

August 5, 2020

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, life sciences companies 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.<sup>1</sup> Under your leadership, HHS has undertaken a “regulatory sprint to coordinated care” that will modernize outdated rules which create unnecessary costs and impair collaboration in healthcare.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.

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

---

<sup>1</sup> 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).”

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,

Advanced Medical Technology Association (AdvaMed)  
AdventHealth  
Adventist Health  
Adventist HealthCare  
Advocate Aurora Health  
Alaska Brain Injury Network  
American Association of Hip and Knee Surgeons  
American Association of Neurological Surgeons  
American Health Quality Association  
AmerisourceBergen  
AMITA Health  
AnMed Health  
Ascension  
Aultman Health Foundation  
Avera Health  
Ballad Health  
Banner Health  
Baptist Health  
Baptist Healthcare System  
BayCare Health System  
Biogen  
Bon Secours Mercy Health  
California Chronic Care Coalition  
California Hepatitis C Task Force  
California Life Sciences Association (CLSA)  
Cancer Treatment Centers of America  
Capstone Health Alliance  
Cedars-Sinai Health System  
The Center for Health Affairs  
Centura Health  
Change Healthcare  
The Christ Hospital Health Network  
CHRISTUS Health  
Chronic Care Policy Alliance

Cleveland Clinic  
Colorado Palliative & Hospice Care  
CommonSpirit Health  
Community Health Network  
Cone Health  
Congress of Neurological Surgeons  
Cotiviti  
CoxHealth  
Dartmouth-Hitchcock Health  
DHR Health  
Dialysis Advocates & Associates Inc.  
Edwards Lifesciences  
Eisenhower Medical Center  
EvergreenHealth  
Federation of American Hospitals  
First Health of the Carolinas  
Flagler Health+  
Genesis Health System  
Guardant Health  
Gundersen Health System  
Hawai'i Pacific Health  
HCA Healthcare  
Healthcare Leadership Council  
Health Care Transformation Task Force  
Health First  
Henry Ford Health System  
Hospital Sisters Health System  
Houston Methodist  
Intermountain Healthcare  
International Association of Hepatitis Task Forces  
John Muir Health  
Kaleida Health  
Kansas Palliative & Hospice Care  
Kettering Health Network  
Lafayette General Medical Center  
Lee Health  
Lehigh Valley Health Network  
Leidos  
LifeBridge Health  
Loma Linda University Health  
MaineHealth  
Marshfield Clinic Health System  
Massachusetts Medical Device Industry Council (MassMEDIC)  
McLaren Health Care  
Medical Alley Association  
Medical Oncology Association of Southern California, Inc.

Medical University of South Carolina  
MedTech Association  
Medtronic  
MemorialCare  
Missouri Palliative & Hospice Care  
Monument Health  
Norton Healthcare  
OhioHealth Corporation  
Oklahoma Heart Hospital  
Oklahoma Palliative & Hospice Care  
Oklahoma Society of Clinical Oncology, Inc.  
Patient Choice Coalition of Texas & Oklahoma  
PeaceHealth  
Premier, Inc.  
Presbyterian Healthcare Services  
Prism Health North Texas  
Providence St. Joseph Health  
Quorum Health Corporation  
ResMed  
SCL Health  
Spectrum Health  
SSM Health Care Corporation  
Stryker  
Sutter Health  
Teladoc Health, Inc.  
Texas Essential Healthcare Partnerships  
Texas Health Resources  
Texas Oncology  
Texas Orthopaedic Association  
Texas Pain Society  
ThedaCare  
Thomas Health System  
Thomas Jefferson University/Jefferson Health  
Tivity Health  
Trinity Health  
UnityPoint Health  
University Hospitals Health System  
Valley Health  
Virginia Hospital Center  
Virtua Health  
Vizient Inc.  
Women Involved in Nurturing, Giving, Sharing, Inc. (WINGS)  
Wyoming Epilepsy Association