to explore all available treatment options, including transplantation.
  - b. Resources to help patients identify transplant programs that align with their specific needs and have a proven track record with similar patient profiles.
  - c. Information for patients in end-of-life care considering organ donation, providing accessible resources on the value and process of donation.
  - d. Guidance for potential living donors, offering comprehensive information on the benefits, risks, and expectations associated with living donation.
2. CMS should host collaboration with universities, leveraging student projects, capstone initiatives, or volunteer-driven efforts to develop and pilot prototype applications in partnership

with Medicare caregivers. This approach can generate cost-effective solutions that can be tested and refined in real-world settings.

3. CMS should host a hackathon with industry and collaborators to drive innovation while bringing the healthcare solution teams together as a community.

## **2. Digital Identity**

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### ***TD–3. Regarding digital identity implementation:***

#### ***a. What are the challenges and benefits?***

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Challenges include the highly disparate nature of organizations involved. Hospitals are not directly part of the OPTN, and system access for the OPTN is managed by individual members rather than a central authority. OPO users may interact with dozens of hospitals, which naturally leads to point-to-point solutions that have varying degrees of development and consistency amongst each other. These challenges are magnified by the importance of security and privacy around data sharing to ensure we are protecting this critical patient information.

Benefits include the ability to ensure we are moving away from physical identification to ensure that accurate and timely sharing of information does not require new data entry. Digital identification could optimize the authorization process and make it easier for authorized users to securely obtain necessary centralized information about a potential donor. Making this event timelier with digital identity can ensure the success of subsequent necessary downhill activities that occur in the organ transplantation system.

## **3. Technical Standards and Certification**

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### ***TD–5. How could a nationwide provider directory of FHIR endpoints improve access to health information for patients, providers, and payers? Who should publish such a directory, and should users bear a cost?***

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Broader directories of FHIR endpoints can certainly enhance initial engagement and awareness efforts. However, maintaining such directories requires clear protocols for access and organizational management, which will inherently differ across systems. Additionally, even when both parties in an API connection have mature FHIR implementations, tailored mappings and data transformations are frequently needed to maximize the value of the integration.

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### ***TD–6. What unique interoperability functions does TECA perform?***

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While transplantation has seen considerable improvement through integrating OPTN members with the OPTN system, TECA has the potential to consolidate connections and thereby lower the barrier for less direct relationships, such as those between donor hospitals and OPOs.

OPO service areas may contain dozens, or even hundreds, of hospitals from which potential deceased donors are identified and referred to them. These hospitals have no formal affiliation with the OPTN or connection to the OPTN system, which contributes to fragmentation in the processes and reviews necessary for deceased donors to enter the system.

While many OPOs have some level of access to hospital EHRs for potential donor chart review, there is little consistency in what this access entails. Users might have access to hospital records remote or on-site only, and they might see different portions of the chart depending on the hospital. TECA, as a universal floor for health interoperability, represents a means to standardize these practices and more efficiently transition deceased donors from hospital to OPO care.

Similarly, the landscape of identifying potential donors and referring them to OPOs for initial screening is characterized by a high degree of point-to-point connections between individual OPOs and hospitals.

These solutions vary significantly by each party's EHR and require implementation effort by each player. While this effort is inherently core to the OPO's business, hospitals that refer fewer donors may be less able to dedicate IT effort to implementing these integrations. Continued expansion of QHINs under TEFCA presents an opportunity to consolidate these connections and achieve broad interoperability across the transplant community.

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***TD-7, d. Given improvements in language models, would you prefer a non-proprietary but less structured format that might improve data coverage even if it requires more processing by the receiver?***

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Leveraging improvements in language models can be helpful in expediting integration and integrated technologies by allowing inference of API connectivity and data exchange. The ability to translate unstructured data into structured data using new technologies and improvements in AI can expedite future integrations.

## **F. Value-Based Care Organizations**

### **3. Technical Standards**

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***VB-14. How could implementing digital identity credentials improve value-based care delivery and outcomes?***

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The implementation of digital identity credentials could enable patients to access their transplant-related medical information that is stored in the OPTN computer system. Access to this information, made possible with digital identity credentials, would allow them to validate the accuracy of critical listing information and could help build trust in the system. Currently, patients rely on transplant hospitals to share this information with them. Enabling patients to access this information themselves would support their ability to be active participants in their care.

Improving access to medical information associated with transplant data stored in the OPTN computer system using standards for digital identity could enable patient-facing solutions with direct access to OPTN records. Using digital identity to authorize OPTN computer system access for patients could allow them to validate the accuracy of their critical listing information. Currently, patients depend on hospitals to share this information with them. Enhanced transparency for patients, enabled by digital identity, could improve public trust in the system. Secure access for patients could even enable real-time information sharing and decision-making related to organ acceptance decisions.

For waitlisted patients, this transparency and access to data could enable conversations with the transplant care team, ensure that patients understand their involvement in ensuring readiness for transplant (follow through with scheduled testing, lab work, etc. to ensure the Waitlist record is reflective of current medical urgency). When organ offers are made to patients, patient-facing tools could enable patients to take an active role in the decision making related to acceptance of an organ. Since the OPTN is not a patient-facing entity or direct care provider, solving digital identity is a must-have for providing secure direct access to these data.

## **CONCLUSION**

UNOS appreciates the opportunity to inform CMS and ASTP/ONC's goal of creating a patient-centric digital healthcare system that is user friendly and provides real-world value for beneficiaries and their families. Our four decades at the center of donation and transplantation have provided us with valuable insight and expertise. We have grown from being the first organ matching system into a multi-dimensional organization that supports domestic and international donation and transplant systems, conducts data-driven research and analysis, develops products and services, advocates for reforms to help patients, and partners to drive a greater public health impact. We hope to work with your Agencies

to enhance interoperability within our healthcare systems to improve care, benefit patients, and enable more Americans live life without boundaries.

Sincerely,

A handwritten signature in black ink that reads "Alicia Hennie". The script is fluid and cursive, with the first letters of each word being capitalized and prominent.

Alicia Hennie  
Vice President, External Affairs