# HEALTH CARE IN THE TIME OF COVID-19: STARK LAW TEMPORARY WAIVERS MAKE THE CASE FOR PERMANENT STARK LAW REFORM

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*He who has health, has hope; and he who has hope, has everything.*[2]
*– Thomas Carlyle*

## I. INTRODUCTION

In the final months of 2019, a deadly novel virus was spreading throughout parts of Asia.[3] At that time, this virus was under the radar of both international governments and the World Health Organization alike.[4] It was not until December 31, 2019, that the World Health Organization "picked up a media statement by the Wuhan Municipal Health Commission from their website on cases of 'viral pneumonia' in Wuhan, People's Republic of China."[5] This statement proved to be the beginning of the timeline of the 2019 novel coronavirus ("COVID-19") global pandemic.[6] In the weeks and months that followed, the world watched as the numbers of those infected with this virus increased in China and spread to other parts of the world.[7]

On January 23, 2020, China instituted a lockdown on travel and moving about in the Wuhan province and other affected areas of the country.[8] Countries in Asia and Europe similarly began lockdown measures and travel restrictions to prevent the spread of this virus as cases began popping up in their region.[9]

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2. *Arabian proverb made famous by Thomas Carlyle.*

3. WORLD HEALTH ORG., CORONAVIRUS DISEASE 2019 (COVID - 19): SITUATION REPORT – 94 2 (2020), https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200423-sitrep-94-covid-19.pdf [https://perma.cc/3KAR-J7C8].

4. *Timeline of WHO's Response to COVID - 19*, WORLD HEALTH ORG. (June 29, 2020), http://www.who.int/news-room/detail/29-06-2020-covidtimeline [https://perma.cc/52FR-T7MJ].

5. *Id.*

6. *Id.* This virus will be referred to as "COVID-19" in this Article. Another official name for the virus is "SARS-Co-V-2," severe acute respiratory syndrome coronavirus 2. For additional information, see *Naming the Coronavirus Disease COVID-19 and the Virus That Causes It*, WORLD HEALTH ORG., https://www.who.int/emergencies/diseases/novel-coronavirus-2019/technical-guidance/naming-the-coronavirus-disease-(covid-2019)-and-the-virus-that-causes-it [https://perma.cc/AW3D-7ALJ] (last visited July 12, 2020).

7. *See* Lidia Morawska & Junji Cao, *Airborne Transmission of SARS-CoV-2: The World Should Face the Reality*, 139 ENV'T INT'L art. 105730 (2020).

8. Evelyn Cheng, *China to Lift Lockdown on Wuhan, the Epicenter of Its Coronavirus Outbreak*, CNBC (Mar. 24, 2020), http://www.cnbc.com/2020/03/24/china-to-lift-lockdown-on-wuhan-city-epicenter-of-coronavirus-outbreak.html [https://perma.cc/N47T-H39R].

9. Changyong Rhee & Poul M. Thomsen, *Emerging from the Great Lockdown in Asia and*

Patients infected with this virus began flooding hospitals first in China and then European countries.[10] The world received media reports of how hospital systems across the world were near collapse with a shortage of beds, essential medical devices such as ventilators and PPEs, and medical personnel.[11] New "hospitals" were being built in a matter of weeks to try and keep up with the demands from the thousands of patients falling ill with COVID-19.[12] Italy was among the first European countries hit especially hard by COVID-19 and reports circulated of elderly COVID-19 patients being denied ventilators because of space and equipment shortage.[13] As the numbers of those infected with COVID-19 began

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*Europe*, INT'L MONETARY FUND: BLOG (May 12, 2020), http://blogs.imf.org/2020/05/12/emerging-from-the-great-lockdown-in-asia-and-europe/ [https://perma.cc/CS88-E7UU]; Lisa Schnirring, *EU Closes Borders to Slow COVID-19*; *Activity Escalates in South Asia*, CTR. FOR INFECTIOUS DISEASE RES. & POL'Y (Mar. 17, 2020), http://www.cidrap.umn.edu/news-perspective/2020/03/eu-closes-borders-slow-covid-19-activity-escalates-south-asia [https://perma.cc/T3HN-MUV4].

10. *Toll from Outbreak Climbs in China as Infections Reach Europe and Australia*, N.Y. TIMES, http://www.nytimes.com/2020/01/24/world/asia/china-coronavirus.html [https://perma.cc/XDH2-36F3] (last updated Mar. 9, 2020).

11. *See* Erin McCormick, *Tests, Masks, Beds: Health Workers Grapple with Shortages as Coronavirus Crisis Grows*, GUARDIAN (Mar. 18, 2020), http://www.theguardian.com/world/2020/mar/18/health care-workers-coronavirus-masks-beds-tests [https://perma.cc/7VLW-EKD4]; Shaun Lintern, *Coronavirus: NHS Doctors 'Gagged' over Protective Equipment Shortages*, INDEPENDENT (Mar. 31, 2020), http://www.independent.co.uk/news/health/coronavirus-nhs-uk-doctors-gagged-england-a9433171.html [https://perma.cc/KS9D-3KQF]; Julia Hollingsworth et al., '*We'll Admit Them If They're Dying': Virus Outbreak Pushes China's Stretched Health Care Workers to Breaking Point*, CNN (Jan. 31, 2020), http://www.cnn.com/2020/01/30/asia/chinese-health-care-virus-intl-hnk/index.html [https://perma.cc/2PM3-5RZR]; Shawn Yuan, *'Utter Chaos': Coronavirus Exposes China Healthcare Weaknesses*, ALJAZEERA (Jan. 29, 2020) http://www.aljazeera.com/news/2020/01/chaos-coronavirus-exposes-china-health care-weaknesses-200129050408104.html [https://perma.cc/T9NT-VFJ9].

12. Associated Press, *China to Quickly Build Hospital to Treat Coronavirus; Shanghai Disneyland Closes*, L.A. TIMES (Jan. 24, 2020), https://www.latimes.com/world-nation/story/2020-01-24/china-coronavirus-hospital [https://perma.cc/F6PU-38DN]. During a peak of COVID-19 infection rates, China built two hospitals in just over two weeks providing over 1,000 additional beds to help alleviate the strain on existing hospitals in Wuhan. Ground was broken on the first facility on January 24, 2020, and the doors opened to the public on February 3, 2020. Johns Hopkins Center for Health Security scholar Eric Toner noted that the facilities might resemble a triage and isolation facility more than a traditional hospital. Marc Silver, *PHOTOS: China Builds a Medical Center from Scratch in Under 2 Weeks*, NPR (Feb. 2, 2020), http://www.npr.org/sections/goatsandsoda/2020/02/02/801537445/photos-china-builds-a-medical-center-from-scratch-in-under-2-weeks [https://perma.cc/KMS2-FQLX].

13. Lisa Schnirring, *ECDC: COVID-19 Not Containable, Set to Overwhelm Hospitals*, CTR. FOR INFECTIOUS DISEASE RES. & POL'Y (Mar. 12, 2020), http://www.cidrap.umn.edu/news-perspective/2020/03/ecdc-covid-19-not-containable-set-overwhelm-hospitals [https://perma.cc/MSP6-CDH7]; Shaun Lintern, *'We are Making Difficult Choices': Italian Doctor Tells of Struggle Against Coronavirus*, INDEPENDENT (Mar. 13, 2020), http://www.independent.

to exponentially increase across the globe, the United States reported its first known case of COVID-19 on January 20, 2020.[14]

The United States was tasked with acting quickly to help prevent the spread of COVID-19, as well as to prepare the health care system for the imminent crisis that lay ahead.[15] Countless measures were taken by the government to both prepare for and react to the increased burden on the United States health care system.[16] One measure taken by the Secretary of the Department of Health and Human Services, Alex Azar II, was to authorize blanket waivers of certain health care regulations.[17] Secretary Azar authorized blanket waivers or modifications of numerous laws impacting Medicare, Medicaid, Children's Health Insurance Program ("CHIP"), and Health Insurance Portability and Accountability Act of 1996 ("HIPAA") requirements.[18] These blanket waivers and modifications were intended to temporarily eliminate regulatory barriers that would impede health care providers as they developed solutions to quickly address the increased burden on the health care system.[19]

On March 30, 2020, the Centers for Medicare and Medicaid Services ("CMS") issued waivers to help alleviate some of the regulatory barriers created specifically by the Physician Self-Referral Law, commonly known as the Stark Law.[20] In a recent administrative action, CMS outlined the specific waivers and

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co.uk/news/health/coronavirus-italy-hospitals-doctor-lockdown-quarantine-intensive-care-a9401186.html [https://perma.cc/S5LD-SMLH].

14. Michelle L. Holshue et al., *First Case of 2019 Novel Coronavirus in the United States*, 382 NEW ENG. J. MED. 929, 929 (2020).

15. Proclamation No. 9994, 85 Fed. Reg. 15,337 (Mar. 13, 2020).

16. *See id.*; CARES Act, S. 3548, 116th Cong. (2020); Proclamation No. 9984, 85 Fed. Reg. 6,709 (Jan. 31, 2020); Jorge L. Ortiz & Grace Hauck, *Coronavirus in the US: How All 50 States Are Responding – and Why Eight Still Refuse to Issue Stay-at-Home Orders*, USA TODAY, http://www.usatoday.com/story/news/nation/2020/03/30/coronavirus-stay-home-shelter-in-place-orders-by-state/5092413002/ [https://perma.cc/8DU3-XK3F] (last updated Apr. 9, 2020). To name a few, economic measures like the CARES Act "flatten the curve" through sheltering in place orders, reserving masks and PPE for health care workers to avoid shortages in hospitals, and placing orders to manufacture more ventilators.

17. Proclamation No. 9994, 85 Fed. Reg. at 15,337; *CMS Takes Action Nationwide to Aggressively Respond to Coronavirus National Emergency*, CTR. FOR MEDICARE & MEDICAID SERV. (Mar. 13, 2020), https://www.cms.gov/newsroom/press-releases/cms-takes-action-nationwide-aggressively-respond-coronavirus-national-emergency [https://perma.cc/MAP7-YT6D].

