

HEALTH CARE FRAUD AND THE EROSION OF TRUST

Katrice Bridges Copeland

ABSTRACT—In health care, trust is a foundational concept. Patients must trust that their medical practitioners are competent to treat them. The trustworthiness of medical practitioners encourages patients to disclose intimate facts about their medical issues. Further, patients must trust health care providers to demonstrate impartial concern for the patients’ well-being, also known as fidelity. In providing care, the needs of the patients, rather than financial incentives, must drive medical practitioners. Without this trust, patients may not cooperate with diagnosis and treatment. In addition to trusting providers, care outcomes are better if patients trust the health care system as a whole.

This Essay examines the importance of the government’s role in building and maintaining trust in health care providers and the health care system. Due to programs such as Medicare and Medicaid, the government is a “participant-payer” in the health care system as well as a “regulator-enforcer” of the system. As regulator-enforcer, the government has many laws and regulations aimed at promoting trustworthy conditions between patients, health care providers, and the health care system. For example, the Anti-Kickback Statute prohibits all health care providers that participate in federal health care programs from benefitting financially from referrals to other providers. It is a criminal law that has substantial penalties attached to it.

While the government’s efforts to promote trustworthy conditions as regulator-enforcer are not without criticism, most of the focus has been on the government’s failure (as participant-payer) to design a payment system that properly incentivizes health care providers to deliver cost-efficient quality care that prioritizes the well-being of patients. Historically, Medicare and Medicaid have used a fee-for-service reimbursement mechanism which reimburses providers for every item or service provided. This incentivizes providers to increase the volume of care, which drives up the costs of providing health care without improving patient outcomes. Thus, fee-for-service reimbursement misaligns the incentives of providers because it serves as an enticement for providers to put their financial aspirations above their patients’ well-being.

The government’s newest reimbursement method—value-based reimbursement—requires the government to pay for outcomes rather than volume of services. With value-based reimbursement, providers take on financial risk based on the quality of care they provide. Value-based reimbursement promotes relationships between providers and continuity of care. Thus, it also has the potential to increase trust in health care providers and the system as a whole because it takes away some of the improper financial incentives inherent in fee-for-service reimbursement.

While value-based reimbursement is promising, it carries its own fraud risks, such as manipulation of quality data, which are not currently addressed by the fraud and abuse laws. This Essay maintains that if value-based reimbursement is going to be successful at realigning incentives, the government as regulator-enforcer must enact criminal fraud laws and regulations to address the fraud risks in value-based reimbursement. Without assurance that the government is closely monitoring fraud and protecting the interests of patients, patients may not trust value-based reimbursement which could ultimately undermine trust in providers and the health care system.

AUTHOR—Professor of Law, Penn State Law, University Park, PA. B.S., University of Illinois; J.D., University of Michigan Law School. For research assistance, the author would like to thank Victoria Crynes, Penn State Law class of 2023, and Julie Pandich, Penn State Law class of 2024

INTRODUCTION	91
I. THE IMPORTANCE OF TRUST IN HEALTH CARE	94
A. <i>Trust in Health Care Providers (Interpersonal Trust)</i>	95
B. <i>Trust in the Health Care System (Institutional Trust)</i>	97
II. HEALTH CARE FRAUD ENFORCEMENT’S IMPACT ON TRUST.....	99
A. <i>The Anti-Kickback Statute and Physician Self-Referral Law (Stark)</i>	100
B. <i>The Physician Payments Sunshine Act</i>	104
III. PAYMENT SYSTEMS AND TRUST	106
A. <i>Fee-For-Service Reimbursement’s Effect on Trust</i>	107
B. <i>Managed Care</i>	108
C. <i>The Shift to Value-Based Reimbursement</i>	110
CONCLUSION	113

INTRODUCTION

In health care, trust is a foundational concept. Patients must trust that their medical practitioners are competent to treat them.¹ The trustworthiness of medical practitioners encourages patients to disclose intimate facts about their medical issues.² Further, patients must trust health care providers to demonstrate impartial concern for the patients' well-being.³ In providing care, the needs of the patients, rather than financial incentives, must drive medical practitioners. Without this trust, patients may not cooperate with diagnosis and treatment.⁴ In addition to trusting providers, care outcomes are better if patients trust the health care system⁵ as a whole.⁶

But in a concerning trend, trust in the health care system has been on the decline. According to Gallup, in 1975, 80% of the public had confidence in the medical system, compared to only 38% in 2019.⁷ While the public generally trusts doctors, the public's trust is lowest in health insurance companies and pharmaceutical companies—33% and 34% respectively.⁸

¹ See Mark A. Hall, Elizabeth Dugan, Beiyao Zheng & Aneil K. Mishra, *Trust in Physicians and Medical Institutions: What Is It, Can It Be Measured, and Does It Matter?*, 79 MILBANK Q. 613, 614, 620–21 (2001).

² M. Gregg Bloche, *Trust and Betrayal in the Medical Marketplace*, 55 STAN. L. REV. 919, 924 (2002).

³ Hall et al., *supra* note 1, at 621.

⁴ See EDELMAN, EDELMAN TRUST BAROMETER 2022 SPECIAL REPORT: TRUST AND HEALTH 17–18 (2022), <https://www.edelman.com/sites/g/files/aatuss191/files/2022-08/2022%20Trust%20Barometer%20Special%20Report%20Trust%20and%20Health%20with%20Talk%20Track.pdf> [<https://perma.cc/4X4V-LPUZ>]. Some drivers of patient mistrust in doctors include doctors spending too little time with patients, not knowing patients, not listening to patients, failing to give patients all of the information, and being too financially motivated. AM. BD. OF INTERNAL MED. FOUND., SURVEYS OF TRUST IN THE U.S. HEALTH CARE SYSTEM 20 (2021), https://www.norc.org/PDFs/ABIM%20Foundation/20210520_NORC_ABIM_Foundation_Trust%20in%20Healthcare_Part%201.pdf [<https://perma.cc/8HN7-49PR>].

⁵ As Professors Talai Osmonbekov, Eric Yordy, and Sean Gregory have explained:

The healthcare sector can be divided into three types of companies: development-of-care, delivery-of-care, and financing-of-care. Development-of-care companies include pharmaceutical companies and other research companies that create medical devices and medicines for use in the provision of services. Delivery-of-care companies include hospitals and physician offices where patients receive the products developed by the development companies. Finally, the financing-of-care companies include insurance companies, health maintenance organizations (HMOs), and government agencies (Medicare, and Medicaid) that subsidize or regulate the payment of services.

Talai Osmonbekov, Eric Yordy & Sean Gregory, *The Affordable Care Act's Impact on Healthcare Marketing*, 20 J.L., BUS. & ETH. 21, 23 (2014). When this Essay refers to the health care system, it is including all of these categories.

⁶ EDELMAN, *supra* note 4, at 16–20.

⁷ *Confidence in Institutions*, GALLUP, <https://news.gallup.com/poll/1597/confidence-institutions.aspx> [<https://perma.cc/H2GP-DJAW>].

⁸ AM. BD. OF INTERNAL MED. FOUND., *supra* note 4, at 8.

There are many dynamic variables that affect trust in the health care system—rising health care costs, frustrations with insurance coverage, availability of physicians, access to care, media coverage of health care, and publicized scandals involving poor or fraudulent behavior.⁹ In recent years, stories of fraud at pharmaceutical companies,¹⁰ telemedicine companies,¹¹ drug rehabilitation treatment centers,¹² and other health care entities and providers¹³ have come to the surface and gained public awareness. These scandals have “contributed to mistrust and reduced confidence in health care entities.”¹⁴

⁹ Robert J. Blendon, *Why Americans Don't Trust the Government and Don't Trust Healthcare*, in *THE TRUST CRISIS IN HEALTHCARE: CAUSES, CONSEQUENCES, AND CURES* 24 (David A. Shore ed., 2007) (explaining that three types of scandals typically plague health care: medical error, problem doctors, and doctors or hospitals “bilking insurance companies or Medicare, fattening his or her own purse at the expense of premium payers or taxpayers”).

¹⁰ *See, e.g.*, Press Release, DOJ, Biogen Inc. Agrees to Pay \$900 Million to Settle Allegations Related to Improper Physician Payments (Sept. 26, 2022), <https://www.justice.gov/opa/pr/biogen-inc-agrees-pay-900-million-settle-allegations-related-improper-physician-payments> [https://perma.cc/2N9Y-4KAT]; Press Release, DOJ, Justice Department Announces Global Resolution of Criminal and Civil Investigations with Opioid Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family (Oct. 21, 2020), <https://www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid> [https://perma.cc/S669-QA2X]; Press Release, DOJ, Justice Department Announces Largest Health Care Fraud Settlement in Its History: Pfizer to Pay \$2.3 Billion for Fraudulent Marketing (Sept. 2, 2009), <https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history> [https://perma.cc/3RQH-7KM5].

