Sanofi US ("Sanofi") appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services'(CMS) 2025 Measures Under Consideration (MUC) List.

Sanofi brings together world-class research and development in pursuit of leading health care solutions that serve several major therapeutic areas including vaccines, diabetes, chronic kidney disease, multiple sclerosis, cardiovascular disease, oncology, rare diseases, immunology, hemophilia, and over-the-counter (OTC) products. We are committed to discovering, developing, and making available to patients and their treating physicians innovative, effective, well tolerated, and high-quality treatments that fulfill vital health care needs.

Sanofi supports the Dialysis Facility Discussion of Patient Life Goals (PaLS) measure and its inclusion on the 2025 CMS Measures Under Consideration (MUC) list. We believe this measure would promote essential discussions between dialysis patients and care teams, ultimately improving goal-concordant treatment planning and outcomes.

As we have commented previously in response to the Request for Information: Health and Safety Requirements for Transplant Programs, Organ Procurement Organizations, and End-Stage Renal Disease Facilities (RFI) and the Alternative Payment Model Updates and the Increasing Organ Transplant Access (IOTA) Model, we recognize the immense value that kidney transplantation brings to patients suffering from kidney disease, including improved quality of life, enhanced survival rates, and reduced healthcare system costs. Outcomes from kidney transplants for patients with kidney disease can include better quality of life, higher survival rates, and lower healthcare system costs, but not enough patients are receiving transplants.

While we support the measure as proposed, we believe it can be strengthened to better serve patients by ensuring comprehensive discussion of all treatment modalities. Sanofi believes that life goals discussions must explicitly include transplant evaluation and pursuit as a core option, given overwhelming evidence of superior long-term survival, quality of life, and cost-effectiveness versus maintenance dialysis.1 We recommend revising survey items or instructions to prompt patients on whether care teams discussed transplant waitlisting and living donor identification. This ensures the measure captures comprehensive shared decision-making, not just dialysis-centric planning.

When finalized for End-Stage Renal Disease Quality Incentive Program (ESRD QIP), we urge CMS to require nephrologist involvement in survey administration protocols—

[1] Schold, Jesse D.; Mohan, Sumit; Huml, Anne; Buccini, Laura D.; Sedor, John R.; Augustine, Joshua J.; Poggio, Emilio D. Failure to Advance Access to Kidney Transplantation over Two Decades in the United States. JASN 32(4):p 913-926, April 2021. | DOI: 10.1681/ASN.2020060888

either directly during clinic visits or via pre-survey education on transplant pathways. Nephrologists, as transplant referral gatekeepers, can contextualize life goals around modality options, boosting response accuracy and actionability. Third-party vendors should coordinate with nephrology teams to maximize clinical impact.

We appreciate CMS's leadership in advancing patient-reported outcomes (PROs) and patient-centered care. We look forward to continued engagement and collaboration in pursuit of our shared goal of enhancing patient outcomes and advancing healthcare excellence.

Sincerely,

/s/

Emily Ahrens
Lead, Federal Reimbursement