18. *See Blanket Waivers of Section 1877(g) of the Social Security Act Due to Declaration of COVID-19 Outbreak in the United States as a National Emergency*, CTR. FOR MEDICARE & MEDICAID SERV. (Mar. 1, 2020), https://www.cms.gov/files/document/covid-19-blanket-waivers-section-1877g.pdf [https://perma.cc/BL3E-B8YB] [hereinafter *Blanket Waivers of Section 1877(g)*].

19. *Trump Administration Makes Sweeping Regulatory Changes to Help U.S. Healthcare System Address COVID-19 Patient Surge*, CTR. FOR MEDICARE & MEDICAID SERV. (Mar. 30, 2020), https://www.cms.gov/newsroom/press-releases/trump-administration-makes-sweeping-regulatory-changes-help-us-health care-system-address-covid-19 [https://perma.cc/T4FK-DQJ2].

20. *Blanket Waivers of Section 1877(g)*, *supra* note 18.

modifications that, if made in good faith and as a response to COVID-19 necessity, would allow health care providers to be reimbursed for items and services and exempted from the sanction of noncompliance with the Stark Law.[21]

This Article will analyze the response taken by the Department of Health and Human Services ("HHS") through CMS to alleviate the Stark Law barriers to addressing the COVID-19 public health emergency and address how these waivers may impact treatment, quality of care, and operations in the health care system.[22] Section II of this Article will discuss how the Secretary of HHS can authorize the use of waivers to provide relief from a health care regulation. This section will explore the use of waivers during various emergency situations in the past. Section III of this Article will discuss the requirements of the Stark Law and explain why a waiver or modification of certain Stark exceptions was necessary in light of the anticipated burden on the United States health care system.[23] Section IV of this Article will analyze the specific Stark Law waivers authorized by CMS and discuss the impact these waivers will have on patients and the many health care stakeholders.[24] Section V will examine whether these waivers have been beneficial to reacting to the increased demand on the health care system, as well as whether these waivers should be reimagined as proposed amendments to the Stark Law after the public health emergency has ended.[25] This section will also explore a few of the Stark Law proposed regulations issued by HHS in October of 2019 to examine whether these proposals, if finalized, would resolve some of the issues these emergency waivers are trying to correct. These waivers, which in part aim to reduce paperwork and red tape during this emergency, may be the testing ground to prove that the law should permanently move in this direction.[26]

## II. THE DEPARTMENT OF HEALTH AND HUMAN SERVICES USES WAIVERS TO ADDRESS IMPORTANT NEEDS IN OUR HEALTH CARE SYSTEM

The Secretary of HHS, through CMS, has the authority to waive compliance with health care regulations in specific situations.[27] For example, section 115A(d)(1) of the Social Security Act authorizes the Secretary to waive certain fraud and abuse laws to foster innovation and allow health care providers to test payment and service delivery models developed by the CMS Innovation Center.[28] The use of a waiver in this context allows a health care provider to set aside the

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21. *Id.*

22. *Id.*

23. *See* discussion *infra* Section III.

24. *See* discussion *infra* Section IV.

25. *See* discussion *infra* Section V.

26. *See* discussion *infra* Section V.

27. *See* 42 U.S.C. § 1320b-5 (2020).

28. *See id.*; *Fraud & Abuse Waivers*, CTR. FOR MEDICARE & MEDICAID SERV., http://www.cms.gov/medicare/physician-self-referral/fraud-and-abuse-waivers [https://perma.cc/T7JE-X8XL] (last visited July 15, 2020).

burdensome requirements of the fraud and abuse laws and instead try a different model approved by the Innovation Center.[29] The health care provider can aim for even greater patient health outcomes because of the coordination of care that is ordinarily hindered by these fraud and abuse laws. Additionally, programs or models in the Innovation Center such as bundled payment models, shared savings programs, or state care model redesign programs can test new approaches of delivering health care that aim to lower the federal program costs while increasing the quality of patient care.[30]

A health care provider must apply to CMS to be eligible to participate in a fraud and abuse waiver program.[31] Not all model-specific waivers are necessarily available to all health care providers.[32] The provider must meet certain required conditions in the proposed arrangement to receive waiver protection.[33] These types of waivers are granted on an individual basis to health care providers who have satisfied the required conditions and received the required approvals.[34]

In contrast, emergency waivers are used in a different way by CMS to accomplish the same goal of suspending a health care regulation for a defined purpose.[35] The waiver may be used in an emergency or disaster situation and could apply to all providers without the need for an individual application and approval.[36] Section 1135 of the Social Security Act authorizes the Secretary of

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29. *See Fraud & Abuse Waivers*, *supra* note 28. Some of the models and programs created by the Innovation Center are the Pioneer Accountable Care Organization Model, Bundled Payment for Care Improvement Models, Comprehensive ESRD Care Model, Comprehensive Care for Joint Replacement Model, Next Generation ACO Model, Oncology Care Model, Maryland Total Cost of Care Model Care Redesign Program, and Medicare Shared Savings Program. *Id.*

30. *Bundled Payments for Care Improvement (BPCI) Initiative: General Information*, CTR. FOR MEDICARE & MEDICAID SERV, http://innovation.cms.gov/innovation-models/bundled-payments [https://perma.cc/85ZR-FN8W] (last updated June 19, 2020).

31. *Medicare Shared Savings Program Initial Application*, CTR. FOR MEDICARE & MEDICAID SERV., https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/MSSP_Application_Initial.pdf [https://perma.cc/5YMB-DD5U] (last visited July 15, 2020).

32. *Fraud & Abuse Waivers*, *supra* note 28.

33. *Id.*

34. David J. Edquist, *COVID-19 von Briesen Task Force Resource: Current Status of Waivers of Federal Fraud & Abuse Laws*, NAT'L L. REV. (Mar. 30, 2020), http://www.natlawreview.com/article/covid-19-von-briesen-task-force-resource-current-status-waivers-federal-fraud-abuse [https://perma.cc/F9P8-6E73].

35. *Waivers & Flexibilities*, CTR. FOR MEDICARE & MEDICAID SERV., https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Resources/Waivers-and-flexibilities [https://perma.cc/XCF8-5L58] (last visited July 18, 2020).

36. *Id.* Sometimes, however, the section 1135 waiver could require the providers to request and receive approval for the waiver. *See* Memorandum from the Dir. of the Survey & Certification Grp., Ctrs. for Medicare & Medicaid Servs., to the State Survey Agency Dirs. (Nov. 6, 2009), https://www.cms.gov/Medicare/Provider-Enrollment-and-Certification/SurveyCertificationGenInfo/Downloads/SCLetter10_06pdf.pdf [https://perma.cc/QWM9-SVLR].

HHS to issue waivers in a disaster or emergency.[37] The waivers can allow health care providers the flexibility to react as needed in a disaster to provide care quickly and allow Medicare and Medicaid patients access to care.[38] In an emergency or disaster situation, the waiver allows the provider to meet the urgent patient needs without being hindered by the regulatory barriers that might be in the way.[39]

Prior to COVID-19, the last time the Secretary of HHS authorized section 1135 waivers in response to a national pandemic was in 2009.[40] A novel influenza A ("H1N1") virus emerged in early 2009 in the United States.[41] This new strain of the influenza virus had not yet been identified in animals or people at that time.[42] The H1N1 virus began to spread throughout the United States and ultimately throughout the world.[43] There was not an effective vaccine available to halt the spread of the virus.[44] The Centers for Disease Control and Prevention estimated that from April 2009 to April 2010, 60.8 million people in the United States contracted this virus.[45]

On October 23, 2009, the President of the United States declared a national emergency as a result of the H1N1 pandemic.[46] On April 26, 2009, the Secretary of HHS declared a public health emergency in response to the H1N1 outbreak.[47] The Secretary renewed that declaration on July 24, 2009, and again on October 1 and December 29.[48] The combination of these declarations allowed CMS to issue section 1135 waivers to allow hospitals the flexibility to address the pandemic.[49]

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37. *See* 42 U.S.C. § 1320b-5 (2020).

38. *Waivers & Flexibilities*, *supra* note 35.

39. *See id*.; *see HHS Office of the Assistant Secretary for Preparedness and Response*, U.S. DEP'T HEALTH & HUM. SERV. (Aug. 5, 2020), https://www.phe.gov/about/aspr/Pages/default.aspx [https://perma.cc/7NDS-X3WG]; *see Emergency*, U.S. Dep't Health & Hum. Serv. (Sept. 16, 2020), https://www.phe.gov/emergency/Pages/default.aspx [https://perma.cc/F5PK-3N7V].

40. *See* Memorandum from the Dir. of the Survey & Certification Grp., Ctrs. for Medicare & Medicaid Servs., to the State Survey Agency Dirs., *supra* note 36; *see also* Proclamation No. 8443, 74 Fed. Reg. 55,439 (Oct. 23, 2009).

41. *2009 H1N1 Pandemic*, CTR. FOR DISEASE CONTROL & PREVENTION (June 11, 2019), http://www.cdc.gov/flu/pandemic-resources/2009-h1n1-pandemic.html [https://perma.cc/XT6E-8FMS].

42. *Id.*

43. *Id.*

44. *Id.*

45. *Id.*

46. *See* Proclamation No. 8443, 74 Fed. Reg. 55,439 (Oct. 23, 2009); *see* Craig A. Conway, *H1N1 Now a "National Emergency": Examining Portions of Federal Public Health Emergency Law*, HOUS. J. HEALTH L. & POL'Y 1, https://www.law.uh.edu/healthlaw/perspectives/2009/(CC)%20PHSA.pdf [https://perma/cc/Q38J-XMVR] (last visited Dec. 6, 2020).

47. *See* Proclamation No. 8443, 74 Fed. Reg. at 55,439.

