First Draft

[DATE]

VIA _____

The Honorable Donald J. Trump
President of the United States
The White House
1600 Pennsylvania Avenue, NW
Washington, DC 20500
Re: A Significant Deregulatory Achievement by the Trump Administration

Dear Mr. President:

The signatories to this letter represent many of the largest health care organizations and employers in the United States.

We are writing to thank you for leading the way to a potentially historic deregulatory victory. All that remains to cement this victory is for you and your White House team to lead the Office of Management and Budget (OMB) in a speedy review and release of new, final rules that the Department of Health & Human Services (HHS) delivered to OMB on July 21, 2020.[1] Under your leadership, HHS has undertaken a "regulatory sprint to coordinated care" that will modernize outdated rules which create unnecessary costs and impair collaboration in healthcare. With the completion of this important work so close at hand, a single word from you would lift your team across the finish line.

We refer to the Centers for Medicare & Medicaid Services (CMS) and Office of Inspector General (OIG) proposed reforms to the Stark Law and Anti-Kickback Statute (AKS) regulations. These improvements will foster collaboration and innovation among healthcare stakeholders, allowing hospitals, physicians, healthcare manufacturers and others to deliver better care at lower cost. The Stark Law and AKS are based on a very sensible premise, which is that the care that health providers deliver should be based strictly on the needs of the patient and should not be improperly influenced by financial considerations or self-interest. However, in many respects, the Stark Law and AKS have failed to keep up with the times. Built for a delivery and payment system that is compensated on a fee for service basis, they do not serve well in a system that is increasingly focused on coordination and payment for value. Your Administration recognized that the time had come to modernize and reform the regulations that implement these laws.

[1] The AKS rules are designated as RIN 0936-AA10 and are titled "Revisions to the Safe Harbors Under the Anti-Kickback Statute and Beneficiary Inducements Civil Monetary Penalties Rules Regarding Beneficiary Inducement." The Stark rules are designated as RIN 0938-AT64 and are titled "Modernizing and Clarifying the Physician Self-Referral Regulations (CMS-1720).

In reforming these regulations, your teams at HHS, CMS and OIG have taken a commendably broad-based approach, seeking input repeatedly from healthcare leaders and the public. There have been roundtables and opportunities for informal public input, as well as the formal and extensive notice and comment rulemaking process. The process included detailed responses by the public to Requests for Information in 2018. The rules were first proposed in October 2019 and the comment period closed at the end of the year, leaving ample time for thorough deliberation by HHS and OMB.

We respectfully ask for your support so that these rules can be promptly finalized and victory can be claimed in the name of helping patients get better coordinated care and reducing overall healthcare costs. We are especially concerned that without your timely support, the hard work of the agency and the significant benefits of these reforms will be lost.

Sincerely,