¹¹ *See, e.g.*, Press Release, DOJ, Justice Department Charges Dozens for \$1.2 Billion in Health Care Fraud: Nationwide Coordinated Law Enforcement Action to Combat Telemedicine, Clinical Laboratory, and Durable Medical Equipment Fraud (July 20, 2022), <https://www.justice.gov/opa/pr/justice-department-charges-dozens-12-billion-health-care-fraud> [https://perma.cc/Q7RY-88N2]; Press Release, DOJ, National Health Care Fraud and Opioid Takedown Results in Charges Against 345 Defendants Responsible for More Than \$6 Billion in Alleged Fraud Losses (Sept. 30, 2020), <https://www.justice.gov/opa/pr/national-health-care-fraud-and-opioid-takedown-results-charges-against-345-defendants> [https://perma.cc/JP33-FQQE] (noting that more than \$4.5 billion of the false and fraudulent claims were attributed to telemedicine).

¹² *See, e.g.*, Press Release, DOJ, Justice Department Announces Series of Cases to Combat Addiction Treatment Kickback Schemes in Southern California (Dec. 16, 2021), <https://www.justice.gov/opa/pr/justice-department-announces-series-cases-combat-addiction-treatment-kickback-schemes> [https://perma.cc/K9GA-7V3U]; Press Release, DOJ, Jackson Woman Pleads Guilty to Soliciting Kickbacks, Making False Statements to Law Enforcement Agents, and Tampering with Records (Jan. 10, 2020), <https://www.justice.gov/usao-edky/pr/jackson-woman-pleads-guilty-soliciting-kickbacks-making-false-statements-law> [https://perma.cc/4PG4-WSBS] (explaining that the Jackson woman was the office manager of a substance abuse treatment clinic).

¹³ *See, e.g.*, Press Release, DOJ, Owner of Durable Medical Equipment Companies Arrested for \$17 Million Kickback Conspiracy (Dec. 15, 2022), <https://www.justice.gov/opa/pr/owner-durable-medical-equipment-companies-arrested-17-million-kickback-conspiracy> [https://perma.cc/7BCZ-XWZP]; Press Release, DOJ, Owner of Sacramento Area Home Health Care and Hospice Agencies Pleads Guilty to Medicare Fraud (July 15, 2021), <https://www.justice.gov/usao-edca/pr/owner-sacramento-area-home-health-care-and-hospice-agencies-pleads-guilty-medicare> [https://perma.cc/6U7P-LCF4].

¹⁴ Dhruv Khullar, *Building Trust in Health Care—Why, Where, and How*, 322 *JAMA* 507, 507 (2019).

Troublingly, the decline in trust in health care has coincided with a decline in trust in the government,¹⁵ resulting in serious consequences for, and negative impacts on, health outcomes. During the COVID-19 pandemic, for example, many people refused to take COVID-19 vaccines, citing their distrust of pharmaceutical companies¹⁶ and the government.¹⁷ As a result, researchers at Brown University and Microsoft AI Health estimated that more than 300,000 deaths could have been avoided if every eligible adult had gotten vaccinated once the vaccines became available.¹⁸

This Essay examines the government's role in building and maintaining trust in health care providers and the health care system. Due to programs such as Medicare and Medicaid, the government is a "participant-payer" in the health care system as well as a "regulator-enforcer" of the system. To build trustworthy conditions, the government as regulator-enforcer ought to protect patients from providers who are driven by financial incentives rather than the needs of their patients. Such providers may otherwise sacrifice the standard of care for their own profit margins. In addition, the government ought to protect the integrity of federal health care programs, which provide stability to the most vulnerable members of our society. This protection comes in the form of health care fraud laws and regulations as well as the government's enforcement activities. As participant-payer, the government needs to ensure that it runs its health care programs well. The government should also design payment policies that incentivize health care providers and institutions to prioritize the needs of their patients by providing cost-effective quality care. If the government could achieve these goals, it

¹⁵ See *Confidence in Institutions*, *supra* note 7.

¹⁶ Allana Akhtar, *Some Americans Were Primed for Vaccine Skepticism After Decades of Mistrust in Big Pharma*, INSIDER (Oct. 24, 2021, 7:35 AM), <https://www.businessinsider.com/big-pharma-mistrust-contributed-to-vaccine-hesitancy-2021-8> [<https://perma.cc/3R44-PMED>] (observing that "publicized claims of mismanagement and greed among some of the world's largest pharmaceutical companies . . . have eroded public trust and, in turn, have contributed to vaccine hesitancy among some Americans"). Only 20% of Americans who said they will "definitely not" get a COVID-19 vaccine reported that they "trust pharmaceutical companies to provide reliable information." *Id.*

¹⁷ Robert Towey, *CNBC Poll Shows Very Little Will Persuade Unvaccinated Americans to Get Covid Shots*, CNBC (Sept. 10, 2021, 11:10 AM), <https://www.cnbc.com/2021/09/10/cnbc-poll-shows-very-little-will-persuade-unvaccinated-americans-to-get-covid-shots.html> [<https://perma.cc/D6T6-NHMK>] ("Americans who are unvaccinated against Covid-19 are largely driven by a mistrust of the government and fears over vaccine side effects, and there is very little that can be done to persuade them to get the shots, a new CNBC/Change Research poll reveals."); see also EDELMAN, *supra* note 4, at 11 (explaining that those who chose not to receive the COVID-19 vaccine relied upon internet searches and friends and family, rather than national health care experts, when they made that choice).

¹⁸ Selena Simmons-Duffin & Koko Nakajima, *This Is How Many Lives Could Have Been Saved with COVID Vaccinations in Each State*, NPR (May 13, 2022, 5:01 AM), <https://www.npr.org/sections/health-shots/2022/05/13/1098071284/this-is-how-many-lives-could-have-been-saved-with-covid-vaccinations-in-each-sta> [<https://perma.cc/VKQ6-58YG>].

would go a long way toward maintaining public trust in health care providers and institutions.

This Essay proceeds in three Parts. Part I lays a foundation by explaining the two types of trust that are central to health care: (1) interpersonal trust between doctors and their patients and (2) institutional trust in the health care system. Part II explains the government’s role as a regulator-enforcer of health care fraud laws and how this role affects trust in the health care system. It focuses on the government’s use of the Anti-Kickback Statute, Physician Self-Referral Law, and Physician Payments Sunshine Act, and how its enforcement of these laws simultaneously furthers—and potentially undermines—trust in health care. Part III explores how the government affects trust as a participant-payer through its payment systems—fee-for-service, managed care, and value-based reimbursement. This Essay concludes that if the government (as regulator-enforcer) wants to further trust in health care providers and the health care system, it must enact regulations to address the fraud risks in value-based reimbursement.

I. THE IMPORTANCE OF TRUST IN HEALTH CARE

Trust¹⁹ matters in health care because “it encourage[s] patients to volunteer intimate facts about their lives, cooperate with diagnosis and treatment, draw reassurance from medical explanations, and experience the doctor-patient relationship itself as empowering and comforting.”²⁰ In return for that vulnerability, patients expect health care providers to share vital information concerning the possibilities and consequences of treatment.²¹ Perhaps more importantly, patients expect health care providers to act in the

¹⁹ Professor David Mechanic defines trust as “the expectation that individuals and institutions will meet their responsibilities to us.” David Mechanic, *The Functions and Limitations of Trust in the Provision of Medical Care*, 23 J. HEALTH POL., POL’Y & L. 661, 662 (1998). He further discusses “five dimensions of trust: (1) expectations about physicians’ competence, (2) the extent to which doctors are concerned with their patients’ welfare, (3) physician control over decision making, (4) physicians’ management of confidential information, and (5) physicians’ openness in providing and receiving information.” *Id.* at 663–64; *see also* Claire A. Hill & Erin Ann O’Hara, *A Cognitive Theory of Trust*, 84 WASH. U. L. REV. 1717, 1724 (2006) (“Trust experts all seem to agree that trust is a state of mind that enables its possessor to be willing to make herself vulnerable to another—that is, to rely on another despite a positive risk that the other will act in a way that can harm the truster.”).

²⁰ Bloche, *supra* note 2, at 924; *see* Hall et al., *supra* note 1, at 614 (“[Trust] has been hypothesized or shown to affect . . . patients’ willingness to seek care, reveal sensitive information, submit to treatment, . . . adhere to treatment regimens, remain with a physician, and recommend physicians to others.”).