48. *Id.*

49. *Id*.; Memorandum from the Dir. of the Survey & Certification Grp., Ctrs. for Medicare

Effective October 23, 2009, CMS authorized facilities to seek waivers to health care regulations in order to quickly and effectively treat patients during the H1N1 emergency.[50] Health care providers were permitted to request waivers from many health care regulations for a period of up to seventy-two hours from the time a facility implemented its disaster protocols, and the waiver would apply to all patients at the facility.[51]

During the H1N1 public health emergency, the health care facilities were permitted to seek waivers to or modifications of (1) conditions of participation, certification, and other participation requirements; (2) pre-approval requirements for health care providers; (3) waiver of sanctions for certain directions or relocations and transfers that otherwise would violate the Emergency Medical Treatment and Labor Act ("EMTALA"); (4) waiver of sanctions related to Stark self-referral prohibitions; (5) deadlines and timetables for the performance of required activities; (6) and waiver of sanctions and penalties arising from non-compliance with certain HIPAA privacy regulations.[52]

The health care facilities could apply for waivers to expand a facility's inpatient or emergency room beds, to provide care in alternate locations, and to alter their patient transfer procedures.[53] Additionally, skilled nursing facilities could apply for a waiver to expand the number of their beds without prior certification, and hospitals could request a waiver to set up additional screening locations away from the hospital's main campus, as well as request a waiver of additional EMTALA and HIPAA regulations.[54] Implementing section 1135 waivers during this public health emergency allowed our health care providers the flexibility to deliver quality health care to patients as quickly as possible.[55]

Going one step further to provide assistance to health care providers, in 2012, CMS authorized *blanket* waivers in response to Hurricane Sandy, the second-largest Atlantic storm on record.[56] Unlike the waivers authorized during the 2009 H1N1 pandemic, these blanket waivers applied to all providers and did not require individual providers to request and receive approval for protection from a waiver.[57] From October 29, 2012, to October 30, 2012, Hurricane Sandy devastated New Jersey and New York with ninety miles-per-hour winds,

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& Medicaid Servs., to the State Survey Agency Dirs., *supra* note 36.

50. Memorandum from the Dir. of the Survey & Certification Grp., Ctrs. for Medicare & Medicaid Servs., to the State Survey Agency Dirs., *supra* note 36.

51. *Id*.

52. *Id*.

53. *Id*.

54. *Id*. at 20; CCH, MEDICARE AND MEDICAID GUIDE NO. 1583 5 (2009).

55. *See* Memorandum from the Dir. of the Survey & Certification Grp., Ctrs. for Medicare & Medicaid Servs., to the State Survey Agency Dirs. *supra* note 36.

56. *Section 1135 Waivers Approved for New York and New Jersey Hurricane Sandy Response*, CTR. FOR MEDICARE & MEDICAID SERV. (Nov. 3, 2012), https://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/1135-Blanket-Waivers-Approved-for-NY-NJ.pdf [https://perma.cc/7YBZ-WT2Z].

57. *Id.*

uprooting trees, creating a fourteen-foot wave surge in the New York harbor, flooding parts of the New York subway system, inundating Manhattan, and causing extensive damage throughout the region.[58] It was one of the most destructive hurricanes in United States history.[59] Hurricane Sandy not only destroyed over $70 billion in property but it also took seventy-five lives in the Caribbean before making its way up the East Coast and taking another seventy-two lives in its path.[60] It is estimated that over 650,000 people had their homes destroyed or damaged by Hurricane Sandy.[61]

In response to the loss of life and property, on October 30, 2012, pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act, President Obama declared that, as a result of the effects of Hurricane Sandy, a major disaster existed in the States of New Jersey and New York.[62] Similarly, on October 31, and November 1, the Secretary of HHS declared that a public health emergency existed in the States of New Jersey and New York respectively and authorized waivers and modifications under section 1135 of the Social Security Act.[63] These blanket waivers authorized by section 1135 of the Social Security Act allowed providers to waive compliance with certain health care regulations without having to apply directly to CMS for waiver approval.[64]

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58. Andrea Peer, *2012 Hurricane Sandy: Facts, FAQs, and How to Help*, WORLD VISION (Sept. 18, 2018), https://www.worldvision.org/disaster-relief-news-stories/2012-hurricane-sandy-facts [https://perma.cc/K6GK-HAF9].

59. *New List of the Costliest U.S. Hurricanes Includes 2017's Harvey, Irma, Maria*, WEATHER CHANNEL (Jan. 29, 2018), http://weather.com/storms/hurricane/news/2018-01-29-americas-costliest-hurricanes [https://perma.cc/YL5X-AR8P].

60. Peer, *supra* note 58.

61. *New List of the Costliest U.S. Hurricanes Includes 2017's Harvey, Irma, Maria, supra* note 59.

62. New Jersey; Major Disaster and Related Determinations, 77 Fed. Reg. 69,647, 69,647 (Oct. 30, 2012); New York; Major Disaster and Related Determinations, 77 Fed. Reg. 69,647, 69,648 (Oct. 30, 2012); Brock Long, *Initial Notice*, FED. EMERGENCY MGMT. AGENCY, http://www.fema.gov/disaster/4085/notices/initial-federal-notice [https://perma.cc/GNN9-JHGF] (last updated Aug. 7, 2020); Press Release, The White House, President Obama Signs New York Disaster Declaration (Oct. 30, 2012), http://obamawhitehouse.archives.gov/the-press-office/2012/10/30/president-obama-signs-new-york-disaster-declaration [https://perma.cc/BXP4-SJJC].

63. *Hurricane Sandy and Medicare Disaster Related Claims*, CTR. FOR MEDICARE & MEDICAID SERV., http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/downloads/SE1247.pdf [https://perma.cc/ZZ8B-F2ST] (last visited Dec. 16, 2020); Letter from Kathleen Sebelius, Secretary, U.S. Dep't of Health & Human Servs., to the Honorable Harry Reid, Majority Leader, U.S. Senate (Oct. 31, 2012), http://www.cms.gov/About-CMS/Agency-Information/Emergency/Downloads/PHE-Declaration-and-Section-1135-Waiver-for-New-York.pdf [https://perma.cc/F5TJ-9FZG].

64. *See* Memorandum from the Dir. of the Survey & Certification Grp., Ctrs. for Medicare & Medicaid Servs., to the State Survey Agency Dirs., *supra* note 36. In addition to the section 1135 waivers, the Secretary also authorized waivers under section 1812(f) of the Social Security Act for both New York and New Jersey. The 1812(f) waivers allow the extension of the scope of benefits

As a result of the blanket section 1135 waivers authorized during Hurricane Sandy, all providers in New York and New Jersey were permitted to process certified bed increases for hospitals and nursing homes, and CMS would suspend onsite survey activities in the impacted areas except for investigations alleging immediate jeopardy.[65] Additional requirements were waived such as: the three-day prior hospitalization for coverage of a skilled nursing facility stay; the timeframe requirements for minimum data set assessments and transmission for skilled nursing facilities; the OASIS transmission timeframes and the two-week aide supervision requirements by a registered nurse for home health agencies; the home health and hospice location restrictions so they could provide services in a shelter or alternate location for patients displaced by the storm; the supervision requirement of hospice aides every fourteen days by a registered nurse; and also allowing patients in need of unscheduled or emergency dialysis treatment to receive that care in an outpatient hospital setting.[66] These blanket waivers that applied to all impacted facilities and agencies in these two states provided the flexibility that the New York and New Jersey health care systems needed to meet the unexpected and severe increase in patient care in the midst of destruction and chaos.[67] Once again, the government used section 1135 waivers as a tool to provide much-needed flexibility to the health care system so providers could care for people as quickly and efficiently as possible in a crisis.[68]

## III. THE STARK LAW IS CENTRAL TO HEALTH CARE OPERATIONS

One law that is central to all health care business arrangements is the Stark Law.[69] This law governs which health care business arrangements are prohibited and which may be permitted.[70] In the event of a public health crisis and the need for added flexibility in our health care system, the Stark Law is one of the key laws that would need to be amended because its reach touches almost every business arrangement between physicians and hospitals. Congress enacted the Stark Law out of concern that physicians who had a financial interest in an entity would disproportionately refer their patients for procedures or diagnostics to that entity compared with physicians who did not have a financial interest in the

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under the Medicare program and is outside the scope of this Article. *See Hurricane Sandy and Medicare Disaster Related Claims*, *supra* note 63; *see* Letter from Kathleen Sebelius, Secretary, U.S. Dep't of Health & Human Servs., to the Honorable Harry Reid, Majority Leader, *supra* note 63.

65. Memorandum from the Dir. of the Survey & Certification Grp., Ctrs. for Medicare & Medicaid Servs., to the State Survey Agency Dirs., *supra* note 36.

66. *See id.*

67. *Id.*

68. *Id.*

69. *See Stark Law,* STARK LAW, http://starklaw.org/stark_law.htm [https://perma.cc/NFF2-32H7] (last visited Dec. 7, 2020).

70. *Id.*

referring entity.[71] Congressman Pete Stark became concerned with the growing problem that physicians were valuing their own financial interests over appropriate treatment for their patients.[72] The physician's self-interested referral could potentially expose the patient to harm and excess costs, as well as deplete federal program resources.[73] With the help of Congressman Stark's efforts, the present-day Physician Self-Referral Law, commonly known as the Stark Law, came into existence through the Omnibus Reconciliation Act of 1989.[74]

Today, this is referred to as Stark I, and it very narrowly regulated physician referrals.[75] Effective as of January 1, 1992, Stark I prohibited a physician from referring patients for clinical laboratory testing if the physician either invested in the laboratory or had a compensation arrangement with the entity.[76] The next year, the modern-day Stark Law was born. As part of the Omnibus Budget Reconciliation Act of 1993, Stark II prohibits referrals not only to tainted clinical laboratory services but also to a detailed list of designated health services ("DHS").[77]

The Stark Law can be essentially broken down as follows: a physician cannot make a referral for DHS that is payable by Medicaid or Medicare to an entity in which they have a financial relationship unless an exception applies.[78] A Stark violation only occurs if each element in the law is met.[79] Thus, it is important to understand each element of the rule to assess as accurately as possible whether an arrangement is prohibited.[80] A physician includes a medical or osteopathic doctor, podiatrist, optometrist, or a doctor of dental surgery or medicine.[81] A referral is a physician's request for a service or item.[82] If the physician personally performs the service, then Stark is not implicated.[83] DHS include: clinical laboratory services; physical therapy services; occupational therapy services; radiology services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services;

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71. Lynn Gordon, *Payors Acquiring Physician Practices: Purchase Price Limitations and Other Stark & Anti-Kickback Rules of the Road*, 26 HEALTH LAW. 24, 25 (2014); *see also* Bailey Wendzel et al., *Health Care Fraud,* 56 AM. CRIM. L. REV 1033, 1068 (2019).

72. Matt Frederiksen & Emily Egan Weaver, *Understanding the Federal Physician Self-Referral Statute: "Stark Law,"* 17 J. HEALTH CARE COMPLIANCE 47, 48 (2015).

