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Dear Dr. DeSalvo:

On behalf of the nation's 58 federally certified organ procurement organizations (OPOs) serving every hospital in the U.S. with a ventilator and operating room, this Association of Organ Procurement Organizations (AOPO) response to the Federal Health IT Strategic Plan 2015-2020 is offered so that the issues we raise will find mention and inclusion in the final document. Collectively, OPOs serve nearly 5,200 Acute Care Hospitals and coordinate organ donation from more than 8,000 deceased donors each year resulting in the transplant of more than 20,000 patients. The number of EHRs related to all death referrals reviewed by the OPOs more than doubles that figure. Additionally, the number of EHRs reviewed and donations coordinated by tissue and eye banks far exceeds this number. The expedience and safety demanded of our nation's organ and tissue donation system requires that the items below be addressed.

Increasing the availability of organs for transplantation is a long standing national priority and legislative, regulatory and advisory bodies continue to advocate for process improvements of this vital national resource. Public Law 98-507, The National Organ Transplant Act (NOTA), October 19, 1984 is the enabling legislation establishing the Organ Procurement and Transplantation Network (OPTN) and the Organ Procurement Organization structure. The Uniform Anatomical Gift Act, revised 2006, facilitates the gifting of organs for transplantation.

Hospital responsibilities for facilitating donation are outlined at 42 CFR 482.45 - Condition of participation: Organ, tissue, and eye procurement. These regulations demonstrate the importance of hospital collaboration with OPOs and define rules for hospital participation in enhancing donation. OPOs' responsibilities are similarly addressed at 42 CFR 486.301-348 - Requirements for Certification and Designation and Conditions for Coverage: Organ Procurement Organizations.

Donation as a national priority is further demonstrated through the U.S. Department of Health and Human Services Advisory Committee on Organ Transplantation, a body established with the goal of enhancing organ donation.

The information contained in a patient's health records is essential to identifying potential life-saving organ donors and acts as a foundational support to an OPO's ability to successfully coordinate medical services to see that donation and subsequently life-saving transplantation come to fruition. This access to, and interaction with, EHRs is also essential to patient safety to ensure immunosuppressed recipients are not exposed to harmful risks that might have been discovered or identified beforehand due to incomplete or restricted access to the EHR.

Everything we recommend in this document is directed toward ensuring that access and ability to interact with patient records for OPOs in this new electronic record paradigm mirrors the same scope of access and ability to interact with those records that were successfully utilized for decades in the paper and pen era.

We have previously conversed with the ONC leadership on two occasions and documented global access and interoperability problems that we have encountered since EHR's came to the fore (see the AOPO's 2014 EMR White Paper on this topic at <http://www.aopo.org/aopo-public-statements/>) A review of this document would be beneficial prior to reviewing our recommendations below, where specific proposed language is provided in red.

Strategic Goals, Objectives and Strategies

RECOMMENDATION: Page 5 - Include specific mention of organ procurement organizations, eye banks and tissue banks in the paragraph that broadens the term “providers”, only for the purposes of the Strategic Plan. Perhaps this inclusion of the OPOs et al can follow the ESRD dialysis facilities mentioned. “...- including for example, acute and ambulatory care, long-term services and supports, post-acute care, behavioral health, emergency medical services, home health, oral health, and end-stage disease dialysis facilities, **organ procurement organizations, eye banks and tissue banks**, pharmacies, laboratories, and public health entities.”

FEDERAL HEALTH IT PRINCIPLES

RECOMMENDATION: Page 7 – “**Respect individual preferences.** Person-centered care embraces the value of the individual inside and outside the health system, where all entities honor individuals’ privacy, needs, values, and choices regarding their information, health care **and decisions regarding organ and tissue donation.**”

Goal 1: Expand Adoption of Health IT

Specifically mentioning OPOs within this goal perfectly meshes the need for sharable use of health information both from the hospital record itself as well as with the requirement that OPOs subsequently be able to send the same health information to the national organ procurement and transplantation network where donors and potential/actual recipients are “matched”. That information then becomes available to physicians and surgeons at the transplant centers to review and approve organ(s) to be used for their patients. This information-gathering process includes the use of portable devices by the OPO, the ability to download relevant hospital EHR information, and long distance/remote access to the hospital’s EHRs.

RECOMMENDATION: Page 9 – “The HITECH Act intended to accelerate the adoption and use of health IT. The HITECH Act authorized CMS to provide financial incentives to eligible hospitals, Critical Access Hospitals, and eligible professionals to adopt and meaningfully use certified EHR technology to improve patient care.

“Incentive payments dramatically accelerated broad use of EHRs by hospitals and providers. However, gaps and challenges remain for nationwide health IT use.”

“This goal aims to expand health IT adoption and use efforts across the care continuum, emphasizing assistance for health care providers serving long-term and post-acute care, behavioral health, **Public Interest and Benefit Activities including the 12 national priority purposes**, community-based, and other populations ineligible to participate in the Medicare and Medicaid EHR Incentives Programs. In

addition, this goal aims to expand the adoption and use of a broader set of technologies, including telehealth and mobile health.