²¹ *See* W. BRADLEY TULLY, FEDERAL ANTI-KICKBACK LAW § 1.B (2022) (“Because medicine is a learned profession, health care consumers are at an information deficit when it comes to making informed choices regarding when and from whom they will receive services.”).

patient's best interest.²² Thus, good medical care depends on patients trusting in the fidelity of their health care providers.

In addition to trusting health care providers, the system works best if patients trust the health care system as a whole, from development-of-care companies to delivery-of-care companies and financing-of-care companies. After all, "patients are dependent on health care institutions to meet their needs for care, a vulnerability that can prove uncomfortable if they mistrust those institutions."²³ Studies have shown that trust in the health care system is a top determinant of good health behaviors.²⁴ While patients typically trust their physicians based on direct experience, patients' trust in medical institutions is often guided by informal public opinion and the media.²⁵ Thus, institutional trust is more difficult to build and easier to lose than interpersonal trust.

This Part will examine key components of both interpersonal and institutional trust and argue that the government (as both regulator-enforcer and participant-payer) must play a key role in maintaining trust in health care providers and the health care system.

A. Trust in Health Care Providers (Interpersonal Trust)

The relationship of trust between doctors and patients does not follow the traditional model of trust.²⁶ In most situations, relationships of trust are built gradually over time. As Professors Claire A. Hill and Erin Ann O'Hara have explained, "A person develops a sense of the trustworthiness of another across specific contexts, and these specific trust assessments appear to cumulate over time to inform a sense of residual trust that guides the general relationship."²⁷ Patients, instead, tend to place "[v]ery high levels of trust" in

²² *Id.* ("With this decision-making power and position of trust comes the physician's responsibility to act as a fiduciary to ensure that decisions are made so as to further the best interests of the patient."); Lucy Gilson, *Trust and the Development of Health Care as a Social Institution*, 56 SOC. SCI. & MED. 1453, 1454 (2003) ("A health care provider is specifically expected to demonstrate impartial concern for the patient's well-being."); Mechanic, *supra* note 19, at 667 ("[M]edicine has been viewed as a selfless endeavor in which physicians would suffer inconvenience and even hardships when major patient interests were at stake."); Kenneth Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 949 (1963) (explaining that a physician's "behavior is supposed to be governed by a concern for the customer's welfare").

²³ Carly Parnitzke Smith, *First, Do No Harm: Institutional Betrayal and Trust in Health Care Organizations*, 10 J. MULTIDISCIPLINARY HEALTHCARE 133, 133 (2017).

²⁴ See, e.g., EDELMAN, *supra* note 4, at 16 (indicating that "higher trust in the health ecosystem" correlates with higher likelihood of vaccination and attending regular check-ups).

²⁵ Mechanic, *supra* note 19, at 662.

²⁶ Hill & O'Hara, *supra* note 19, at 1750, 1764.

²⁷ *Id.* at 1749.

their physicians.²⁸ This high initial trust makes it more difficult for patients to accept information that counters their perception of the trustworthiness of their doctors.²⁹ And sicker or more vulnerable patients trust their doctors even more than average patients.³⁰ Thus, patients have a tendency to overtrust their doctors.³¹

One area where patients may overtrust their doctors is with respect to the issue of fidelity.³² Patients want some guarantee that “the physician is using his knowledge to the best advantage” of the patient.³³ Further, as noted above, patients expect physicians to act with impartial concern for the well-being of the patient. Unfortunately, when it comes to the issue of fidelity, patients suffer from asymmetries of information. Patients are in a vulnerable position because to a large extent, they “must delegate to the physician much of [their] freedom of choice . . . [because they do] not have the knowledge to make decisions on treatment, referral, or hospitalization.”³⁴ Patients also do not know whether physicians are free from conflicts of interest, such as economic incentives to prescribe certain drugs, order tests from a particular laboratory, or refer patients to a particular specialist. Thus, they may be unable to recognize when a health care provider is putting her own financial interests ahead of the welfare of patients. Despite their lack of information, patients trust that their doctors have their patients’ best interests at heart.

Unfortunately, in some situations, doctors are driven by financial incentives in addition to or instead of the best interests of their patients. If such conflicts do arise, the doctor can potentially retain trust by disclosing the financial relationship and giving the patient other options.³⁵ Avoiding

²⁸ *Id.* at 1764.

²⁹ See Smith, *supra* note 23, at 134 (“Trust plays an insulating role in that it allows for mistakes or errors to be made in the provision of health care without disastrous consequences.”).

³⁰ Hill & O’Hara, *supra* note 19, at 1764 (“Some scholars describe the beliefs and behaviors of the sick patient as regressive—a return to an infantile state where the physician is placed in an all-powerful, parental role. Others note that “[e]ven short-term medical relationships can generate strong bonds and intense feelings of intimacy.” (quoting Mark A. Hall, *Law, Medicine, and Trust*, 55 STAN. L. REV. 463, 477 (2002))); Hall et al., *supra* note 1, at 615 (“Because trust arises from patients’ need for physicians, the greater the sense of vulnerability, the higher the potential for trust.”).

³¹ Hill & O’Hara, *supra* note 19, at 1764 (explaining that patients overtrust their doctors when they “trust them beyond what a rational calculative assessment would warrant”).

³² Hall et al., *supra* note 1, at 621 (“*Fidelity* is pursuing a patient’s best interests and not taking advantage of his or her vulnerability. This can be expressed through the related concepts of agency or loyalty, and it consists of caring, respect, advocacy, and avoiding conflicts of interest.”).

³³ Arrow, *supra* note 22, at 965.

³⁴ *Id.* at 965–66; see also Hill & O’Hara, *supra* note 19, at 1767 (explaining that patients often overtrust their doctors, which likely makes them “poor monitors of their doctors’ caregiving”).

³⁵ See, e.g., BENJAMIN HO, WHY TRUST MATTERS 210 (2021) (“[M]any have argued recently that the key to trust in the field of medicine is transparency. For example, the Sunshine Act provision of the

these conflicts of interest, or disclosing them when they do arise, reinforces the patient's belief that the physician's loyalty is to the patient. But when undisclosed conflicts, such as improper financial relationships between physicians and pharmaceutical manufacturers, come to light, it harms the physician relationship for patients directly involved and "threaten[s] trusting relationships between all patients and their doctors."³⁶ Although patients can forgive medical errors and still trust their doctors, the same cannot be said when doctors act contrary to the best interests of the patient.³⁷ Patients view those situations as betrayals of trust and are unlikely to continue their doctor-patient relationship.³⁸ Thus, when it comes to health care fraud, the riskiest part of the doctor-patient relationship is that a health care provider might prioritize the provider's financial interests to the detriment of the patient's well-being.

Because doctor-patient relationships are bolstered by trust but plagued by asymmetries of information, the government (as regulator-enforcer) must play a role in protecting patients. When patients overtrust their doctors, they are less effective at monitoring them and fraud may result.³⁹ As participant-payer, the government also needs to make sure that its payment system properly incentivizes health care providers to provide necessary care. Without government regulation of the financial risks of the physician-patient relationship, patients will be at a severe disadvantage and may be less trusting of physicians.

B. Trust in the Health Care System (Institutional Trust)

Trust in the health care system is much more complicated and fragile than trust in doctors.⁴⁰ Trust in the health care system is much more likely to follow the Hall and O'Hara model for building trust: rather than beginning

Affordable Care Act, passed during the Obama administration, has required increased disclosure by doctors of payments received from pharmaceutical companies. Distrust breeds where information is lacking."); Mechanic, *supra* note 19, at 673 (explaining that nondisclosure of arrangements where physicians make referrals to facilities in which they have an economic interest can erode trust).

³⁶ Eli Y. Adashi, I. Glenn Cohen & Jacob T. Elberg, *Transparency and the Doctor-Patient Relationship—Rethinking Conflict-of-Interest Disclosures*, 386 N. ENGL. J. MED. 300, 301 (2022); see Carmel Shachar & Gregory Curfman, *Reconsidering Health Care Fraud and Abuse Laws*, 324 JAMA 1735, 1736 (2020) ("[T]hese payments may undermine the reputation and trust of the medical profession, potentially damaging the complex relationship between patients and physicians.").

³⁷ See Smith, *supra* note 23, at 134.

³⁸ *Id.* at 140.

³⁹ Hill & O'Hara, *supra* note 19, at 1720.

