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July 21, 2020.1 Under your leadership, HHS has undertaken a “regulatory sprint to coordinated care” that will modernize outdated rules which create unnecessary costs and impair collaboration in healthcare.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.

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

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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).
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,

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