

On Mon, Feb 25, 2019, at 5:36 PM Duvall, Tom (CMS/CMMI) <Tom.Duvall@cms.hhs.gov> wrote:

To all,

Thank you for reaching out to us and telling us about the work that you all are doing. We had a few follow-up questions for you that we wanted to write out and share:

- Could you share the NIH study where your technology was tested or point to where we could find it?
- Could you let us know specifically what requirements that you think CMS should include in a follow-up ESCO program around data interoperability? We would love your specific thoughts about which providers, data types, data frequency and anything else that could be included in a potential model. We would love to know what you think would be **best for patient care** and how you would structure it if you were CMS.
- What do you see as the best way to bridge the divides between different providers in the kidney care space? Specifically, what are the best ways to encourage care coordination and greater communications between dialysis facilities, nephrologists, and the transplant centers/OPOs that guide beneficiaries through the transplant process?

We appreciated talking with you and look forward to following up with you at some point soon.

Thanks,
Tom

03/17/19 DRAFT - *IT Proposal for Expanded CEC*

To improve the efficacy and efficiency of health delivery, Health and Human Services (HHS) is facilitating opportunities for new market entrants and removing barriers to interoperability and electronic health information (EHI) exchange, which would greatly benefit health care providers and patients.¹ Policy from HHS and Center for Medicare and Medicaid Services (CMS) support a centralized data model for the patient as they move among various providers and payers. The proposed rule requires health payers and providers to make data available through an application programming interface (API) to which third-party software products connect to make the data available to patients.² Alex Azar, HHS secretary, gave a speech to the National Kidney Foundation (NKF) last week denouncing the current state of care coordination and incentivization for kidney treatment providers. Individual providers must communicate and work together to provide optimal and comprehensive care for patients with kidney disease.³ CMS is planning to implement a new payment model focused on improving late-stage chronic kidney disease care to stabilize care short of renal replacement therapy, improving rates of home dialysis, bundling services, ... and increasing rates of transplant (Tx), including pre-emptive transplantation.

The Office of the National Coordinator for Health Information Technology (ONC) [21st Century Cures Act](#) was created to advance interoperability, support the access, exchange and use of electronic health information, and address occurrences of information blocking.⁴ ONC support establishing application programming interfaces (APIs) for several interoperability purposes, including patient access to their health information without special effort. Key to this effort was to establish a federal certification program for certified Health IT products (CHP), whereby, a CHP shall not be barred access to EHI (via API).⁵ CHP and their developers shall not block access to EHI, shall make specific assurance for certification compliance, shall publish APIs, and shall not restrict communications or documentation.⁶ CMS led this initiative with the launch of [Blue Button 2.0](#) allowing API access to Medicare patients/providers/developers for relevant health/claims data and EHI.⁷

The CMS has outlined a seven-step pathway from late-stage chronic kidney disease (CKD) and end-stage kidney/renal disease (ESKD/ESRD) to transplantation (seven steps to transplant). Our novel information technology (IT) platform is designed to catalogue, update, and communicate pertinent patient-level data at each step on the path from patient identification, education, referral, evaluation, to waitlisting, and proactive clinical tracking of patients after they are waitlisted.

¹ Executive Order 13813 and MyHealthEData

² <https://www.federalregister.gov/documents/2019/03/04/2019-02200/medicare-and-medicaid-programs-patient-protection-and-affordable-care-act-interoperability-and>

³ <https://www.hhs.gov/about/leadership/secretary/speeches/2019-speeches/remarks-to-the-national-kidney-foundation.html>

⁴ <https://www.congress.gov/114/bills/hr34/BILLS-114hr34enr.pdf>

⁵ <https://www.healthit.gov/sites/default/files/nprm/ONCCuresActNPRM.pdf>

⁶ <https://www.himss.org/news/onc-proposes-new-requirements-around-information-blocking-and-health-it-certification>

⁷ <https://bluebutton.cms.gov/>

Seven Steps to Transplant

1. Identifying clinical **suitability** for transplantation – IT platform will include standardized and validated patient education tools which the patient can navigate independently, or with assistance. Platform will also document which education tool was used, and the date and time of education session.
2. Assessing/confirming patient's **interest** in transplant – IT platform will survey the patient's interest in transplantation after education, as well as clinical judgment as to the suitability for referral.
3. Making the initial **referral** to transplant center – IT platform will permit a secure, trackable, paperless referral to the transplant center.
4. Patient's **first visit** to transplant center – Transplant center end-user will be able to upload pertinent data regarding the initial evaluation and multidisciplinary assessment, which will be visible and available to the dialysis provider and/or nephrology practice end-user.
5. **Completing** the transplant center work-up – Once the patient is waitlisted, the dialysis provider and/or nephrology care provider will be able to track patients in their unit currently waitlist active or Status 7.
6. Engaged Waitlisting – *Keeping patients “transplant ready”* – IT platform will allow bidirectional communication between the patient, dialysis provider, nephrology practice, and transplant center to share pertinent clinical information to ensure waitlisted patients continue to be suitable for active listing. Patient adherence to dietary, lifestyle, and medical demands may be tracked passively through apps and wearables or by direct engagement between patient and providers.
7. Identifying potential **living donor** candidates – IT platform will allow for the registration on living donor registries, such as the National Kidney Registry (NKR).