⁴⁰ Mark A. Hall, *Arrow on Trust*, 26 J. HEALTH POL., POL'Y & L. 1131, 1140 (2001) ("Concerns about the fragility of trust are appropriately directed to *institutional* trust in contrast with interpersonal physician trust.").

with residual trust, trust in institutions is built over time.⁴¹ Thus, each time patients visit a particular hospital (whether for themselves or a family member), they are evaluating the trustworthiness of the hospital. If the patient has a series of positive experiences at a hospital, such as being seen quickly, helpful staff interactions, and clear-cut billing, the patient will trust the hospital. In this way, “[t]rust is also iterative and self-reinforcing . . . which means that the organization that creates a trusted brand can count on sustained trust over lifetimes, even generations.”⁴² On the other hand, if a person has a history of positive interactions at a hospital and then has an incredibly negative experience, she may never return to that hospital or only do so when it is absolutely necessary (depending on one’s range of hospital choices). This can undermine the effectiveness of treatment by leading patients to make choices such as not complying with treatment or not seeking medical care when it is necessary.⁴³ Thus, institutional trust “can be lost in a heartbeat.”⁴⁴

Much like interpersonal trust, however, fidelity is of high importance in maintaining trust in institutions. To have trust in institutions, patients need to believe that those institutions are concerned with the well-being of their patients. One concern that patients have about health care institutions is that institutional business models have “turned health care into an industry and patients into customers.”⁴⁵ If patients are treated as customers, it is more difficult to foster trust because the patients do not believe that health care institutions have their patients’ best interests at heart. Instead, patients believe that health care institutions are driven by profit maximization and every interaction is transactional.⁴⁶ As a result, patients tend to question the motives and incentives of health care institutions.⁴⁷ This leads to a climate of distrust.

It should be noted, however, that interpersonal and institutional trust are not completely separate. They are intertwined.⁴⁸ Interpersonal and

⁴¹ David A. Shore, *Gaining Competitive Advantage in the Healthcare Marketplace by Building Trust*, in *THE TRUST CRISIS IN HEALTHCARE: CAUSES, CONSEQUENCES, AND CURES* 149, 156 (David A. Shore ed., 2007).

⁴² *Id.*

⁴³ Smith, *supra* note 23, at 140.

⁴⁴ Shore, *supra* note 41, at 156.

⁴⁵ Ankit Mehta & Benji K. Mathews, *Hospitalists Talk About Rebuilding Trust in Health Care*, *HOSPITALIST* (May 2, 2022), <https://www.the-hospitalist.org/hospitalist/article/32120/hospital-medicine/hospitalists-talk-about-rebuilding-trust-in-health-care/> [<https://perma.cc/9BNP-CR24>].

⁴⁶ *Id.*

⁴⁷ David Mechanic, *Changing Medical Organization and the Erosion of Trust*, 74 *MILBANK Q.* 171, 178 (1996).

⁴⁸ Smith, *supra* note 23, at 135.

institutional trust can be “mutually supportive.”⁴⁹ For example, strong interpersonal trust between a doctor and a patient can lead a patient to trust the hospital or other health care institution that employs the doctor or that the doctor recommends. Similarly, the stellar reputation of a hospital, such as the Johns Hopkins Hospital or Cedars-Sinai Medical Center,⁵⁰ may convince a patient to trust the doctors in the hospital. The connection between the two is important to keep in mind as the government employs its enforcement strategy.

Much like with interpersonal trust, the government as participant-payer has an important role to fulfill in building institutional trust. If the government can institute a payment system that prioritizes patients, respects the medical judgment of doctors, and delivers quality care without incentivizing over or undertreatment, it will increase both interpersonal and institutional trust. Institutions will benefit because they will not be seen as only being concerned about the bottom line. Further, to the extent that the government does this successfully, private institutions will follow suit.

II. HEALTH CARE FRAUD ENFORCEMENT’S IMPACT ON TRUST

The government’s health care fraud enforcement efforts are principally centered around federal health care programs, such as Medicare and Medicaid. When Congress created the Medicare and Medicaid programs in 1965, and became a major participant-payer in the health care system by providing access to health insurance for millions of Americans,⁵¹ it was not concerned about fraud. Prior to enactment, Congress received pushback from the medical profession.⁵² As a result, Congress was concerned that providers would not participate in Medicare. Thus, it modeled Medicare after private insurance, such as Blue Cross and Blue Shield plans, where Medicare would make direct payments to health care providers using fee-for-service

⁴⁹ Mechanic, *supra* note 47, at 174.

⁵⁰ *U.S. News and World Reports* ranks both the Johns Hopkins Hospital and Cedars-Sinai Medical Center in the top five hospitals in the United States. Ben Harder, *America’s Best Hospitals: The 2022-2023 Honor Roll and Overview*, U.S. NEWS & WORLD REP. (July 26, 2022), <https://health.usnews.com/health-care/best-hospitals/articles/best-hospitals-honor-roll-and-overview> [<https://perma.cc/W2H4-F429>].

⁵¹ Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286 (1965). The Medicare program provides health insurance to individuals aged sixty-five and older and the disabled without respect to wealth or income. Medicaid is a joint federal-state program that provides health insurance for those whose incomes fall below specific levels.

⁵² Julian E. Zelizer, *How Medicare Was Made*, NEW YORKER (Feb. 15, 2015), <https://www.newyorker.com/news/news-desk/medicare-made> (noting the American Medical Association’s aggressive campaign against Medicare).

reimbursement.⁵³ Congress wanted to create a system that reimbursed providers quickly because it did not want to discourage providers from participating in Medicare and Medicaid. These early choices in the creation of Medicare and Medicaid, while reasonable at the time, gave rise to fraud, waste, and abuse that went unchecked for many years because the government was slow to step into its regulatory and enforcement roles.

Despite its initial reluctance to do so, the government ultimately embraced its role as regulator-enforcer and began promoting trustworthy conditions through its enactment of health care fraud laws and its vigorous enforcement of these laws.⁵⁴ As Professor David Mechanic has explained, “Good regulatory policy makes trust more possible by deterring or controlling its most risky aspects and by reassuring patients that they can trust safely.”⁵⁵ The riskiest aspect of the doctor–patient relationship is that a doctor may put her own financial interests above the best interests of the patient. Given patients’ propensity to overtrust their doctors, it is imperative that the government protect patients from providers who are driven by financial incentives rather than the needs of their patients. This is necessary to maintain the interpersonal trust that is essential to well-functioning doctor–patient relationships. In addition, the government, as regulator-enforcer, ought to protect the integrity of federal health care programs, which can improve the institutional trust in the health care system as a whole. In this case, the question becomes whether the government’s regulatory policy and enforcement efforts actually build or restore trust to the health care system.

This Part will examine how anti-fraud laws, such as the Anti-Kickback Statute, the Physician Self-Referral Law, and the Physician Payments Sunshine Act contribute to or detract from interpersonal and institutional trust. It also examines the government’s enforcement efforts and how those efforts may undermine interpersonal and institutional trust.

A. *The Anti-Kickback Statute and Physician Self-Referral Law (Stark)*

Congress did not address fraud in Medicare and Medicaid until 1972, allowing fraud, waste, and abuse to fester for seven years after the enactment of Medicare and Medicaid. Congress passed the Anti-Kickback Statute (AKS) as part of amendments to the Social Security Act in 1972, which made it a misdemeanor to solicit or receive bribes or kickbacks in return for

⁵³ *Strengthening and Improving the Medicare Program: Hearing Before the S. Comm on Finance*, 108th Cong. (2003) (statement of the preferred provider organizations).

⁵⁴ Hill & O’Hara, *supra* note 19, at 1755 (“Law can promote trust by helping to minimize the likelihood of untrustworthy behavior.”).

⁵⁵ Mechanic, *supra* note 19, at 663.

furnishing items or services for which payment is made by Medicare or Medicaid.⁵⁶ With limited punitive power, the AKS was a weak and ineffective enforcement tool for addressing health care fraud and maintaining interpersonal trust. It was not until 1977, twelve years after the enactment of Medicare and Medicaid, that the AKS became a felony statute, making violations punishable by up to five years imprisonment.⁵⁷

The AKS is the primary criminal statute used to prosecute health care fraud. As currently formulated, the AKS prohibits all providers that participate in federal health care programs from knowingly and willfully giving, receiving, or soliciting remuneration in exchange for patient referrals.⁵⁸ The statute is designed to prevent the corruption of medical decision-making, overutilization, patient steering, and unfair competition.⁵⁹ The concern with the corruption of medical decision-making is that if a provider receives a payment for a referral, then the referral decision may not be made with the best interests of the patient in mind. If providers are paid for referrals, the reasoning goes, then they may decide to increase their referrals (overutilization) or direct patients to providers furnishing the referral kickback (patient steering and unfair competition). This can lead to referrals and medical decisions that benefit the provider without any concomitant benefits for the patients. A criminal violation of the AKS can lead to up to ten years of imprisonment, up to \$100,000 in fines, or both.⁶⁰

Much like the AKS, the Physician Self-Referral Law (Stark Law),⁶¹ which was enacted in 1989,⁶² is designed to prevent providers' conflicts of interest.⁶³ It initially prohibited physicians from referring Medicare patients to clinical labs with which the physician had a financial relationship.⁶⁴ The law was later expanded to prohibit physicians from referring Medicare patients for eleven types of services, "designated health services," if the physician or family member has a financial relationship with the entity

⁵⁶ Social Security Amendments of 1972, Pub. L. No. 92-603, 86 Stat. 1329.