73. Gordon, *supra* note 71, at 24, 25.

74. DAVID E. MATYAS ET AL., LEGAL ISSUES IN HEALTH CARE FRAUD AND ABUSE: NAVIGATING THE UNCERTAINTIES 131 (4th ed. 2012).

75. *See Stark Law*, *sup*ra note 69.

76. MATYAS ET AL., *supra* note 74, at 133.

77. *Id.* at 134.

78. *See* 42 U.S.C. § 1395nn (2020); Frederiksen & Weaver, *supra* note 72, at 47-48.

79. Frederiksen & Weaver, *supra* note 72, at 48.

80. *Id.*

81. 42 C.F.R. § 411.351 (2020).

82. 42 U.S.C. § 1395nn(h)(5)(A) (2020).

83. 42 U.S.C. § 1395nn(b)(1) (2020).

outpatient prescription drugs; inpatient and outpatient hospital services; and outpatient speech-language pathology services.[84] The entity is the business that performs the DHS or submits the claim to Medicare.[85]

A financial relationship constitutes either a direct or indirect investment interest or a direct or indirect compensation arrangement with the entity.[86] Further, the physician does not need to be the one with the financial relationship; instead, a physician's immediate family member, including spouses, children, stepfamily, in-laws, grandparents, and grandchildren themselves and their spouses, could trigger a Stark violation.[87]

Stark Law is a solely civil statute, but Stark II expanded the law's reach by making a physician strictly liable for a violation.[88] As such, the physician does not need to be aware of or intend to enter into an inappropriate referral arrangement for a violation to occur. Instead, even if a physician refers a patient for a service and the patient inadvertently goes to a facility that has a financial relationship with the prescribing physician, a violation may occur unless an exception applies.[89] A violation can result in any or a combination of the following consequences: denial of payment, mandated return of payments received, civil monetary penalties up to $15,000 per service provided, and exclusion from Medicare and Medicaid.[90] Additionally, civil monetary penalties of up to $100,000 can be imposed for each scheme in which the physician was involved. However, civil monetary penalties or exclusion would only be imposed if the physician knowingly committed a violation.[91] Physicians act knowingly when they either knew or should have known that the claim was fraudulent.[92]

The complexity and ambiguity of the Stark Law and its exceptions have been a source of critique for years, and there have been many calls for reform to the Stark Law.[93] Even the well-meaning can unknowingly run afoul of this law due

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84. 42 U.S.C. § 1395nn(h)(6) (2020).

85. 42 C.F.R. § 411.351.

86. 42 U.S.C. § 1395nn(a)(2) (2020).

87. 42 C.F.R. § 411.351.

88. 42 U.S.C. § 1395nn(b)–(e) (2020); Jo-Ellyn Sakowitz Klein, *The Stark Laws: Conquering Physician Conflicts of Interest?*, 87 GEO. L.J. 499, 500 (1998).

89. Klein, *supra* note 88, at 515.

90. 42 U.S.C. § 1395nn(g)(1)–(3) (2020).

91. 42 U.S.C. § 1395nn(g)(4) (2020).

92. 42 U.S.C. § 1320a-7a(a)(1)(B) (2020).

93. Ayla Ellison, *Stark Law: The 27-Year-Old Act Killing Healthcare Reform Before It Can Begin?*, BECKER'S HOSP. REV. (Sept. 7, 2016), https://www.beckershospitalreview.com/legal-regulatory-issues/stark-law-the-27-year-old-act-killing-health care-reform-before-it-can-begin.html [https://perma.cc/2GUL-CK4X]; Medicare Program; Request for Information Regarding the Physician Self-Referral Law, 83 Fed. Reg. 29,524 (June 25, 2018) (to be codified at 42 C.F.R. pt. 411); *see also* 42 C.F.R. §§ 1001, 1003 (2020); *see* Kathy H. Butler, *Stark Law Reform: Is It Time?*, 18 J. HEALTH CARE COMPLIANCE 5 (2016); *see* Nicholas J. Diamond, *Giving Disclosure Its Due: A Proposal for Reforming the Stark Law*, 16 DEPAUL J. HEALTH CARE L. 1 (2014); *see* Christian D. Humphreys, *Regulation of Physician Self-Referral Arrangements: Is Prohibition the Answer or*

to the strict liability and complicated framework.[94]

## IV. BALANCING THE NEED TO DETER FRAUD WHILE ALLOWING FLEXIBILITY IN OUR HEALTH CARE SYSTEM

The sheer volume of medical claims that are processed by Medicare and Medicaid each year makes the health care industry an easy target for fraudsters.[95] In 2018, the National Health Expenditure grew 4.6% to $3.6 trillion.[96] Medicare spending also increased by 6.4% to $750.2 billion, and Medicaid spending grew 3.0% to $597.4 billion.[97] These numbers are astronomical, among the highest in the world spent on health care, and this amount accounts for 16.9% of our nation's gross domestic product.[98] Ferreting out the fraudsters in our health care system is essential to solving our health care crisis because fraud and abuse of the health care laws contribute to these skyrocketing costs.[99] Health care fraud

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*Has Congress Operated on the Wrong Patient?*, 30 SAN DIEGO L. REV. 161 (1993).

94. United States *ex rel.* Drakeford v. Tuomey, 792 F.3d 364, 395 (4th Cir. 2015) (Wynn, J., concurring); *see* MAJORITY STAFF, SENATE COMM. ON FIN., WHY STARK, WHY NOW? SUGGESTIONS TO IMPROVE THE STARK LAW TO ENCOURAGE INNOVATIVE PAYMENT MODELS 17 (2016), https://www.finance.senate.gov/imo/media/doc/Stark%20White%20Paper,%20SFC%20Majority%20Staff.pdf [https://perma.cc/G92A-P2FN].

95. *See The $272 Billion Swindle*, ECONOMIST (May 31, 2014), https://www.economist.com/united-states/2014/05/31/the-272-billion-swindle [https://perma.cc/DQL6-WA7N]; Fred Schulte & David Donald, *How Doctors and Hospitals Have Collected Billions in Questionable Medicare Fees*, CTR. FOR PUB. INTEGRITY (May 19, 2014), https://publicintegrity.org/health/how-doctors-and-hospitals-have-collected-billions-in-questionable-medicare-fees/ [https://perma.cc/8ATS-SVTP].

96. *NHE Fact Sheet*, CTR. FOR MEDICARE & MEDICAID SERV. (Mar. 24, 2020), http://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet [https://perma.cc/4HAN-H57C].

97. *Id.*

98. *Health Spending*, OECD, https://data.oecd.org/healthres/health-spending.htm [https://perma.cc/2CZH-QNED] (last visited Dec. 7, 2020); Roosa Tikkanen & Melinda K. Abrams, *U.S. Health Care from a Global Perspective, 2019: Higher Spending, Worse Outcomes?*, COMMONWEALTH FUND (Jan. 30, 2020), http://www.commonwealthfund.org/publications/issue-briefs/2020/jan/us-health-care-global-perspective-2019 [https://perma.cc/EPN3-ACW5] ("The second-highest ranking country, Switzerland, spent 12.2 percent. At the other end of the spectrum, New Zealand and Australia devote only 9.3 percent, approximately half as much as the U.S. does.").

99. *The Challenge of Health Care Fraud*, NAT'L HEALTH CARE ANTI-FRAUD ASS'N, http://www.nhcaa.org/resources/health-care-anti-fraud-resources/the-challenge-of-health-care-fraud.aspx [https://perma.cc/BR7V-G74P] (last visited Dec. 7, 2020); *see* Katherine Drabiak & Jay Wolfson, *What Should Health Care Organizations Do to Reduce Billing Fraud and Abuse?*, 22 AMA J. ETHICS 221 (2020); *see* Jennifer Tolbert et al., *Key Facts About the Uninsured Population*, KAISER FAM. FOUND. (Nov. 6, 2020), http://www.kff.org/uninsured/issue-brief/key-facts-about-the-uninsured-population/ [https://perma.cc/83VK-YZB8] (discussing how the lack of health coverage

damages our health care system in a myriad of ways.[100] Health care fraud harms individual patients by exposing them to unnecessary medical services, which could result in bodily harm as well as the patient's payment of frivolous cost-sharing obligations.[101] It drains federal government resources, thus limiting the amount of coverage available under the federal programs.[102] It increases the overall cost of health care which in turn makes health care unaffordable for a large percentage of Americans.[103] It also harms health care businesses because health care fraud interferes with market forces, results in unfair competition, and leads to patient steering.[104] The tension lies, however, in finding the balance between enacting regulations that deter fraud while still allowing the health care industry flexibility to enter into arrangements that benefit the facility and patient care.[105] Therefore, Congress enacted the Stark Law, as well as additional laws, to help combat the rampant fraud and abuse of our health care system while still creating numerous exceptions to those laws to permit arrangements that do not pose a high risk of abuse of the federal programs.[106]

Despite the fact that the Stark Law has potentially saved the federal programs billions of dollars in deterring fraud, many argue that, because of its outdated and complicated language, the Stark Law has prevented the evolution of health care to a more streamlined delivery and payment system that would ultimately provide better patient care and save billions of dollars in costs.[107]

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has been a persistent problem in the United States); Michael L. Millenson, *Half a Century of the Health Care Crisis (and Still Going Strong)*, HEALTH AFF. (Sept. 12, 2018), http://www.healthaffairs.org/do/10.1377/hblog20180904.457305/full/ [https://perma.cc/G5LY-EWD9] (discussing how drug prices are spiking).

100. *The Challenge of Health Care Fraud*, *supra* note 99; *see* Drabiak & Wolfson, *supra* note 99.

101. Drabiak & Wolfson, *supra* note 99, at 221; U.S. DEP'T OF HEALTH & HUMAN SERVS., A ROAD MAP FOR NEW PHYSICIANS: AVOIDING MEDICARE AND MEDICAID FRAUD AND ABUSE 16-17, http://oig.hhs.gov/compliance/physician-education/roadmap_web_version.pdf [https://perma.cc/67UH-YUUW].

102. *See* Drabiak & Wolfson, *supra* note 99; U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 101.

103. *The Challenge of Health Care Fraud*, *supra* note 99.