In consultation with subject-matter experts and through an extensive literature review, OmniLife designed and defined the platform implementation strategy to complement CMS seven steps to transplant defined above. This IT platform can bridge communication and data sharing gaps among the CKD/ESRD network of care providers; nephrology practices, dialysis units, and transplant centers. Bi-directional and timely communication, data sharing, and interoperability are required of this network to adequately support the seven steps to transplant at a patient level.

- **Nephrology** practices - caring for late-stage CKD patients who would benefit from early transplant referral toward the end of increasing pre-emptive transplants.
- **Dialysis** units - track all their patients based on Tx candidacy status, standardized Tx education, executed Tx referrals (date), why they are not a candidate if they aren't, real-time status in the evaluation process, and when they are waitlisted (date), as well as ability to track waitlisted patient.
- **Transplant** center - timely bi-directional communication and data sharing allow better and timely decisions regarding candidacy, transplantation, and adherence.

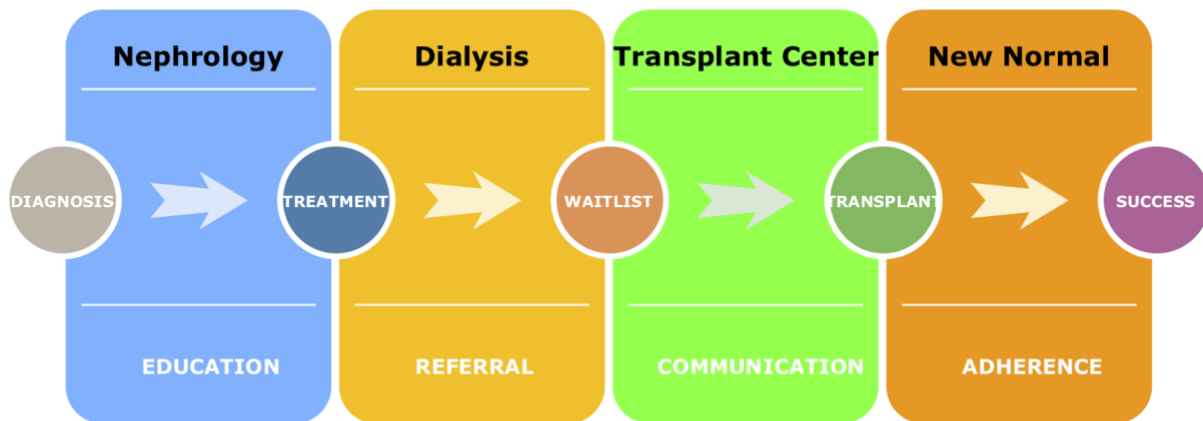


Figure 1. This figure is an simplified illustration of the ESKD provider care network. The figure depicts a sequential and siloed process, but we know that this progression is not sequential or siloed. This process requires many bidirectional communication channels, data transfers, interoperability, referral networks, and coordination among these providers. Especially in the case of preemptive transplantation, dialysis may be skipped. Education and communication are needed throughout.

Many useful IT solutions exist in isolation for each provider. An IT platform facilitating interoperability allow the network of ESKD providers to leverage these innovations and data that were previously isolated. The Health IT companies XYNManagement, MedAmica, and OmniLife operate successfully within the provider network, each providing value to patients and providers.

XYNManagement founded by David Axelrod, MD, Mark Schnitzler, Ph.D., Krista Lentine, MD, Ph.D, and Jennifer Milton, RN, MBA. The leaders of Xyn are recognized within the transplant sphere as innovators in health economic analysis, business practice and leadership, living donation (Dr. Lentine directed the recent KDIGO international guideline development), and QAPI assessment. The company includes expertise in transplant surgery, medicine, quality enhancement, administration. XYNManagement provide IT and direct client service to transplant programs and candidates to improve waitlist management/readiness, increase transplant quality, and improve dialysis to transplant transitions.

MedAmica, founded by Nick Jones, improves patient medical adherence after organ transplantation. Automated direct messaging to patient with reminders, education, and updated regimen with guardian/caregiver “buddy” reinforcement and accountability can mitigate graft loss due to non-adherence. Especially relevant for pediatric and adolescent patients. MedAmica enables the patient to create a personal and confidential real-time reminder schedule of medications. MedAmica prompts the patient to take each medication. MedAmica is available for mobile technologies and can be integrated into patient’s daily activities. The patient must confirm that he/she has taken each medication or explain why not. In addition, patients are supported in adherence by messages to a nominated "buddy" when he/she skips a medication or are overdue with critical anti-rejection medications.