⁵⁷ Medicare-Medicaid Anti-Fraud and Abuse Amendments of 1977, Pub. L. No. 95-142, 91 Stat. 1175. The 1977 amendments broadened the AKS statute to prohibit "any remuneration (including kickbacks, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind." *Id.*

⁵⁸ 42 U.S.C. § 1320a-7b(b).

⁵⁹ LAURA F. LAEMMLE-WEIDENFELD, *LEGAL ISSUES IN HEALTH CARE FRAUD AND ABUSE* 31 (5th ed. 2020).

⁶⁰ 42 U.S.C. § 1320a-7b(b).

⁶¹ *Id.* § 1395nn. The law is named after United States Congressman Pete Stark, who sponsored the initial bill in 1989.

⁶² Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, § 6204, 103 Stat. 2106, 2236.

⁶³ 83 Fed. Reg. 29,524, 29,525 (June 25, 2018) ("By design, the physician self-referral law is intended to disconnect a physician's health care decision making from his or her financial interests in other health care providers and suppliers.").

⁶⁴ Pub. L. No. 101-239, 103 Stat. 2106.

providing the designated health services.⁶⁵ A financial relationship can be an ownership interest or a compensation arrangement.⁶⁶ The regulations concerning when a financial relationship constitutes a compensation arrangement are extremely complex, making compliance with the law difficult.⁶⁷ Violations of the Stark Law can lead to civil penalties of up to \$15,000 per item billed, denial of payments for services, overpayment or refund obligations, and civil assessment of up to three times the amount claimed.⁶⁸

With their strong criminal and civil penalties, the AKS and Stark Law incentivize providers to act in the best interests of their patients rather than their own financial interest. This is a key component of interpersonal trust in the provider–patient relationship. Indeed, the American Medical Association’s *Code of Medical Ethics* provides that “[t]he primary objective of the medical profession is to render service to humanity; reward or financial gain is a subordinate consideration. Under no circumstances may physicians place their own financial interests above the welfare of their patients.”⁶⁹ Thus, by enacting the AKS and Stark Law, and by vigorously enforcing them, the government reinforces the ethical obligations of providers and assists in creating trustworthy conditions for provider–patient relationships.

There is some question, however, about whether these laws are, in fact, vigorously enforced. The principal enforcement mechanism for the AKS is not criminal. Instead, the AKS is most often enforced through the civil False Claims Act (FCA), a statute designed to combat fraud against the government.⁷⁰ Similarly, the FCA is the primary enforcement mechanism of the Stark Law. The FCA imposes a civil penalty and treble damages for knowingly presenting or causing to be presented false or fraudulent claims to the federal government for payment or approval.⁷¹ For purposes of the FCA, a reimbursement claim is considered false if it involves an underlying

⁶⁵ 42 U.S.C. § 1395nn.

⁶⁶ *Id.*

⁶⁷ AM. HOSP. ASS’N, LEGAL (FRAUD AND ABUSE) BARRIERS TO CARE TRANSFORMATION AND HOW TO ADDRESS THEM 4 (2017) (explaining that the Stark Law’s “oversight of compensation arrangements is built for a nearly outmoded system where physicians were self[-]employed, hospitals were separate entities, and the payment system treated them as operating in distinct silos. It micromanages the circumstances in which a compensation arrangement is permitted, the amount paid and the manner in which the compensation is calculated.”).

⁶⁸ 42 U.S.C. § 1395nn(g)(4).

⁶⁹ *Opinion 11.2.2: Conflicts of Interest in Patient Care*, AM. MED. ASS’N, <https://code-medical-ethics.ama-assn.org/ethics-opinions/conflicts-interest-patient-care> [<https://perma.cc/V2BB-XY8U>].

⁷⁰ 31 U.S.C. §§ 3729–3732; Joan Krause, *Health Care Providers and the Public Fisc: Paradigms of Government Harm Under the Civil False Claims Act*, 36 GA. L. REV. 121, 134 (2001).

⁷¹ 31 U.S.C. § 3729(a).

AKS or Stark Law violation.⁷² The FCA allows individuals, known as qui tam relators, to bring actions on behalf of the government for violations of the AKS and Stark Law.⁷³ The government then has the option to take over the action, decline to intervene and allow the individual to proceed, or move to dismiss the action.⁷⁴ Relators are incentivized to act as whistleblowers and bring FCA cases because they can receive up to 30% of the government's recovery.⁷⁵

The fact that relators and the government use the FCA to enforce the AKS and Stark Law may lessen the government's ability (as regulator-enforcer) to further interpersonal and institutional trust. Importantly, it shifts the government's focus from policing conflicts of interest and promoting trustworthy conditions to recovery of federal funds. It also reduces the government's autonomy in making enforcement decisions because enforcement is largely driven by qui tam suits.⁷⁶ In addition, these cases often focus on technical violations (such as the proper method under Stark to distribute bonuses) rather than actual patient harm from improper financial incentives.⁷⁷ This leads to inconsistent enforcement of the AKS and Stark Law.⁷⁸ Further, it may reduce the deterrent value of the AKS criminal sanction because health care providers and institutions may believe that they can simply settle these cases civilly and thereby avoid the criminal penalties and their collateral consequences.⁷⁹ Thus, if the government wants its enforcement efforts to build trust in the health care system, it must take control of the enforcement of the AKS and Stark Law and bring the focus away from FCA cases. Unfortunately, given the level of recoveries that result from FCA cases—over \$2 billion in the 2022 fiscal year alone—it is unlikely

⁷² 42 U.S.C. § 1320a-7b(g).

⁷³ 31 U.S.C. § 3730(b).

⁷⁴ *Id.* § 3730(b)–(c).

⁷⁵ *Id.* § 3730(d) (2018). The relator's recovery is limited to 25% if the government intervenes in the suit, or 30% if the government does not intervene in the suit. *Id.*

⁷⁶ Krause, *supra* note 70, at 203.

⁷⁷ Salvatore Filippello, *Healthcare Fraud Investigations: Overview of Overbroad Investigative Regime and Recommendations for a More Targeted Approach*, 31 ANNALS HEALTH L. & LIFE SCIS. 141, 141 (2022).

⁷⁸ Krause, *supra* note 70, at 126–27, 201.

⁷⁹ An AKS criminal conviction leads to automatic exclusion from participation in federal health care programs. It is still possible for an entity to be excluded based on an FCA violation, but such exclusion is discretionary, and if the providers enter into a Corporate Integrity Agreement (CIA) as part of their settlement, it usually spares the provider from exclusion. *See generally* Katrice Bridges Copeland, *Enforcing Integrity*, 87 IND. L.J. 1033 (2012) (explaining the use of CIAs and arguing that CIAs are ineffective as standalone enforcement mechanisms).

that the government intends to change course which jeopardizes interpersonal and institutional trust.⁸⁰

B. The Physician Payments Sunshine Act

The Physician Payments Sunshine Act established the Open Payments program, which requires pharmaceutical and medical device manufacturers to report all gifts and payments that they make to physicians.⁸¹ This law was passed following a series of lawsuits in which pharmaceutical companies and medical device manufacturers paid settlements of billions of dollars for providing bribes and kickbacks to doctors to induce them to prescribe their drugs and devices.⁸² Unlike the AKS and Stark Law, the Physician Payments Sunshine Act uses transparency in reporting rather than prohibition of payments to achieve its goal of discouraging pharmaceutical companies and medical device manufacturers from providing bribes and kickbacks to physicians.⁸³ There are, however, financial penalties for failure to report.⁸⁴

Presumably, transparency of payments will further interpersonal trust between patients and their health care providers because patients can verify that their providers are not receiving bribes and kickbacks and be reassured of their physicians' fidelity. It may even improve institutional trust in pharmaceutical companies and medical device manufacturers if their behavior changes in response to that transparency. But, ten years into the program, there is "little evidence" that the Open Payments program has

⁸⁰ Press Release, DOJ, False Claims Act Settlements and Judgments Exceed \$2 Billion in Fiscal Year 2022 (Feb. 7, 2023), <https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-2-billion-fiscal-year-2022> [<https://perma.cc/N8JW-CMSM>].