104. U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 101, at 5.

105. Medicare and State Healthcare Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 84 Fed. Reg. 55,694, 55,695 (Oct. 17, 2019) (to be codified at 42 C.F.R. pts. 1001, 1003).

106. Press Release, Department of Justice, Justice Dep't Recovers Over $3 Billion from False Claims Act Cases in Fiscal Year 2019 (Jan. 9, 2020), https://www.justice.gov/opa/pr/justice-department-recovers-over-3-billion-false-claims-act-cases-fiscal-year-2019 [https://perma.cc/S56K-299T]. The Anti-Kickback Statute was another major law used to deter fraud and is very closely tied to the Stark Law. Also, the False Claims Act is another law used to prosecute health care fraud.

107. Butler, *supra* note 93, at 7-8; Diamond, *supra* note 93, at 1; Press Release, U.S. Dep't of Health & Human Servs., HHS Proposes Stark Law & Anti-Kickback Statute Reforms to Support

The Stark Law, with its numerous requirements, has created a system that makes it very difficult, if not impossible, for a health care provider or facility to be nimble in making changes to their existing models of delivering patient care and accepting payments. This problem is especially apparent in emergency situations, which may require a health care system to act quickly and adjust to the changing public health needs. The COVID-19 crisis required our health care system to adapt overnight to address the needs of the many sick patients flooding our health care facilities.[108] Secretary Azar authorized blanket waivers to the Stark Law because the Stark Law was a barrier to making swift and necessary changes to the health care facilities' procedures.[109] These waivers have allowed health care systems to focus on patient needs, rather than the fraud-deterring regulations that may inhibit the provisions of those needs.

## V. STARK LAW WAIVERS ARE NECESSARY IN A PUBLIC HEALTH EMERGENCY

As discussed above, section 1135 of the Social Security Act allows the Secretary of HHS to issue waivers or allow modifications to certain health care regulations.[110] Before the Secretary may exercise his or her authority to grant waivers, two requirements must be met. First, the President must declare a state of emergency or disaster under the Stafford Act or the National Emergencies Act.[111] For the COVID-19 crisis, this requirement was satisfied on Friday, March 13, 2020. Second, the Secretary must have declared a Public Health Emergency under section 319 of the Public Health Service Act.[112] This requirement was satisfied on January 31, 2020.[113] Both prerequisites were met, therefore allowing

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Value-Based & Coordinated Care (Oct. 9, 2019), https://www.hhs.gov/about/news/2019/10/09/hhs-proposes-stark-law-anti-kickback-statute-reforms.html [https://perma.cc/QDB6-BV5G].

108. *See* AM. HOSP. ASS'N, HOSPITALS AND HEALTH SYSTEMS FACE UNPRECEDENTED FINANCIAL PRESSURES DUE TO COVID-19 1 (2020), https://www.aha.org/guidesreports/2020-05-05-hospitals-and-health-systems-face-unprecedented-financial-pressures-due [https://perma.cc/9EGQ-46LN]; *Using Telehealth to Expand Access to Essential Health Services During the COVID-19 Pandemic*, CTR. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/coronavirus/2019-ncov/hcp/telehealth.html [https://perma.cc/28TT-8ZTV] (last updated June 10, 2020).

109. 42 U.S.C. § 1320b-5 (2020); *Fraud & Abuse Waivers*, *supra* note 28; *COVID-19 Emergency Declaration Blanket Waivers for Health Care Providers*, CTR. FOR MEDICARE & MEDICAID SERV. (Sept. 29, 2020), https://www.cms.gov/files/document/summary-covid-19-emergency-declaration-waivers.pdf [https://perma.cc/4FGB-LQM9].

110. 42 U.S.C. § 1320b-5.

111. *Id.*; Proclamation No. 9994, 85 Fed. Reg. 15,337 (Mar. 13, 2020).

112. 42 U.S.C. § 1320b-5(b) (2020); 42 U.S.C. § 247d (2020); Press Release, Alex M. Azar II, Sec'y Azar Delivers Remarks on Declaration of Pub. Health Emergency for 2019 Novel Coronavirus (Jan. 31, 2020), https://www.hhs.gov/about/leadership/secretary/speeches/2020-speeches/secretary-azar-delivers-remarks-on-declaration-of-public-health-emergency-2019-novel-coronavirus.html [https://perma.cc/LS25-PRF3].

113. Press Release, Alex M. Azar II, *supra* note 112.

Secretary Azar to authorize blanket waivers of sanctions of the Stark Law.[114] Secretary Azar outlined eighteen different situations that would ordinarily violate the Stark Law, but during the COVID-19 emergency, such would instead be covered by the blanket waivers. If a provider takes any of the enumerated actions or provides any of the services or items in good faith to help provide care, absent any finding of fraud or abuse by the governor of each state, the health care provider may be reimbursed for services or items provided and will be exempted from penalties for noncompliance with the Stark Law.[115] In addition to the enumerated blanket waivers, CMS may also approve additional section 1135 waivers on a case-by-case basis by specific request from a health care provider.[116]

The blanket waivers were retroactively effective as of March 1, 2020, and apply nationwide.[117] These blanket waivers apply to all health care providers.[118] Health care providers do not need to provide notice to the Secretary of CMS prior to utilizing one of the blanket waivers, however, the providers should develop and maintain records in a timely manner.[119] The blanket waivers apply only to financial relationships and referrals related to the COVID-19 national emergency. "The remuneration and referrals described in the blanket waivers must be solely related to COVID-19 [p]urposes."[120] These waivers will terminate as set forth in section 1320b-5 (e)(1) of the Social Security Act.[121]

### *A. Secretary Azar Authorizes Eighteen Waivers Available to the Stark Law to Be Used Solely for COVID-19 Purposes*

The eighteen enumerated blanket waivers were authorized by Secretary Azar to ensure that recipients of Medicare, Medicaid, and CHIP were able to receive the health care items and services that they need during this emergency. Additionally, health care providers that furnish such items and services in good faith to assist with COVID-19 purposes can expect to be reimbursed and not face sanctions if their arrangements meet the requirements of the blanket waivers.

The first blanket waiver is for "[r]emuneration from an entity to a physician . . . that is above or below the fair market value for services personally performed by the physician . . . to the entity."[122] In other words, the blanket waiver allows

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114. *See* Proclamation No. 9994, 85 Fed. Reg. at 15,337; *see* Press Release, Alex M. Azar II, *supra* note 112.

115. *Blanket Waivers of Section 1877(g)*, *supra* note 18, at 3-5.

116. *Id.* at 1-2.

117. *Id.* at 2.

118. *Id.* at 1 ("For purposes of section 1135 of the Act, 'health care providers' means any entity that furnishes health care items or services, and includes a hospital or other provider of services, a physician or other health care practitioner or professional, a health care facility, or a supplier of health care items or services.").

119. *Id.* at 2.

120. *Id.* at 3. For a description of COVID-19 purposes, see *id*.

121. *See* 42 U.S.C. § 1320b-5(e)(1) (2020).

122. *Blanket Waivers of Section 1877(g)*, *supra* note 18, at 2; *see also* 42 U.S.C. § 1395nn

remuneration paid by an entity that performs DHS to a physician that is either below or above fair market value for his or her personal services. Under the standard "personal service arrangements" exception in the Stark Law, the regulation includes several requirements that must be met to avoid liability under the Stark Law.[123] One of the requirements of this exception is that the compensation amount for personal services cannot exceed fair market value[124] This blanket waiver will eliminate the need to comply with the fair market value requirement in the personal services arrangement exception if the service is part of the COVID-19 purposes. However, the additional requirements included in the personal service arrangements must still be met.[125] As a result of this waiver, a hospital may pay a physician a rate for contracted services during this pandemic that is higher than fair market value to account for caring for patients in an extremely exhausting, stressful, and hazardous environment.[126] This scenario would be permitted under this blanket waiver assuming the additional requirements of the personal services exception were met.

Blanket waivers two through four allow rental charges to be paid by an entity to a physician that are below fair market value for the entity's lease of office space, equipment, or items or services purchased by the entity from the physician.[127] Similar to blanket waiver one, exceptions currently exist in the Stark Law to allow for exceptions for rental of office space, equipment, and purchasing items or services from the physician.[128] The blanket waiver essentially eliminates the need to comply with the fair market value element of the exceptions while keeping the rest of the exceptions' requirements intact.[129] As a result of these waivers, a hospital can rent office space from a physician group at below fair market value or even free of charge to help provide space for patients during a

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(2020). When looking at whether there is a financial interest in an entity that performs DHS, the law states that the violation will also occur if a financial interest exists with an immediate family member of the physician. *See* 42 U.S.C. § 1395nn.

123. 42 C.F.R. § 411.357(d) (2020).

124. 42 C.F.R. § 411.357(d)(1)(v) (2020) ("The compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and, except in the case of a physician incentive plan (as defined at § 411.351 of this subpart), is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties.").

125. *Explanatory Guidance: March 30, 2020 Blanket Waivers of Section 1877(g) of the Social Security Act*, CTR. FOR MEDICARE & MEDICAID SERV. 6 (Apr. 21, 2020), https://www.cms.gov/files/document/explanatory-guidance-march-30-2020-blanket-waivers-section-1877g-social-security-act.pdf [https://perma.cc/K5AS-XWYY]; *see also* 42 C.F.R. § 411.357(d).

126. *Explanatory Guidance: March 30, 2020 Blanket Waivers of Section 1877(g) of the Social Security Act*, *supra* note 125.

127. *Blanket Waivers of Section 1877(g)*, *supra* note 18, at 3-4.

128. *See* 42 C.F.R. § 411.357(a), (b), (*l*) (2020).

129. For more information about the "rental office space" exception and its requirements, see 42 C.F.R. § 411.357(a).

patient surge.[130] The entity must still meet the remaining requirements in the exceptions for rental of office space, rental of equipment, and purchase of services or items from a physician.[131]

Blanket waivers five through seven allow rental charges to be paid by a physician to an entity that are below fair market value for the physician's lease of office space, equipment, or items or services purchased by the physician from the entity.[132] As mentioned above, exceptions currently exist in the Stark Law to allow for exceptions for rental of office space, equipment, and purchasing items or services from an entity.[133] As a result of these waivers, an entity can sell telehealth equipment to physicians at below fair market value or even at no charge to allow physicians to provide timely care to their patients without the patient having to come into a hospital or facility.[134] The blanket waiver essentially eliminates the need to comply with the fair market value element of the exceptions while keeping the rest of the exceptions' requirements intact.[135]

These waivers that remove the requirement for fair market value for office space rental, equipment rental, and purchasing of services or items will be critical to the need to act quickly to meet patient demands.

