## Important update to users of Buckeye Transplant Services

## **Update 7/20/2023**

Issues relating to Buckeye Transplant Services' access to the OPTN computer system to go to arbitration

Buckeye Transplant Services has voluntarily dismissed its federal lawsuit against UNOS in favor of binding arbitration between Buckeye and UNOS to resolve the issues that remain in dispute.

We maintain our position that all OPTN members have certain obligations to obtain and manage OPTN data responsibly. These same responsibilities apply to any vendor the member chooses to use to manage parts of the transplant match or for data reporting.

Regardless of the outcome of arbitration, no transplant program, or an OPO acting on a program's behalf, will experience any interruptions in receiving organ offers according to OPTN policy.

We will continue to share information as it becomes available. If you have questions in the meantime, please contact the Help Desk at (800) 978-4334, or email unethelpdesk@unos.org.

## **Statement 7/7/2023**

## **OPTN statement concerning Buckeye Transplant Services**

Protecting the security of patient and donor data is of paramount importance to United Network for Organ Sharing (UNOS), the Health Resources and Services and Administration (HRSA), and the entire organ donation and transplantation system, including patients and families across the country.

While there has been media attention and discussion about our investigation into data use by Buckeye Transplant services, a third-party vendor providing services to some members of the transplant community, we want to state unequivocally that no transplant program, or organ procurement organization (OPO) acting on a program's behalf, will experience any interruptions receiving organ offers as a result of this investigation.

As part of UNOS' role as the Organ Procurement and Transplantation Network (OPTN) under contract with the federal government, we have a responsibility to ensure the privacy and integrity of donor and patient data maintained in the OPTN computer system. All OPTN members, including transplant hospitals and OPOs, must meet OPTN obligations in order to access OPTN systems and data. These same OPTN responsibilities apply to any vendor an OPTN member chooses to work with.

Buckeye Transplant Services recently developed and currently uses two automated tools to access OPTN data on behalf of its clients. These automated tools enable Buckeye to accumulate OPTN data without a Terms of Use agreement or OPTN oversight.

Both HRSA and UNOS are extremely concerned that these tools provide Buckeye with unauthorized access to OPTN data of vulnerable patients and donors; this is data that every authorized OPTN member and their authorized vendors can access through a secure process provided free-of-charge by the OPTN. This is the same process Buckeye utilized prior to developing and deploying its automated tools without giving notice to or seeking

authorization from HRSA or the OPTN. The use of these automated tools without permission violates the UNOS Systems Terms of Use that all users agree to follow.

Following the discovery of these automated tools and at HRSA's direction, UNOS requested Buckeye cease using these tools on June 21, that Buckeye use the established OPTN systems to access OPTN data\* like all other users, and that they comply by July 5. On July 3, Buckeye chose instead to file a suit against UNOS in federal court. We have since deferred any follow-up action for at least two weeks to allow the court an appropriate amount of time to consider Buckeye's request. During that time, we will continue to work with Buckeye to seek an acceptable solution.

The suit alleges that UNOS misinterpreted its own Systems Terms of Use and that Buckeye deserves unrestricted access to OPTN data once they receive authorization from their clients. We disagree with Buckeye's interpretation and throughout our investigation, HRSA has made it clear it expects UNOS to take all necessary steps to secure OPTN data against this unauthorized use.

At this point, no specific action related to Buckeye Transplant Services' access to the OPTN computer system has been put into place.

We are in contact with all OPTN members who contract with third-party vendors. We have reminded OPTN members that they should have alternate options in place for screening organ offers, in case a vendor is unable to provide service for any reason.

\*The OPTN Final Rule states: "The OPTN, as appropriate, shall provide data to an OPTN member, without charge, that has been assembled, stored, or transformed from data originally supplied by that member."

The OPTN- and HRSA-approved method for members or vendors acting on their behalf to obtain a copy of the patient-identified data the member submitted to the OPTN is to submit a data request to the OPTN. Any vendor would also include documentation that the member(s) has granted them the proper authority to obtain the data the member submitted to the OPTN. The OPTN will then create and provide a report with automated recurring delivery. UNOS uses this same OPTN data request process to obtain the data we use to produce tools we provide to members outside of the OPTN contract. This process provides government oversight and helps protect the security and integrity of OPTN data.

To obtain a copy of the patient-identified data that members submit to the OPTN, members or vendors acting on their behalf must, according to UNOS Systems Terms of Use:

- Submit an OPTN data request
- Include proper documentation if a third-party vendor is submitting the request on an OPTN member's behalf

This OPTN- and HRSA-approved process provides government oversight and helps protect the security and integrity of OPTN data.

UNOS, like all OPTN members, is also required to use this process to obtain data for tools we provide to
members outside of the OPTN contract.