⁸¹ 42 U.S.C. § 1320a-7h(a)(1)(A), (e)(2), (e)(6).

⁸² See, e.g., Press Release, DOJ, Johnson & Johnson to Pay More Than \$2.2 Billion to Resolve Criminal and Civil Investigations (Nov. 4, 2013), <https://www.justice.gov/opa/pr/johnson-johnson-pay-more-22-billion-resolve-criminal-and-civil-investigations> [<https://perma.cc/KGW7-TSHH>] (explaining that the resolution included allegations of kickbacks to physicians); Press Release, DOJ, Abbott Labs to Pay \$1.5 Billion to Resolve Criminal & Civil Investigations of Off-Label Promotion of Depakote (May 7, 2012), <https://www.justice.gov/opa/pr/abbott-labs-pay-15-billion-resolve-criminal-civil-investigations-label-promotion-depakote> [<https://perma.cc/Q4Y8-UB2K>] (noting that the civil settlement resolved allegations that Abbott paid illegal remuneration to health care professionals); Press Release, DOJ, Justice Department Announces Largest Health Care Fraud Settlement in Its History (Sept. 2, 2009), <https://www.justice.gov/opa/pr/justice-department-announces-largest-health-care-fraud-settlement-its-history> [<https://perma.cc/7B6R-YZC5>] (explaining that part of Pfizer's \$2.3 Billion settlement resolves allegations regarding kickbacks to health care providers).

⁸³ Adashi et al., *supra* note 36, at 300 ("Open Payments aims to use transparency to discourage improper payments and encourage[] physicians to make decisions uninfluenced by compensation from manufacturers.").

⁸⁴ The statute includes a civil monetary penalty between \$1,000 and \$10,000 for each unreported payment. 42 U.S.C. § 1320a-7h(b). If a manufacturer "knowingly" fails to report payments, the manufacturer is subject to a civil monetary penalty between \$10,000 and \$100,000 for each unreported payment. *Id.*

changed the behavior of pharmaceutical companies or medical device manufacturers.⁸⁵ And, despite the fact that the information about payments is publicly available, patients are likely unaware of the information's existence.⁸⁶ According to one study, only 3% of patients actually looked up their physicians on Open Payments.⁸⁷ If patients do not know about the information, then there can be no resultant impact on interpersonal or institutional trust.

Dr. Adashi and Professors I. Glenn Cohen and Jacob Elberg have argued that it may be “time to consider whether practitioners should be required to disclose financial relationships directly to patients” because “[t]here is some evidence that mandatory disclosure policies cause professionals to avoid entering into relationships that would create a conflict of interest to avoid having to report them.”⁸⁸ Even if the payment information is disclosed directly to patients, however, patients may not know how to interpret this information from physicians—some payments may indicate that the doctor is an expert being compensated at fair market value for his expertise while others may be nefarious.⁸⁹ However, requiring doctors to disclose payments directly to patients does not guarantee an increase of interpersonal or institutional trust. Patients are principally concerned about fidelity. They may decide that they can trust their provider because of the disclosure, but it is also possible that they could become suspicious of their doctors' motives. It is possible that excessive regulations requiring disclosure of financial conflicts may actually confirm attitudes of distrust rather than build trust.⁹⁰

The use of disclosure rather than prohibition and resultant penalties may be less effective at maintaining trust because it is more difficult to police compliance with the requirements. Even if disclosure requirements were required to be in writing and signed by patients, there is still no guarantee of actual, as opposed to constructive, disclosure. Thus, patients may not receive vital information that they need to make judgements about the trustworthiness of their doctors.

⁸⁵ Adashi et al., *supra* note 36, at 300.

⁸⁶ *Id.*

⁸⁷ Genevieve P. Kanter, Daniel Carpenter, Lisa S. Lehmann & Michelle M. Mello, *US Nationwide Disclosure of Industry Payments and Public Trust in Physicians*, JAMA NETWORK OPEN, Apr. 12, 2019, at 1, 7.

⁸⁸ Adashi et al., *supra* note 36, at 300–01.

⁸⁹ *Id.* at 301.

⁹⁰ See Hall, *supra* note 40, at 1141.

III. PAYMENT SYSTEMS AND TRUST

The government's role as a participant-payer in the health care system is significant. National health care expenditures reached \$4.3 trillion in 2021, or 18.3% of U.S. gross domestic product.⁹¹ Medicare spending grew to \$900.8 billion in 2021, approximately 21% of total national health care expenditures.⁹² Medicaid spending grew to \$734 billion in 2021 which accounted for 17% of national health care expenditures.⁹³ Importantly, like with private insurance, the government program—rather than the actual recipient of the services—pays for the health care services. The government's concerns as a participant-payer of health care services are different than those as a regulator. In this context, the government's primary concern is “to provide its beneficiaries with the health care coverage . . . that federal and state governments have required.”⁹⁴ Thus, the government as participant-payer can further trustworthy conditions by ensuring that its programs like Medicare and Medicaid are well run and meet the needs of their participants. This would demonstrate fidelity. The government has been largely successful on this score. Both Medicare and Medicaid are popular programs, and the majority of Americans think they work well.⁹⁵

With hundreds of billions of government health care dollars at stake, the system of payment is incredibly important. This is because fraudulent schemes “thrive on the ingenuity of perpetrators in manipulating a system in which the payer of services is a different party from the person receiving the services.”⁹⁶ This Part will examine how fee-for-service reimbursement and managed care have damaged institutional trust in the health care system. It will also assess whether the newest system of payment, value-based

⁹¹ U.S. DEP'T HEALTH & HUMAN SERVS., CTRS. FOR MEDICARE & MEDICAID SERVS., NATIONAL HEALTH EXPENDITURES 2021 HIGHLIGHTS (2021), <https://www.cms.gov/files/document/highlights.pdf> [<https://perma.cc/DCG4-RMQ4>].

⁹² *NHE Fact Sheet*, CMS (2022), <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData/NHE-Fact-Sheet> [<https://perma.cc/5X6F-SMCA>].

⁹³ *Id.*

⁹⁴ MICHAEL K. LOUCKS, PROSECUTING AND DEFENDING HEALTH CARE FRAUD CASES § 3.I (2021).

⁹⁵ *5 Charts About Public Opinion on Medicaid*, KFF (Mar. 3, 2023), <https://www.kff.org/medicaid/poll-finding/data-note-5-charts-about-public-opinion-on-medicaid/> [<https://perma.cc/3429-2DTV>] (“Most Americans say the current Medicaid program is working well for most low-income people covered by the program.”); Mollyann Brodie, Elizabeth C. Hamel & Mira Norton, *Medicare as Reflected in Public Opinion*, 39 J. AM. SOC'Y ON AGING 134, 135 (2015), <https://www.kff.org/wp-content/uploads/2015/06/generations-medicare-as-reflected-in-public-opinion-brodie-et-al.pdf> [<https://perma.cc/24PC-MQLS>] (“[A] majority of Americans (including about eight in ten older adults) think [Medicare] works well.”).

⁹⁶ LOUCKS, *supra* note 94, § 3.I.

reimbursement, has the potential to restore institutional trust in the health care system.

A. *Fee-For-Service Reimbursement's Effect on Trust*

Historically, the government has used a fee-for-service reimbursement mechanism in Medicare and Medicaid.⁹⁷ Under fee-for-service reimbursement, the provider receives payment for each service or product provided to the patient. This payment method incentivizes providers to increase the number of claims because the higher the volume of services or items that a provider furnishes, the more the government (as the third-party insurer) will pay the provider.⁹⁸ Further, the fact that a third party is paying the bill “results in a lack of cost consciousness in health care purchasing decisions.”⁹⁹

Patients also play a role in driving up health care costs in a fee-for-service environment by accepting arguably excessive care recommendations. Patients often view the provision of more care as good care.¹⁰⁰ And because patients are not paying directly for their care, it “strengthens patients’ own bias towards using whatever methods are available when their health is at stake.”¹⁰¹ In addition, patients may not be aware of providers’ financial incentives to increase services and provide more costly health care. Thus, when doctors recommend additional tests or treatments, patients go along because they believe the recommendation is in their own best interests and they trust the recommendation of their doctor.¹⁰²

Unfortunately, the fee-for-service reimbursement method is a major driver of fraud in federal health care programs such as Medicare. The majority of health care fraud cases involve some form of false billing.¹⁰³

⁹⁷ See *supra* note 53 and accompanying text.

⁹⁸ Jessica L. Mantel, *Accountable Care Organizations: Can We Have Our Cake and Eat It Too?*, 42 SETON HALL L. REV. 1393, 1403 (2012).