> For example, a physician practice may be willing to rent or sell needed equipment to a hospital at a price that is below what the practice could charge another party. Or, a hospital may provide space on hospital grounds at no charge to a physician who is willing to treat patients who seek care at the hospital but are not appropriate for the emergency department or inpatient care.[136]

Assuring that a rental or sale of equipment meets the fair market value standards takes time that the health care providers do not have during this emergency situation. The methods to determine fair market value can be time-consuming and complex.[137] The health care providers need to be able to rent or sell equipment,

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130. *Explanatory Guidance: March 30, 2020 Blanket Waivers of Section 1877(g) of the Social Security Act*, *supra* note 125, at 3.

131. *Id.* at 6; *see also* 42 C.F.R. § 411.357(a).

132. *Blanket Waivers of Section 1877(g)*, *supra* note 18, at 4.

133. *See* 42 C.F.R. § 411.357(a), (b), (*l*).

134. *Blanket Waivers of Section 1877(g)*, *supra* note 18; *see also* 42 C.F.R. § 411.357(a).

135. For more information about the fair market value element of the exceptions, see 42 C.F.R. § 411.357(*l*).

136. *Durable Medical Equipment, Prosthetics, Orthotics and Supplies: CMS Flexibilities to Fight COVID-19*, CTR. FOR MEDICARE & MEDICAID SERV. 2, https://www.cms.gov/files/document/covid-dme.pdf [https://perma.cc/6NLH-6FKP] (last updated Sept. 8, 2020).

137. *Teaching Hospitals, Teaching Physicians and Medical Residents: CMS Flexibilities to Fight COVID-19*, CTR. FOR MEDICARE & MEDICAID SERV. 9, https://www.cms.gov/files/document/covid-teaching-hospitals.pdf [https://perma.cc/DX4W-9CHM] (last updated Sept. 29, 2020). Generally, health care entity valuation methods can be categorized into one of three general valuation approaches: (1) the asset-based approach, (2) the income approach, and (3) the market approach. Jason Ruchaber & Albert Hutzler, *A Balanced Approach to Valuation of Physician*

lease office space, or purchase products as quickly as possible to meet the very time-sensitive and critical needs of COVID-19 patients.

Blanket waiver eight allows remuneration from a hospital to a physician in the form of medical staff incidental benefits that exceed the limits set forth in 42 C.F.R. § 411.357(m)(5).[138] Currently, the incidental benefits limit is $36 per occurrence.[139] The blanket waiver does not specify how much the incidental benefits can surpass the limits in the regulations, but as stated in the preamble, all the remuneration provided to the physician from the entity should be in good faith and directly related to COVID-19 purposes. This will allow hospitals the ability to provide multiple daily meals, comfort items such as a change of clothing, laundry service for clothes used while at the hospital, and even child care fees so that the physicians are able to stay at long hours at the hospital to care for patients.[140] Without providing this support to the physicians, these daily tasks would be an additional burden for them and might lead to a faster burnout because they are working around the clock in high stress and potentially dangerous conditions.[141]

Similar to blanket waiver eight, blanket waiver nine allows the remuneration from an entity to a physician in the form of nonmonetary compensation to exceed the limit set forth in 42 C.F.R. § 411.357(k)(1).[142] Currently, the nonmonetary compensation may not exceed an aggregate of $423 per calendar year.[143] The

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*Practices*, 13 AM. HEALTH LAW. ASS'N 1, 3 (2011); *see also* 42 C.F.R. § 411.351 (2020) ("'General Market Value' means the price that an asset would bring as a result of bona fide bargaining between well-informed buyers and sellers who are not otherwise in a position to generate business for the other party, or the compensation that would be included in a service agreement as a result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, on the date of acquisition of the asset or at the time of the service agreement.").

138. *Blanket Waivers of Section 1877(g)*, *supra* note 18, at 4; 42 C.F.R. § 411.357(m) (2020); *see also Physician Self-Referral*, CTR. FOR MEDICARE & MEDICAID SERV. (Jan. 5, 2015), https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index?redirect=/PhysicianSelfReferral/10_CPI-U_Updates.asp [https://perma.cc/SN3Z-LNE8].

139. 42 C.F.R. § 411.357(m)(5) (2020); *CPI-U Updates*, CTR. FOR MEDICARE & MEDICAID SERV. (Dec. 20, 2019), https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/CPI-U_Updates [https://perma.cc/ZG2H-JJG8].

140. *Blanket Waivers of Section 1877(g)*, *supra* note 18, at 3.

141. *Caring for Our Caregivers During COVID-19*, AMA, https://www.ama-assn.org/delivering-care/public-health/caring-our-caregivers-during-covid-19 [https://perma.cc/2J7F-KQKS] (last updated June 17, 2020); *see* Pamela Hartzband & Jerome Groopman, *Physician Burnout, Interrupted*, 382 NEW ENG. J. MED. 2485 (2020); *see* OFFICE OF INSPECTOR GEN., OEI-06-20-00300, HOSPITAL EXPERIENCES RESPONDING TO THE COVID-19 PANDEMIC: RESULTS OF A NATIONAL PULSE SURVEY MARCH 23–27, 2020 (2020), http://www.oig.hhs.gov/oei/reports/oei-06-20-00300.pdf [https://perma.cc/Q5JN-LW3Q].

142. *Blanket Waivers of Section 1877(g)*, *supra* note 18, at 4; 42 C.F.R. § 411.357(k)(1) (2020).

143. 42 C.F.R. § 411.357(k)(1).

blanket waiver does not specify how much the incidental benefits can surpass the limit in the regulation, but the requirement of good faith and avoidance of fraud should guide the entity in its decisions. "For example, a home health agency may provide continuing medical education to physicians in the community on the latest care protocols for homebound patients with COVID-19."[144] Similarly, a hospital may provide food, supplies, transportation, and isolation-related services such as hotel fees and child care expenses to the physician or their immediate family member while they are working in the hospital's emergency department.[145]

Blanket waivers ten and eleven concern when a physician makes a loan to an entity or the entity makes a loan to a physician.[146] Under these waivers, either party is able to extend or receive a loan that has an interest rate that is below fair market value or a loan that would not be otherwise available from a traditional lender.[147] This is also a very important waiver to allow the continuity of health care operations when resources are being depleted at unprecedented rates. The waiver allows a physician to make a loan to a hospital so that the hospital can make its payroll obligations or pay vendors to ensure operations can continue.[148] Additionally, a hospital would be permitted to make a loan to a physician who, for example, has lost revenue due to the cancellation of elective procedures during quarantine to ensure capacity for COVID-19 needs.[149]

Blanket waiver twelve allows a physician-owned hospital to temporarily expand its facility to allow for more beds, operating rooms, and procedure rooms.[150] This expansion is permitted without prior application approval as normally required under section 1877 of the Social Security Act and 42 C.F.R. § 411.362.[151] This blanket waiver is critical to allowing hospitals to expand to meet the needs of the community. As the numbers of patients surge in certain pockets of the country, makeshift hospitals and other creative solutions are necessary to accommodate for additional patients as facilities exceed capacity.[152]

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144. *Durable Medical Equipment, Prosthetics, Orthotics and Supplies: CMS Flexibilities to Fight COVID-19*, *supra* note 136.

145. *Coronavirus Waivers & Flexibilities*, CTR. FOR MEDICARE & MEDICAID SERV., http://www.cms.gov/about-cms/emergency-preparedness-response-operations/current-emergencies/coronavirus-waivers [https://perma.cc/N6RJ-FEDU] (last updated Dec. 10, 2020).

146. *Blanket Waivers of Section 1877(g)*, *supra* note 18, at 4.

147. *Id.*

148. *Coronavirus Waivers & Flexibilities*, *supra* note 146.

149. *Blanket Waivers of Section 1877(g)*, *supra* note 18.

150. *Id.* at 4.

151. *Id.*

152. Andis Robeznieks, *CMS Offers More Flexibility, Financial Stability for COVID-19 Care*, AMA (Apr. 1, 2020), https://www.ama-assn.org/practice-management/medicare/cms-offers-more-flexibility-financial-stability-covid-19-care [https://perma.cc/X78B-B49F]; Liz Szabo & Cara Anthony, *More than 5,000 Surgery Centers Can Now Serve as Makeshift Hospitals During COVID-19 Crisis*, KAISER HEALTH NEWS (Mar. 30, 2020), https://khn.org/news/more-than-5000-surgery-centers-can-now-serve-as-makeshift-hospitals-during-covid-19-crisis/ [https://perma.cc/678B-MDRK] ("Outpatient surgery centers will be allowed to treat patients with other critical needs . .

One example is where hospitals convert observation beds to inpatient beds, or they simply add more inpatient beds to their facility.[153] This will allow hospitals to be prepared to meet increased demand.

Blanket waiver thirteen allows referrals by a physician-owner of a hospital that converted from a physician-owned ambulatory surgical center to a hospital on or after March 1, 2020, provided criteria are met.[154] This blanket waiver requires, among other things, that the hospital must be enrolled in Medicare as a hospital during the period of the public health emergency, and the enrollment is not inconsistent with the Emergency Preparedness Pandemic Plan of the state in which it is located.[155] This waiver will allow the ambulatory surgical centers, which are largely empty due to the cancellation of elective procedures, to qualify as "hospitals" and provide necessary care to patients even though they have not met all of the requirements of section 1877(i)(1) of the Social Security Act.[156]

Blanket waiver fourteen addresses the home health agencies during this public health emergency.[157] This waiver allows a physician to refer a Medicare beneficiary for DHS to a home health agency that does not qualify as a rural provider and in which the physician has an ownership or investment interest.[158] Ordinarily, the physician would not be able to refer a Medicare beneficiary to a home health agency for DHS if the physician had an ownership or investment interest in the home health agency unless the home health agency was a rural provider.[159] This blanket waiver removes this barrier so that referrals to home health agencies may be made because there is an increased need for in-home health care as hospitals are nearing capacity.[160]

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. unrelated to COVID-19, allowing hospitals to conserve scarce resources and reduce the risk of infection to these patients."); *Two Makeshift Hospitals Just Opened in New York City to Help Battle the Coronavirus Pandemic*, CNBC (Apr. 1, 2020), http://www.cnbc.com/video/2020/04/01/coronavirus-two-makeshift-hospitals-just-opened-in-new-york-city.html [https://perma.cc/LM8N-NUVG]; *In Response to COVID-19, NYC Health + Hospitals Opens New 350-Bed Temporary Hospital on Roosevelt Island*, NYC HEALTH & HOSP. (Apr. 10, 2020), http://www.nychealthandhospitals.org/pressrelease/in-response-to-covid-19-nyc-health-hospitals-opens-new-350-bed-temporary-hospital-on-roosevelt-island [https://perma.cc/QCP8-DJ9B].

