



August 3, 2020

President Donald Trump
The White House
1600 Pennsylvania Avenue NW
Washington, DC 20500

President Trump:

I am writing today to urge you to complete your administration's historic regulatory victory and lead your White House team and the Office of Management and Budget (OMB) in a speedy review and release of new, final rules reforming the Stark Law and Anti-Kickback Statute (AKS) regulations. These rules were delivered to OMB on July 21, 2020 and are the product of significant public input, insight and feedback from healthcare industry leaders, and an extensive notice and rulemaking process that began with an initial Request for Information in 2018. I am concerned that, unless these are finalized promptly, that the hard work of your agencies – and the benefits these updated rules would provide – will be lost.

As The Global Epicenter of Health Innovation and Care™, Medical Alley is home to world-leading care providers, payers, and health technology organizations that have been a driving force in the move to value-based care – no doubt a significant factor in your administration's selection of Minnesota (home to Medical Alley) as the location to formally announce the release of the draft rules here, in October 2019.

Organizations throughout Medical Alley are already collaborating to create value-based arrangements that improve outcomes for patients while simultaneously lowering costs. Medical Alley organizations are taking a leadership position in the efficiency of delivering the highest quality care with the appropriately aligned incentives. These proposed regulations will allow agreements like many developing in Medical Alley to become a new standard for healthcare's future, driving value and collaboration.

The Stark Law and Anti-Kickback Statute are designed around one thing: prohibiting improper influence and self-dealing in determining a patient's course of care. While well intended, these regulations are rapidly becoming inhibitors to realizing a healthcare system based on value, rather than the outdated system based on a fee for service model. The improvements proposed by the Centers for Medicare & Medicare Services (CMS) and Office of Inspector General (OIG) retains the prohibitions on true self-dealing, but provides empowers multi-party value based arrangements that will enable patients to receive the best care possible, at a lower cost. Your administration was right to recognize the need for these regulations to be modernized and now needs to ensure these updated rules are implemented.

On behalf of the Medical Alley Association, I appreciate the opportunity to share these comments with you today and respectfully request your support in efficiently finalizing

these rules so that patients in Medical Alley, and throughout the world, will be able to access the best care at a lower cost.

Sincerely,

A handwritten signature in blue ink, appearing to read 'Shaye Mandle', written in a cursive style.

Shaye Mandle
President & CEO
The Medical Alley Association

cc: Russell Vought, Director, Office of Management and Budget