**Carolina Donor Services Concerns with CMS Proposed Rule Metrics**

We support the intent of the President's Executive Order on Advancing American Kidney Health (Executive Order) of improving America's transplant system; however, we have three major concerns with the CMS proposed rule's metrics for organ procurement organizations. The proposed rule is found here.

## What This Means to North Carolina

**If passed unchanged, the unintended consequences** of the CMS proposed metrics would be **devastating to the current North Carolina donation and transplant system**. In fact:

- There would be **immediate destabilization of the organ donation and recovery process.**
- The destabilization will cause fewer organ donors resulting in more deaths of North Carolina men, women, and children **waiting for organ transplants.**
- **The public trust** in the donation system that has taken decades to establish **would be shattered.**
- **Strong relationships** with eye banks, tissue banks, over 100 donor hospitals, five transplant centers, 125 DMVs, approximately 500 funeral homes, and hundreds of North Carolina donor families **will cease to exist**.
- Up to 75% of the existing 58 organ procurement organizations, including Carolina Donor Services could close.

## Rational for the Three Concerns

### Performance threshold based on flawed data that is not reflective of potential donor health issues, including chronic issues that impact the health of donor organs.

The proposed CMS metrics would base performance thresholds on several arbitrary and unreasonable factors that are outside the control of organ procurement organizations. Areas with healthy populations are compared to areas that struggle with higher rates of illness and chronic diseases.

The diabetes rates in North Carolina and across the southeast region of the United States are above the national average. According to American Diabetes Association 2020 Statistics, approximately 11.3% of the adult population in North Carolina, have diagnosed diabetes and 34.6% of the adult population have prediabetes. Other common health risk factors in North Carolina include very high hypertension, stroke, and obesity rates. In 2018, the United Network for Organ Sharing (UNOS) established clusters of OPOs with similar qualities. North Carolina is clustered with Alabama, Georgia, Louisiana, Mississippi, South Carolina, and the Memphis, TN area. According to the data set modeled in the proposed rule, all of these highly vulnerable populations would suffer the instability of the decertification of their organ procurement organization.

Additionally, organ procurement organizations cannot control health factors that limit the viability of organs transplanted and the likelihood of transplant centers accepting the organs from medically complex and unhealthy donors.

### Use of inaccurate death certificates

Death certificate data alone, in a non-COVID-19 environment, are flawed and there are quality issues. Unfortunately, states are compared to each other. North Carolina is one of a few states that has an antiquated paper-based system that flows through many organizations and countless people, including the hospital, physician, funeral home, and state Vital Records staff. The data reported to CDC is preliminary and is updated throughout the year. Typically, North Carolina death certificates are finalized **nine to 20 months after** the day of death and there is a high probability of inaccuracies.

### Redundancy with the Organ Transplant and Organ Donation Metrics

It is proposed that organ procurement organizations be measured on both Organ Transplant and Organ Donation Metrics. This too is flawed because both share the same denominator, i.e. a calculation of donor potential based on death certificates. Both metrics measure the same thing and in effect there is **only one OPO performance measure not two.**