⁹⁹ MARK A. HALL & DAVID ORENTLICHER, *HEALTH CARE LAW AND ETHICS IN A NUTSHELL* 12 (4th ed. 2020).

¹⁰⁰ See, e.g., *id.* at 10 (“Because a third party is footing most of the bill, patients are eager to receive (and have now come to expect and demand) all care that is of any conceivable benefit.”).

¹⁰¹ Jerry L. Mashaw & Theodore R. Marmor, *Conceptualizing, Estimating, and Reforming Fraud, Waste, and Abuse in Healthcare Spending*, 11 YALE J. REG. 455, 458 (1994).

¹⁰² Marc J. Roberts, *Trust in Healthcare, Trust in Society*, in *THE TRUST CRISIS IN HEALTHCARE: CAUSES, CONSEQUENCES, AND CURES* 190 (David A. Shore ed., 2006) (explaining that patients have to “rely on the doctor-as-seller to determine what the patient should purchase” but that fee-for-service “gives [doctors] reason to do more”).

¹⁰³ LOUCKS, *supra* note 94, § 3.I. Loucks explains:

At its core, a false bill asserts some lie about whether, how, where, or when a service or item was provided. Every health insurer has rules regarding claims: The service must be provided in a

Providers and institutions take advantage of the fee-for-service system to the government and public's detriment. It is not simply providing unnecessary care that is at issue; some doctors and institutions falsify bills to make it seem as though they have provided more items or services than the patient actually received.¹⁰⁴ Further, the government as participant-payer has historically employed a pay-and-chase model where it pays claims quickly and then identifies overpayments or fraud at a later date.¹⁰⁵ This further incentivizes false claims because providers may believe that they are unlikely to get caught. As patients become aware of fraudulent billing schemes through media reports or other means, their institutional trust declines because the fraud demonstrates a lack of fidelity on the part of providers.

Ultimately, fifty-plus years of abuse of the fee-for-service system in federal health care programs has given fee-for-service the appearance of being untrustworthy. Despite the well-known problems with fee-for-service reimbursement, the government as participant-payer has been slow to address the reimbursement system. This failure undermines the government's efforts as regulator-enforcer to further trustworthy conditions in the health care system.

B. Managed Care

In the 1990s, managed care became popular with private insurers as a means to limit the out of control costs from third-party payment systems that principally relied on fee-for-service as a reimbursement mechanism.¹⁰⁶ Managed care organizations "intervene[] between the doctor and the patient, and through such processes as utilization review and capitation . . . limits the

defined manner to an eligible beneficiary; the care must be necessary and reasonable; and certain 'coverage criteria' must be met. Fraudulent billers will cut these corners.

Id.

¹⁰⁴ Katrice Bridges Copeland, *Telemicine Scams*, 108 IOWA L. REV. 69, 91–93 (2022).

¹⁰⁵ Thomas Sullivan, *CMS and OIG Discuss "The Use of Data to Stop Medicare Fraud" Before House Ways and Means Subcommittee*, POL'Y & MED. (May 5, 2018), <https://www.policymed.com/2015/04/cms-and-oig-discuss-the-use-of-data-to-stop-medicare-fraud-before-house-ways-and-means-subcommittee.html> [<https://perma.cc/D3HD-47MU>].

¹⁰⁶ Michelle M. Kwon, *Move Over Marcus Welby, M.D. and Make Way for Managed Care: The Implications of Capitation, Gag Clauses, and Economic Credentialing*, 28 TEX. TECH. L. REV. 829, 831 (1997). The federal government ultimately followed suit with managed care in Medicaid and Medicare, but it is much different than the managed care for private insurance plans that arrived in the early to mid-1990s. *See generally* MEDICAID AND CHIP PAYMENT AND ACCESS COMM'N, REPORT TO CONGRESS: THE EVOLUTION OF MANAGED CARE IN MEDICAID (2011), <https://www.govinfo.gov/content/pkg/GPO-MACPAC-2011-06/pdf/GPO-MACPAC-2011-06.pdf> [<https://perma.cc/Q75X-JFRF>].

ultimate payment received by the health care provider.”¹⁰⁷ In addition, the incentives for doctors in a managed care context are drastically different than a fee-for-service system. In many managed care plans, physicians are paid by capitation, and typically consists of a fixed rate per patient.¹⁰⁸ Thus, physicians are incentivized to minimize treatment and keep costs down because if the physician’s services for a patient exceed the monthly capitation amount, the physician bears the loss.¹⁰⁹ Thus, primary care physicians in a managed care setting must constantly evaluate the cost of care they are providing to their patients.

The structure of and incentives in managed care organizations negatively impacts both interpersonal and institutional trust. Professor Daniel P. Maher has argued that managed care has turned physicians into “double agents” whose loyalty is divided between the well-being of the individual patient and the financial constraints of the managed care organization.¹¹⁰ If patients know that financial incentives are driving the decisions that physicians make, then patients lose trust in their physicians, and “patients are reduced to looking upon their physicians with suspicion.”¹¹¹ And, in many situations, patients did not know what treatment options were being withheld from them because of gag clauses that prevented physicians from telling their patients about alternative treatment options.¹¹² Thus,

¹⁰⁷ Daniel N. Burton & Michael S. Popok, *Managed Care 101*, 72 FLA. B.J. 26, 28 (1998); Kwon, *supra* note 106, at 830–31 (“Managed care is defined as ‘[a]ny type of intervention in the delivery and financing of health care that is intended to eliminate unnecessary and inappropriate care and to reduce costs.’” (quoting Deven C. McGraw, *Financial Incentives to Limit Services: Should Physicians Be Required to Disclose These to Patients?*, 83 GEO. L.J. 1821, 1825 (1995))).

¹⁰⁸ Kwon, *supra* note 106, at 838. The capitated fee is determined through a risk-rating process and considers factors about patients in the risk pool such as age, sex, family history, income, and education. *Id.* In theory, if one patient exceeds the capitated amount, this cost is “offset by payments made for a patient with costs below the capitated amount.” *Id.* Managed care can have other payment models, such as bonus or withhold arrangements where physicians are either rewarded or partial payment is withheld depending on the physician’s ability to control costs and limit referrals, hospital stays, and emergency room visits. *Id.* at 838–39. A full discussion of all of the payment models for managed care organizations is beyond the scope of this Essay.

¹⁰⁹ *Id.* at 838; Patricia K. Greenstreet, *The Perils of Managed Care*, WASH. ST. BAR NEWS, Apr. 1996, at 28, 28.

¹¹⁰ Daniel P. Maher, *Managed Care and Undividing Loyalties*, 18 J. CONTEMP. HEALTH L. & POL’Y 703, 704 (2002) (asserting that managed care, in trying to control costs, can “concentrate[] the physician’s attention on his or her own personal interests precisely at the time that the physician is supposed to be suppressing those interests in favor of the patient”).

¹¹¹ *Id.*

¹¹² Kwon, *supra* note 106, at 845–47 (explaining the criticisms directed at managed care organizations for their use of gag clauses). Due to the poor public image surrounding gag clauses, many states passed legislation prohibiting gag clauses. *Id.* at 848.

managed care created a “climate of distrust” between patients and their physicians.¹¹³

Similarly, institutional trust was damaged by the managed care revolution because patients’ health care choices were limited, and patients believed that physicians’ health care decisions were being overseen or questioned based on cost rather than the needs of the patients. Many employers stopped offering indemnity plans and only offered HMOs to their employees which limited the employees’ ability to choose providers. In addition, managed care placed significant barriers between patients and access to the care that they needed through, among other things, utilization review, limited access to specialists, and preauthorization requirements for expensive medical services, such as surgery.¹¹⁴

Over time, there was a huge backlash to managed care. The media began reporting stories about managed care plans denying services to cancer patients and sick children.¹¹⁵ The public began to worry whether coverage would be available to them when they needed it.¹¹⁶ Ultimately, the financial incentives and administrative burdens of managed care eroded patients’ trust in managed care and the health care system more generally. Indeed, only 29% of people expressed confidence in managed care in 2000 compared to 51% in 1997.¹¹⁷ Although managed care plans have evolved significantly and provide more choices to patients than they did in the 1990s, the public perception of them as limiting choices and rationing care has not changed. The negative public perception of managed care may affect the government’s ability as participant-payer to transition to value-based reimbursement.

C. *The Shift to Value-Based Reimbursement*

In 2018, the U.S. Department of Health and Human Services (HHS) launched the “Regulatory Sprint to Coordinated Care” to accelerate the

¹¹³ Hall, *supra* note 40, at 1140.