153. *Blanket Waivers of Section 1877(g)*, *supra* note 18.

154. *Id.* at 5.

155. *Id.*

156. *Id*; *see also* 42 U.S.C. § 1395nn(i)(1) (2020).

157. *Blanket Waivers of Section 1877(g)*, *supra* note 18, at 5.

158. *See* 42 C.F.R. § 411.356(c)(1) (2020); *see also Blanket Waivers of Section 1877(g)*, *supra* note 18.

159. *Blanket Waivers of Section 1877(g)*, *supra* note 18.

160. *Id.*; *Moving to a New Normal Dashboard*, MIAMI-DADE COUNTY (July 9, 2020), https://www.miamidade.gov/information/library/2020-07-09-new-normal-dashboard.pdf [https://perma.cc/NSG8-UUPJ] (discussing how intensive care unit beds in Miami-Dade were at 91.9% capacity as of July 9, 2020); Brian Hamacher, *Miami-Dade ICU Hospital Beds Hit 90% Capacity, as Daily COVID Case Positivity Reaches 33%*, 6 S. FLA. (July 9, 2020), http://www.nbcmiami.com/news/local/miami-dade-icu-hospital-beds-hit-90-capacity-as-daily-covid-case-

Blanket waiver fifteen allows referrals by physicians in group practices for medically necessary DHS furnished by the group practice in a location that does not qualify as the "same building" or a "centralized building" for the purposes of 42 C.F.R. § 411.355(b)(2).[161] This waiver will broaden the in-office ancillary services exception under the Stark Law. The exception ordinarily requires that physicians in a group practice provide the ancillary services in the same building as the referring provider, but with this blanket waiver, the ancillary service can be performed by a physician without the "same building" requirement. This will allow physicians the flexibility to provide the care to the patient in the most convenient and efficient place without worry about the location. For example, group practices can furnish medically necessary DHS such as MRIs and CT scans from mobile vans in parking lots that are leased on a part-time basis.[162]

Blanket waiver sixteen allows

> [t]he referral by a physician in a group practice for medically necessary [DHS] furnished by the group practice to a patient in his or her private home, an assisted living facility, or independent living facility where the referring physician's principal medical practice does not consist of treating patients in their private homes.[163]

This loosening of location restrictions when providing DHS will allow flexibility to accommodate patients that do not want to go to a hospital and possibly be exposed to COVID-19.[164] For example, a physician can visit the patient using telehealth technology and then order DHS to be performed by a nurse or technician in the patient's home.[165] This is both convenient and safe for a patient who may need to be in quarantine, and it also alleviates the need for that patient to occupy a bed in a hospital or clinic that could be used by a very sick patient.

Blanket waiver seventeen allows a physician to refer a patient to an entity in which the physician's immediate family member has a financial interest if the patient resides in a rural area.[166] Again, the loosening of restrictions of where a patient may be referred for medically necessary DHS is necessary during this pandemic because of a shortage of available places to provide the necessary DHS. This shortage is only exacerbated in rural areas where there are fewer health care facilities to serve the population.[167]

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positivity-reaches-33/2260114/ [https://perma.cc/EW4M-YBPS]; *In Response to COVID-19, NYC Health + Hospitals Opens New 350-Bed Temporary Hospital on Roosevelt Island*, *supra* note 152 ("The public hospital system is working to open 3,000 additional [intensive care unit] beds by May 1, nearly tripling the base [intensive care unit] capacity of its [eleven] hospitals.").

161. *Blanket Waivers of Section 1877(g)*, *supra* note 18, at 5.

162. *See Coronavirus Waivers & Flexibilities*, *supra* note 146.

163. *Blanket Waivers of Section 1877(g)*, *supra* note 18, at 5.

164. *See Coronavirus Waivers & Flexibilities*, *supra* note 146.

165. *See id.*

166. *Blanket Waivers of Section 1877(g)*, *supra* note 18, at 5.

167. *See* K. Kelly White Bryant & Ozair M. Shariff, *Healthcare Fraud & Abuse Laws Are Relaxed During COVID-19*, MED. NEWS (Apr. 27, 2020), http://www.medicalnews.md/health care-

Blanket waiver eighteen allows a physician to refer a patient to an entity where the physician

> has a compensation arrangement that does not satisfy the writing or signature requirement[] of an applicable exception but satisfies each other requirement of the applicable exception, unless such requirement is waived under one or more of the blanket waivers set forth above.[168]

This waiver allows the health care providers to put "patients over paperwork."[169] Normally, the health care providers would need a written contract or body of documents to evidence that a business arrangement meets an exception of the Stark Law. Many exceptions also require the parties to sign the agreement. This waiver eliminates the need to have lawyers draft contracts before health care providers are allowed to engage in business and referrals with each other. This waiver helps get the patients the items or care they need as quickly as possible. During this emergency, HHS does not want the drafting or signing of paperwork to be a barrier or delay in meeting the patients' health care needs. For example, a physician with extra supplies may deliver masks and gloves to a hospital before the purchase arrangement is documented and signed by the parties.[170] Therefore, if an already existing Stark Law exception requires writing or a signature, this is now waived during this public health emergency.[171] However, the remaining requirements of the exception must still be met unless they are also waived under a separate blanket waiver.[172]

### *B. The Impact of the COVID-19 Stark Law Waivers on Patient Care and Hospital Operations*

When reviewed as a whole, these eighteen blanket waivers help patients by giving providers the flexibility to swiftly move to increase access to care for patients. Access to care is increased in several ways by the blanket waivers. Staffing needs can be met by allowing physician arrangements with hospitals without needing the formality of a written agreement and valuation assessments which will postpone the ability for a physician to begin treating patients.[173]

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fraud-and-abuse-laws-are-relaxed-during-covid-19/ [https://perma.cc/T26P-RQAV]; *see also* Sandra C. Melvin et al., *The Role of Public Health in COVID-19 Emergency Response Efforts from a Rural Health Perspective*, 17 PREVENTING CHRONIC DISEASE art. E70 (2020).

168. *Blanket Waivers of Section 1877(g)*, *supra* note 18, at 6.

169. *Hospitals: CMS Flexibilities to Fight COVID-19*, CTR. FOR MEDICARE & MEDICAID SERV. 1, https://www.cms.gov/files/document/covid-hospitals.pdf [https://perma.cc/W33M-2JKQ] (last updated Aug. 20, 2020).

170. *Blanket Waivers of Section 1877(g)*, *supra* note 18, at 5.

171. *Id.*

172. *Id.* Some of the Stark Law exceptions that require a writing or signature are rental of office space, rental of equipment, personal service arrangements, physician recruitment, and group practice arrangement with a hospital. *See* 42 U.S.C. § 411.357 (2020).

173. *Blanket Waivers of Section 1877(g)*, *supra* note 18, at 5.

Furthermore, hospitals will be able to provide meals, laundry services, child care assistance, lodging, and more to help physicians provide more hours of work to the hospital, thus increasing access to care for patients when the hospital is appropriately staffed.[174]

Access to care will also be increased by authorizing alternate locations for services. CMS has authorized the "hospitals without walls" approach to ensure that the right care can be given in the best location.[175] If patients can receive an MRI or lab work in a mobile health services van, or even in the comfort of their home, this will allow patients without means for transportation or patients with fear of getting infected with COVID-19 in a hospital or clinic, the ability to receive the care they need. Similarly, a physician in a group practice can make a referral for DHS to a group practice member even if the service or item is performed in the patient's home or an alternate, more convenient, location for the patient.[176] Additionally, access to care is increased when a physician can refer a patient for DHS to any home health agency and not have to restrict where he or she may refer a patient because of an ownership interest.[177] More locations may also be available for patients to receive care because ambulatory surgical centers can convert to hospitals to accommodate a surge of patients.[178]

Along these same lines, access to care will increase because physician-owned hospitals are allowed to increase the number of operating rooms, procedure rooms, and beds so they can appropriately care for patients without causing them undue delay or turning them away altogether.[179] This is especially critical now because an overflowing waiting room with coughing and symptomatic patients may infect otherwise COVID-19-free patients. Access to care can also increase with the sharing of equipment, space, and medical supplies between physicians and hospitals.[180] These items can be used or sold between the parties without delay of waiting for a fair market value assessment or written agreements to be finalized.[181]

Access to care will increase when loans are permitted between hospitals and physicians if either is in financial trouble due to the stress on their business due to COVID-19.[182] Hospitals can continue with payroll and operations expenses if they receive a loan from a physician to help with increased expenses due to

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174. *Id.* at 4.

175. Press Release, Rick Pollack, AHA Statement on CMS Emergency Declaration Waivers for Health Providers (Mar. 31, 2020), http://www.aha.org/press-releases/2020-03-31-aha-statement-cms-emergency-declaration-waivers-health-providers [https://perma.cc/BFR9-KNAE]; *Hospitals: CMS Flexibilities to Fight COVID-19*, *supra* note 169.

176. *Blanket Waivers of Section 1877(g)*, *supra* note 18, at 5.

177. *Id.*

178. *Id.*

179. *Id.* at 4-5.

180. *Id.* at 4.

181. *Id.* at 5.

