



June 22, 2021

The Honorable Chaquita Brooks-LaSure
Administrator
Center for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building
200 Independence Ave., SW
Washington, DC 20201

Dear Administrator Brooks-LaSure:

On behalf of the National Disease Research Interchange (NDRI), we write to communicate our serious concern regarding the Center for Medicare & Medicaid Services (CMS) Hospital Inpatient Prospective Payment Systems (IPPS) for Acute Care Hospitals and the Long Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2022 Rates Proposed Rule – that would dramatically discourage the use (or acquisition) of human tissues for biomedical research and stifle medical breakthroughs.

Funded in part by the National Institutes of Health (NIH) for more than thirty consecutive years, NDRI's mission is the procurement and distribution of human organs and tissues from a diverse pool of normal and diseased donors to support the advancement of biomedical research. As a not-for-profit 501 (c) (3) organization, NDRI is recognized as a world leader in providing critical infrastructure resources to scientists to advance discovery across the full range of disease and disability. We interface with thousands of scientists in government, academia, industry and philanthropy whose research success is dependent on timely and affordable access to human organs for research.

Under the current rule, Medicare covers certain donor-related costs such as testing, hospitalization, or operating room costs. Under the proposed rule, CMS would no longer recognize organs intended for research as counting toward Medicare organ acquisition costs and would apportion these significant costs to research organs, lowering the costs recoverable by transplant centers and other organ procurement entities. This change would shift organ and donor acquisition costs to research organizations in the form of significantly higher acquisition fees for research organs.

It is impossible to overstate the importance of research organs as a vital resource to investigators. Progress with underlying etiology in addition to discovery and testing of treatments and cures for disease depends on the availability and accessibility of organs for research.

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NDRI is honored to serve as a resource for scientists who are performing cutting-edge research that requires access to organs. Some examples are noted below:

- ***Developing novel techniques to improve liver transplantation rates:*** The availability of human livers for transplant remains a significant public health need. Investigators are developing methods to enhance the function of damaged donor livers not suitable for transplant, such as by machine perfusion and other regenerative techniques, that would increase the donor pool qualified for life-saving liver transplants.
- ***Understanding the underlying biology in kidney cells, with the goal of developing drugs to treat kidney diseases.*** Investigators are looking at various cellular processes and how disruption in the function of key mechanisms has an impact on cellular functions in order to learn how individual cellular functions can cause kidney disease, as well as how to interrupt these functions to prevent kidney disease.
- ***Advancing therapeutics for pulmonary disease:*** Investigators using advanced molecular and imaging methodologies are working to create an atlas of gene and protein expression in the lung to understand mechanisms of lung development and regeneration as a resource for the research community and public education tool. Understanding the development of the lung will aid in the development of novel treatments for diseases of the lung that develop early in life, such as childhood asthma, or following infection with pathogens, such as the respiratory syncytial virus (RSV) or the SARS-CoV-2 virus.
- ***Facilitating the development of therapeutics capable of preventing or reversing Type-1 diabetes:*** The pathogenic origin of Type-1 diabetes is still unknown, making a cure for the disease elusive. Investigators require pancreata and immunological organs from non-diseased and Type-1 diabetic organ donors to identify a variety of immunologic, metabolic, genetic, and environmental factors contributing to the disease that can be used to uncover strategies for a cure.
- ***Identifying effective non-opioid pain therapeutics:*** Chronic pain is a significant health burden in the US, costing the US healthcare system hundreds of billions of dollars a year. Current pain treatments are limited in effectiveness and highly addictive, contributing to the current opioid epidemic. Dorsal root ganglia, the site of peripheral neurons involved in pain transmission, isolated from organ donors are an essential resource for investigators seeking to identify effective drug candidates for patients suffering from chronic pain. Access to dorsal root ganglia enhances the speed at which alternative, non-opioid drug candidates can be identified.
- ***Enhancing the efficacy and safety of drugs on human donor hearts for use during the pre-clinical stage to avoid placing patients at risk during clinical trials.*** The full development of these methodologies will greatly improve the selection of the safest and most effective compounds for clinical development, which will result in faster and more efficient drugs to patients at a lower cost. Given that the animal models used by the industry in the past have proven to be inaccurate and non-predictive of drug toxicity in humans, the human heart-based studies conducted by investigators are being evaluated by the FDA for the possible adoption as the gold standard in pre-clinical safety assessment.

These examples are only a sub-set of the critical, groundbreaking research efforts that NDRI supports through our partnership with organ procurement organizations. As experimental methodologies advance and the pathway for scientists to translate their findings from the bench to the bedside accelerates, the need for access to human organs will continue to grow and be an essential component of future therapeutic development across the spectrum of disease.

The proposed CMS rule change has the potential to stifle advancement of biomedical research and erode our nation's preeminent standing as the world leader in research by limiting the availability and affordability of research organs. Further, while research organs are not used for transplantation purposes, their use for research provides a tangible benefit to Medicare beneficiaries – one of the communities likely to receive the greatest benefits from groundbreaking medical research. This proposed rule change is a direct contradiction to the Biden Administration's commitment to advancing medical research.

We know that most research programs operate with limited resources, particularly those in government and academia. If the proposed rule is finalized as currently written, we anticipate that access to affordable research organs will greatly decrease, thus slowing discovery in vital areas of medical research.

We respectfully urge CMS in the strongest possible terms not to finalize this proposed rule change as currently drafted.

Sincerely,



Bill Leinweber
President and CEO



Mary J.C. Hendrix, PhD
Chair of the Board of Directors