OmniLife, previous products improve “day of transplant” communication (**TXP Chat™**) and decision support (**Ask Alan™**). **Phase I** - TXP Chat HIPAA compliant messaging mobile app for the timely coordination of organ procurement and transplantation. OmniLife’s first customers were Iowa Donor Network, Iowa Methodist Transplant Center Des Moines, and the University of Iowa Transplant Center. OmniLife was supported from Aug. 2017 - Sept. 2018 by a Phase I Small Business Innovative Research (SBIR) grant sponsored by the National Institutes of Health (NIH) National Library of Medicine (NLM). OmniLife successfully completed the aims of the Phase I study, presented the results at the American Society of Transplantation (AST) Cutting Edge of Transplantation (CEoT) and the American Society of Transplant Surgeons (ASTS) Winter Symposium conferences. Use of TXP Chat was correlated with a 35% increase of kidneys transplanted, and a reduction of 10 hours (50%) of organ offer evaluation time (time from initial offer to transplant). Results, as presented to AST and ASTS, are available here: https://info.omnilife.ai/hubfs/20190110-ericpahl-PhaseI-ASTS-Poster_final.pdf. The company is in the process of submitting the research and results for publishing in an academic journal, the American Journal of Transplantation (AJT). **Phase II** - Clinical Decision Support (CDS), Ask Alan, supporting the transplantation of additional deceased donor kidneys that may be at risk of discard. OmniLife has developed a machine learning infrastructure to deploy Ask Alan on TXP Chat for real-time CDS. The Phase II SBIR grant was submitted on January 05, 2019 to NIH (NIDDK/NLM). The Phase II study includes a randomized control trial where deceased donor kidney offers are evaluated with Ask Alan in real-time or without. According to our preliminary research, we hypothesize that up to 26% increase in kidney acceptance for transplantation with Ask Alan. Laboratory results, as presented to AST and ASTS, are available here: https://info.omnilife.ai/hubfs/20190110-ericpahl-PredictingDDKT-ASTS-Poster_final.pdf. The paper is currently under review with the academic journal, Transplantation International (TI).

The proposed IT platform permits data informing pertinent quality metrics to be gathered, collated and tracked for all end-users. The most recent iteration of CMS Conditions for Coverage includes a transplant based metric applicable to dialysis facilities, the Percentage of Prevalent Patients Waitlisted (PPPW). The IT platform will allow facilities to track their PPPW rates in real time. In addition to the PPPW, the IT platform will offer a novel tool dialysis facility can use to design and implement quality improvement projects around all steps of transplantation. Transplant centers can also make use of the IT platform to inform quality improvement projects around waitlist criteria and waitlist management. Nephrology practices can make use of the IT platform to actualize population-health level tracking the transplant education, referral, evaluation and listing of prevalent patients with advanced CKD.

Technical Requirements

1. Active on the federally certified Health IT product list.⁸
2. Linked to a patient record with unique patient identifier (UPI).
3. Facilitates instant and bi-directional communication capabilities among the patients, payers, providers, and other Health IT systems:
 1. Videos/Pictures/Files/Medical Imaging

⁸ <https://chpl.healthit.gov>

2. Recorded audio and video calls
3. Text messaging
4. Customizable Notifications
5. Delivered/Read receipts
6. Acknowledgement emojis
7. Patient record data fields (e.g. Seven Steps to Transplant, Labs, order entry, test results, evaluation results)

Request that CMMI fund a demonstration project “IT Platform for Expanded CEC” that includes organ Tx with Metrics and IT infrastructure/platform to support the communication and coordination of the patients and providers in the network. The OmniLife platform provides the infrastructure supporting all technical requirements above, including an upcoming interface with BlueButton 2.0. OmniLife leverages existing partnerships with XYN and MedAmica to accelerate implementation throughout the provider network. Existing centers and dialysis units are already customers of XYN and OmniLife can be implemented relatively quickly. **Aim 1:** implement the IT platform among an ESRD care provider network. **Aim 2:** reduce cost of care for patient population through better coordination of patients among treatment providers.

OmniLife was founded in the Spring of 2016 and has had commercial products deployed in the organ transplantation arena since Summer 2017. The company has received more than \$2.5M in investment from private and public sources and recruited a team of world-class experts and thought leaders in organ transplantation and business development. We have two passionate and energetic founders, Dalton Shaul CEO and Eric Pahl CTO, that were intimately affected by organ transplantation. Dalton, a former D1 football player, received a nerve transplant curing his arm of permanent paralysis. Eric, a Ph.D. candidate in Health Informatics (machine learning for organ transplantation), has three aunts suffering from organ failure in need of replacement. Our company is backed by private investment led by Dr. Manny Villafana, our Board Chair, who was the Founder of St. Jude Medical and 7+ other medical device companies started from scratch and taken public. We have thoracic and abdominal transplant experts that have personally invested and direct the medical aspects of the company; Drs. Alan Reed, David Axelrod, Ben Hippen, Karl Welke, and Robert Emery. Additionally, we have leaders in medical informatics, computer science, and engineering; Drs. Hans Johnson, Nick Street, and Nick Jones. The OmniLife business operations are coordinated by an experienced management team led by Cindy Edge, former IT executive at Rockwell Collins with more than 30 years of experience.