182. *Id.* at 4.

overtime pay and additional expenses.[183] Similarly, physicians who are missing months of work because of the cancellation of appointments and elective procedures can get a loan from the hospital to help pay rent or other expenses.[184] These loans prevent business interruption and allow patients to access care from these providers. Operations will run more smoothly and care will be delivered in the most easily accessible modality as a result of these eighteen Stark blanket waivers.[185]

## VI. COVID-19 STARK LAW WAIVERS' IMPACT ON THE STARK LAW REFORM

As discussed above, the blanket waivers essentially relinquished many critical components of the Stark Law during the COVID-19 pandemic. How does this temporary dismantling of the Stark Law speak to the debate over the bigger picture of the future of the law? These waivers shed light on the greater debate on Stark Law reform. Some, including the now-deceased author of the law itself, Pete Stark, have previously called for a full repeal of the Stark Law because of its overly technical and complicated requirements which hinder our health care system.[186] However, a full repeal of the Stark Law would ignore the very real fact that rampant fraud exists in our health care system.

During the COVID-19 pandemic, the urgency to meet the extraordinary health care needs of patients and communities requires us to push aside the potential for fraud and focus on meeting patient needs as quickly and effectively as possible.[187] Waiving key components of the Stark Law, however, should not be sustained permanently. Requirements such as "fair market value" for compensation arrangements prevent hospitals, physicians, labs, or other entities from "buying" patients.[188] Financial gain should never influence medical decision making, and without the Stark Law, patients could be harmed by a physician's desire for financial gain over the patient's best interest. If the blanket waivers were to continue in perpetuity, it could cause a breakdown in the integrity of our health care system. The Stark Law has value in protecting patients from the undisclosed financial interests of their physicians.

On the other hand, it is impossible to ignore the need for permanent Stark Law reform. Shouldn't the efficient delivery of care and meeting patient needs

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183. *Id.*

184. *Id.*

185. *See id.* at 4-5.

186. Rebecca Olavarria, *Macra and Stark: Strange Bedfellows at the Heart of Health Care Reform*, 62 WAYNE L. REV. 131, 155 (2017). Even Congressman Stark lamented that the Stark law is riddled with ambiguities, technicalities, and complexities as a result of "high-priced lawyers who tried to build loopholes for their clients." *Id.* He argued for the entire repeal of the law so that it could get back to the initial intent of preventing kickbacks and the solicitation of referrals. *Id.* Olavarria argues that if the Stark Law was repealed, the Anti-Kickback Statute could accomplish much of the same goals of it. *See id.*; *see also Stark Law*, *supra* note 69.

187. *See Blanket Waivers of Section 1877(g)*, *supra* note 18, at 5.

188. *See* 42 C.F.R. § 411.357 (2020).

*always* trump paperwork and expensive formalities which slow down the delivery of care and increase operation costs? As part of CMS's Patients Over Paperwork Initiative and the HHS Regulatory Sprint to Coordinated Care, a proposed rule was issued to amend the Stark Law on October 17, 2019.[189] HHS acknowledged that the health care fraud and abuse laws, including the Stark Law, potentially restrict beneficial arrangements that would advance the transition to value-based delivery of care and the coordination of care among providers.[190] Coordination of care is important to delivering the best care because fragmented health care systems result in duplicative treatments and medications, delays, communication failures, thus potentially harming the patient and increasing the overall costs. Similarly, when payment is tied to providers delivering high-quality care measured by patient outcomes and incentivizing coordination among providers, the patient will receive better care at a lower cost. Therefore, HHS is motivated to amend the Stark Law and alleviate undue regulatory burdens that hinder the coordination of care among providers.

The proposed rule could be the answer. In this season of the COVID-19 pandemic, where CMS has acknowledged that the Stark Law is impeding access to health care, it might be the push needed to enact these major changes to the Stark Law. CMS proposed new compensation arrangement exceptions that provide maximum flexibility for value-based care models to coordinate care across settings and share payment across the arrangement.[191] The proposed rule was drafted to provide flexibility in the legal formalities and to encourage physician participation and a broad transition to value-based care models in our health care system. Flexibility is what is needed now during the COVID-19 emergency, and, if some of these broad and flexible value-based exceptions were in place, many of the blanket waivers would not have been necessary.

For example, unlike the existing Stark exceptions that are focused on

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189. Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. 55,766 (proposed Oct. 17, 2019) (to be codified at 42 C.F.R. pt. 411); Press Release, Ctrs. for Medicare & Medicaid Servs., CMS Administrator Verma Announces New Meaningful Measures Initiative and Addresses Regulatory Reform; Promotes Innovation at LAN Summit (Oct. 30, 2017), https://www.cms.gov/newsroom/press-releases/cms-administrator-verma-announces-new-meaningful-measures-initiative-and-addresses-regulatory-reform [https://perma.cc/B2FL-WL6R] (" The Administrator's remarks come a few days after the public launch of the agency's 'Patients Over Paperwork' Initiative, a cross-cutting, collaborative process that evaluates and streamlines regulations with a goal to reduce unnecessary burden, increase efficiencies, and improve the beneficiary experience."); Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. at 55,771 ("The Regulatory Sprint is focused specifically on identifying regulatory requirements or prohibitions that may act as barriers to coordinated care, assessing whether those regulatory provisions are unnecessary obstacles to coordinated care, and issuing guidance or revising regulations to address such obstacles and, as appropriate, encouraging and incentivizing coordinated care.").

190. Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. at 55,767.

191. *Id.* at 55,813.

technical requirements and the structure of the arrangement, the three proposed value-based exceptions take a new approach and focus on the purpose of the arrangement and the amount of risk exposure in the arrangement. If the entities meet the definitions to be included in one of the three value-based exceptions, then they will have substantially fewer requirements to comply with once inside the exception. Each value-based exception would have unique requirements depending on the level of risk-sharing to which the entity is exposed, however, all three exceptions would include basic safeguards. Additionally, an important distinction in these proposed exceptions is that there is not a prohibition on the compensation arrangement taking into account the volume or value of referrals. This is a big shift from the many current exceptions that include this limitation. Stark is a strict liability statute, so the proposed rule is attempting to provide more flexibility and less technical requirements so that there does not become a "gotcha" moment for failing to comply with one minor technicality.

Other proposals included in the rule clarify key definitions that are used in many of the Stark Law exceptions that have caused confusion in the health care industry. The confusion of key terms has led to the chilling of business innovation for fear of running afoul of the law unintentionally. For example, one term that has been waived through the COVID-19 section 1135 blanket waivers several times is the "fair market value" requirement for remuneration from a hospital or physician to the other providing services, supplies, loans, or in the rental of office space or equipment by an entity or physician. This key term is used extensively in the Stark Law exceptions.[192]

"Fair market value" is defined as "the value in arms length transactions, consistent with general market value."[193] However, over the years, confusion ensued as to a modification of the "fair market value" definition in Stark II. The Phase II definition of "fair market value" provided that

> fair market value is [usually] the price at which bona fide sales have been consummated for assets of like type, quality, and quantity in a particular market at the time of acquisition, or the compensation that has been included in bona fide service agreements with comparable terms at the time of the agreement, where the price or compensation has not been determined in any manner *that takes into account the volume or value of anticipated or actual referrals*.[194]

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192. *See id.* The fair market value requirement appears in compensation arrangements pertaining to rental of office space, rental of equipment, bona fide employment relationships, personal service arrangements, isolated transactions, and payments by a physician, as well as additional exceptions for academic medical centers, indirect compensation arrangements, electronic health records items and services, and assistance to compensate a nonphysician practitioner. 42 U.S.C. § 411.357.

193. 42 U.S.C. § 1395nn(h)(3) (2020). Additional terms were added for the fair market value of a lease of office space. *See id.*

194. 42 C.F.R. § 411.351 (2020) (emphasis added); *see also* Medicare Program; Physicians' Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69

This modification created uncertainty because the requirement that an arrangement not "take[] into account the volume or value of . . . referrals" was a separate element of many exceptions.[195] Many health care providers communicated to CMS in response to the Request for Information the challenges of applying this current definition of "fair market value" and confusion exists as to whether the Phase II regulations had conflated these two terms.

In the proposed rule, CMS has proposed to clearly separate and make distinct the definition of "fair market value" from the "volume or value standard." Additionally, the proposal would modify the "fair market value" definition to provide a separate definition for the rental of office equipment and another for the rental of office space. The proposal also included another definition for "general market value" that is consistent with the recognized principle of "market" valuation to ease the burden on parties attempting to ensure compliance with the fair market value requirement.[196] The proposed language may hopefully clear up some of the ambiguity with overlapping terms in the law and give providers more confidence in entering into new business arrangements.

If the proposed fair market value changes were currently in place, on that issue at least, no waiver may have been needed if a provider could quickly and confidently establish fair market value. If the rule were clear and straightforward to function in an emergency, then a provider would not have a problem navigating it in a normal scenario. The waivers have been effective in addressing the Stark Law barriers to providing care in this crisis. Hopefully, HHS will see the success from these waivers as evidence that more flexibility is warranted in the next round of Stark Law reforms.

## VII. CONCLUSION

COVID-19 has changed the world as we know it. Especially in the United States health care system, COVID-19 has shined a light on where we need to improve and be better prepared to handle this type of emergency. Stark Law is one of the key health care laws that must be reformed to provide flexibility and clarity in health care business arrangements. One main goal of Stark Law reform should be to make compliance with this law clear and straightforward to establish. As critics have argued, the current version of the Stark Law is quite the opposite. Stark Law, with its complicated exceptions and draconian penalties, has prevented a more modern and integrated approach to health care delivery. The COVID-19 public health emergency has highlighted the many areas of the Stark Law that are barriers to a flexible and efficient health care system that can

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Fed. Reg. 16,053, 16,128 (proposed Mar. 26, 2004) (to be codified at 42 C.F.R. pts. 411, 424); 42 U.S.C. § 1395nn (2020); Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. at 55,766.

195. *See* 42 C.F.R. § 411.351 (discussing isolated transactions and professional courtesy services).

196. Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 84 Fed. Reg. at 55,798.

provide access to the multitudes.

The necessary section 1135 waivers authorized during this pandemic point to areas where the Stark Law's antiquated requirements need to change to put the focus back on patients and achieve the best care possible for them. CMS has recently issued proposals to reform the Stark Law in hopes that it can usher in a new era of health care that is focused on increased value and improved care. The current section 1135 blanket waivers are a temporary fix to the Stark Law to alleviate an unexpected crisis. But hopefully, Stark Law will soon be permanently reformed so that clarity and flexibility are achieved, and in times of crisis or in times of peace, the health care industry can provide efficient, high-quality value-based care.