¹¹⁴ Timothy S. Hall, *Bargaining with Hippocrates: Managed Care and the Doctor-Patient Relationship*, 54 S.C. L. REV. 689, 694–95 (2003) (explaining the external controls placed on physicians’ spending decisions); *see also* Maher, *supra* note 110, at 705 (explaining that “the difficulty patients encounter when dealing with the administrative end of managed care might be a deliberately chosen strategy to control costs by discouraging access to the system”).

¹¹⁵ David Mechanic, *The Rise and Fall of Managed Care*, 45 J. HEALTH & SOC. BEHAV. 76, 80 (2004).

¹¹⁶ *Id.* (explaining that there was not objective evidence that this was actually happening, but the perception was enough for the backlash).

¹¹⁷ *Id.* at 76 (citing a Harris poll in May 2000 and explaining that only tobacco companies ranked lower than managed care at 28%).

transition from fee-for-service to a value-based system.¹¹⁸ Value-based reimbursement puts the focus on quality of care rather than quantity of care.¹¹⁹ Under value-based models, providers seek relationships with other providers and organizations to provide continuity of care.¹²⁰ Thus, payments are based on health outcomes and cost reductions. Because value-based reimbursement requires coordination of care between providers and financial incentives for cost reductions, the AKS and Stark laws (which are focused on separating financial incentives from care decisions) would stand in the way of coordinated care. To remedy the conflict with existing fraud and abuse laws, HHS Office of Inspector General and HHS Centers for Medicare and Medicaid Services issued Final Rules that introduce new safe harbor protections under AKS and Stark for certain coordinated and risk-sharing agreements.¹²¹ The end result is that value-based compensation is exempted from AKS and Stark so long as they meet the strict regulatory requirement of the safe harbors.¹²²

Although the safe harbors remove significant impediments to the transition to value-based care, they do not address the potential for fraud in value-based reimbursement systems. Value-based reimbursement will likely remedy the misaligned incentives that exist in fee-for-service and managed care. Notably, value-based reimbursement will probably reduce overutilization by making it less profitable to order additional tests or treatment. In addition, it will remove incentives for undertreatment because health care providers are paid based on outcome. Thus, failure to treat could lead to negative health outcomes and lower compensation for physicians.

¹¹⁸ Medicare Program: Request for Information Regarding the Physician Self-Referral Law, CMS, 83 Fed. Reg. 29,524, 29,524 (June 25, 2018); Medicare and State Health Care Programs: Fraud and Abuse; Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP, OIG, 83 Fed. Reg. 43,607, 43,608 (Aug. 27, 2018).

¹¹⁹ See CTRS. FOR MEDICARE & MEDICAID SERVS., REPORT TO CONGRESS: FRAUD AND ABUSE LAWS REGARDING GAINSHARING OR SIMILAR ARRANGEMENTS BETWEEN PHYSICIANS AND HOSPITALS 3 (2015), <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/Report-to-Congress-2015.pdf> [<https://perma.cc/R74A-K4BP>].

¹²⁰ See Jacqueline Garry Lampert & Dave Kendall, *Clearing a Regulatory Path for Value-Based Health Care*, THIRD WAY (2018). As OIG has observed, however, these “arrangements, including those that improve or maintain quality of care, reduce waste, and/or increase efficiency, may implicate the Federal fraud and abuse laws.” *Id.* at 7. As a result, CMS and OIG have waived the requirements of AKS and other fraud laws to carry out the shared savings program. *Id.* at 7–8.

¹²¹ Medicare and State Health Care Programs: Fraud and Abuse; Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 85 Fed. Reg. 77,684 (Dec. 2, 2020) (to be codified at 42 C.F.R. pts. 1001, 1003); Medicare Program: Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77,492 (Dec. 2, 2020) (to be codified at 42 C.F.R. pt. 411).

¹²² A full discussion of the value-based safe harbors and their requirements is beyond the scope of this Essay.

Nevertheless, there are fraud risks inherent in value-based reimbursement as well. Value-based arrangements require providers to take on financial risk based on the quality of the care they provide.¹²³ Some providers may view value-based payments as “a threat to their livelihood because they will lose the certainty that comes from being paid based on the services they provide.”¹²⁴ As a result, some providers may falsify data to earn incentives or prevent a reduction in payment based on quality measures.¹²⁵ This type of fraud would greatly harm trust in both individual providers and institutions because it would demonstrate a lack of fidelity to patients.

Value-based reimbursement has great potential to increase patient trust through higher quality of health care and control of costs.¹²⁶ As Professor David Mechanic argued in 1998, “[T]o the extent that [quality assurance processes and performance measures] achieve legitimacy in professional communities and with the public, they have the potential to contribute to patient trust.”¹²⁷ The key, however, will be legitimacy with the public. The transition from fee-for-service to value-based reimbursement is not going to happen overnight.¹²⁸ It will take many years to completely convert our system for both public and private payers. In the interim, the government needs to rigorously enforce the requirements of the safe harbors to minimize fraud risks. At the same time, the government must continue its efforts in the fee-for-service reimbursement space. The government will also likely need a public relations campaign to convince the public of both the merit of value-based care and how it differs from managed care, or it may risk a similar backlash and loss of trust that happened in the 1990s.

Ultimately, in accordance with the Hill and O’Hara model, it will take time and experience with value-based reimbursement before patients have interpersonal and institutional trust in the reimbursement system. Patients need to trust that doctors working in a value-based reimbursement environment have their best interests at heart. Specifically, they will need to see that their doctors’ autonomy in decision-making is being respected and not overridden by the administrators of the system. They will also require some showing that care is not being rationed. To gain institutional trust,

¹²³ Copeland, *supra* note 104, at 120.

¹²⁴ *Id.*

¹²⁵ Reed Abelson & Margot Sanger-Katz, *The Cash Monster Was Insatiable: How Insurers Exploited Medicare for Billions*, N.Y. TIMES (Oct. 8, 2022), <https://www.nytimes.com/2022/10/08/upshot/medicare-advantage-fraud-allegations.html> [<https://perma.cc/WTK5-3DBF>].

¹²⁶ Khullar, *supra* note 14, at 508 (“The shift toward value-based care provides an opportunity for payers, clinicians, and health organizations to work together to improve quality and stabilize costs.”).

¹²⁷ Mechanic, *supra* note 19, at 677–78.

¹²⁸ Khullar, *supra* note 14, at 508 (“[I]t may take time to reverse decades of care fragmentation and misaligned incentives facilitated by fee-for-service payment.”).

patients will need to see the promises of value-based reimbursement realized—improvements in quality of care and coordination of care, and reduction of health care costs—before they will fully trust the system.

Despite the great potential for improvements in quality and trust, there is still reason for concern. At this point, the government has exempted qualifying value-based arrangements from the two major health care fraud laws without implementing a new law to specifically address the fraud risks that exist in value-based arrangements. The failure to tackle the fraud risks in value-based arrangements could lead to further distrust in the health care system. The government (as regulator-enforcer) simply cannot afford to make the same mistakes it made when it came to implementing sufficiently deterrent fraud laws to deal with risks of fee-for-service reimbursement in Medicare and Medicaid. The government should act immediately to consider criminal fraud and abuse laws that specifically target the risks of falsified data and undertreatment in value-based reimbursement. Although the civil FCA will still be available in the absence of new fraud and abuse laws, it may be more prudent to have a criminal health care fraud provision that addresses value-based reimbursement. The deterrent effect of a criminal law would go a long way toward building both interpersonal and institutional trust.

CONCLUSION

The importance of the government's role in maintaining trust in the health care system cannot be understated. Government regulation and enforcement of conflict-of-interest laws sends a strong message to health care providers, institutions, and patients about the importance of placing the interest of patients above any competing financial interests. This fidelity is essential to a healthy therapeutic relationship between patients and physicians. It is also critical for trust in health care institutions.

Similarly, the government's role in setting payment policy is critical to properly aligning the incentives of both providers and institutions to furnish quality care that is necessary and of high quality. Although the government has struggled in creating an appropriate payment system, the government's transition to a value-based reimbursement model is incredibly promising for restoring trust and properly aligning incentives to prevent over or undertreatment of patients. But the government in its regulatory role must step up and address the specific fraud risks inherent in these types of arrangements. Otherwise, they risk a situation where fraud and abuse go unchecked in value-based reimbursement. If patients are to put their trust in doctors and institutions being paid under a value-based reimbursement system, they need assurance that the government is closely monitoring fraud

and protecting the interests of patients. The government cannot afford to take a wait-and-see approach with respect to fraud in value-based reimbursement. Such an approach may undermine the goals of value-based reimbursement and lead patients not to trust the new system.