“Digitizing health information collection allows for easier, appropriate sharing of that high-quality, accurate, and relevant information to connect care and empower individuals to manage their health and well-being.”

Objective 1A: Increase the adoption and effective use of health IT products, systems, and services

As stated in the plan, “It is important to capture electronic health information from all sources in order to obtain a more complete picture of overall health.” This is essential to OPOs and transplant centers in order to provide safe and effective biological “gifts” to immunosuppressed recipients and that means the OPO staff must have timely, unfettered and unrestricted access to the entire EHR of every prospective donor.

RECOMMENDATION: Page 10, Strategy 5 – We recommend that the ONC include comprehensive OPO access to EHRs as well as hospital EHRs achieving meaningful interoperability with OPO EHRs as a part of the ONC HIT Certification Program.

Goal 2: Advance Secure and Interoperable Health Information

Objective 2A: Enable individuals, providers, and public health entities to securely send, receive, find, and use electronic health information

“Since the passage of the HITECH Act, certain types of health information exchange and use among providers have increased; however, gaps and challenges remain for widespread secure and interoperable health information across health care and long-term supports and services providers, settings of care, individuals, health IT platforms, and payers.”

RECOMMENDATION: Page 14 - “Interoperable exchange of health information allows individuals, providers, public health departments, **organ, tissue and eye recovery organizations** and payers to find, securely exchange, and use vital health information, enhancing care delivery, public health, and research, and empowering individuals to make informed choices regarding their health **and decisions regarding organ and tissue donation.** “

RECOMMENDATION: Page 14, Strategy 4 - “Ensure health IT products and services support the privacy, technical, and vocabulary standards necessary for capturing, finding, exchanging, and using standard health information across the health care and long-term services and supports continuum, and with individuals, **organ procurement organizations** and public health entities .”

Objective 2C: Protect the privacy and security of health information

Many hospital IT departments, information officers, and privacy officers unfamiliar with hospital/OPO practices that have existed for decades, create access and security systems that effectively block or retard timely, effective access to EHRs, without which, organ donation and transplantation patient safety is potentially compromised.

This Objective should include a statement that privacy concerns and the security of health information must be reasonably balanced against needed, authorized, streamlined access and the interoperable-use goals as they apply to all users, including federally-designated OPOs; all of whom serve the many hospitals within their federally designated service area.

RECOMMENDATION: Page 16, Strategy 2 – “Continue development, **revision**, administration and enforcement of federal privacy and security regulations and standards for HIPAA-covered entities,

business associates and Public Interest and Benefit Activities including the 12 national priority purposes.”

Goal 3: Strengthen Health Care Delivery

“This goal and respective objectives aligns with multiple national strategies to improve specific components of health and health care, including quality, prevention, disparities reduction, health security, and safety. The Plan aims to remain flexible in its strategic actions and tactics to allow agencies engaged in achieving these aims to test and experiment various approaches so the public can derive the most benefit from federal policy and programs and align with state, local and private efforts.

“Expanded use of health IT that combines decision supports and quality measures will allow the nation to achieve continuous quality improvement and important health outcomes, including aiding in the prevention of chronic and debilitating disease, making care safer and more person-centered, and assisting communities in promoting wellness and continuity of care, particularly for their most vulnerable individuals.”

Objective 3B: Support the delivery of high-value health care

“Advance multi-source data integration, innovative data use agreements, open data sources, and reliable connectivity and computational power to connect care across time, geography, and appropriate users of health information”

RECOMMENDATION: Page 19, Strategy 5 - The Donor Hospital/OPO/Transplant Center model captures the absolute essence of this Goal and its attendant Strategy 5 in its purest form in every donor case - “Advance multi-source data integration, innovative data use agreements, open data sources, and reliable connectivity and computational power **to connect care across time, geography, and appropriate users of health information** (emphasis added)”. The care of the patient by the original hospital turns into the care of the donor at that same hospital by the OPO then directly transforms to the care of the recipients of the donated gifts at other disparate (and frequently distant) hospitals. **We recommend** the OPO community be closely connected and engaged to both 3 year Outcomes, with CMS and HRSA support, to ensure “the delivery of high-value health care” is achieved. This will also aid in aligning CMS’ “conditions” for both hospitals and OPOs as well as HRSA’s requirements of, and guidelines for, OPOs and transplant centers.

Goal 5: Advance Research, Scientific Knowledge, and Innovation

RECOMMENDATION: Page 24 - Add the following paragraph:

“Electronic health data can improve the process of assuring organ and tissue donation possibilities are fully realized knowing that all relevant information is acquired and shared in a timely, comprehensive and accurate way to prevent disease transmission and enhance the integrity of a biologically compatible lifesaving gift.”

Sincerely,



G. Kent Holloway
AOPO President