Volume 33 | Issue 2
SPRING 2024

LOYOLA UNIVERSITY CHICAGO
SCHOOL *of* LAW

BEAZLEY INSTITUTE FOR HEALTH LAW AND POLICY

Annals of Health Law and Life Sciences

ADVANCE DIRECTIVE

The Health Policy and Law Review of
LOYOLA UNIVERSITY CHICAGO SCHOOL *of* LAW

ANNALS OF HEALTH LAW
Advance Directive

THE STUDENT HEALTH POLICY AND LAW REVIEW OF
LOYOLA UNIVERSITY CHICAGO SCHOOL OF LAW

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Beazley Institute for Health Law and Policy

VOLUME 33, STUDENT ISSUE 2 SPRING 2024

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ANNALS OF HEALTH LAW AND LIFE SCIENCES
Advance Directive

Editors' Note

The *Annals of Health Law and Life Sciences* is proud to present the second issue of the thirty third volume of our online, student-written publication, *Advance Directive*. This Issue's articles focus on fraud and abuse laws and health equity.

The *Spring 2024 Advance Directive* Issue will highlight and explore the impact of fraud and abuse on health equity. Our student authors have also proposed adjustments to the current implementation, legal guidance, and regulatory landscape of the current fraud and abuse laws.

This Issue advocates for an intersection of healthcare fraud and abuse with health equity. It will examine the ways in which fraudulent healthcare practices may exacerbate health disparities and cause patient harm, as well how enforcement practices may either exacerbate or ameliorate disparities in access to care. Further, the Issue will highlight the need for broader changes in the fraud and abuse space to reflect evolving healthcare needs, delivery systems, and equity concerns.

We would like to thank Kathryn Van Sistine, our Annals Editor-in-Chief, for her leadership and support. We would also like to thank and acknowledge our Annals Executive Board Members: Divya Das, Manuel (Manny) Franco, Grace Connelly, Jenna Miller, and Farisa Khan. The members of Annals deserve recognition for their hard work, dedication, and well-thought articles. Lastly, we must thank the Beazley Institute for Health Law and Policy and our faculty advisors, Professors Nadia Sawicki and Kristin Finn for their guidance and support.

We hope you enjoy this Issue of *Advance Directive*.

Sincerely,

Bennett Murphy
Advance Directive Editor
Annals of Health Law and Life Sciences
Loyola University Chicago School of Law

Natasha Ganesh
Advance Directive Editor
Annals of Health Law and Life Sciences
Loyola University Chicago School of Law

Ariana Devereaux
Assistant Advance Directive Editor
Annals of Health Law and Life Sciences
Loyola University Chicago School of Law

Modifying Statutory Regulation for Damages Recovery to Improve Health Equity in the Forgotten Victims of Healthcare Fraud & Abuse

Kelechi Anyatonwu, MPH

I. INTRODUCTION

It is quite amazing how much money the government collects when it seeks recovery from those who commit healthcare fraud and abuse activities against it. In the 2022 Fiscal Year, the Department of Justice ("DOJ") experienced its "second-highest number of settlements in history".[1] Under the False Claims Act ("FCA"), the DOJ exceeded $2.2 billion from 351 settlements and judgments.[2] The press release stated that more than $1.7 billion of the overall amount related to matters concerning the healthcare and life sciences industries, and only reflected recoveries from purely federal losses.[3] The press release framed this historic fact as an achievement in enforcing federal rules and regulations.[4] In its semiannual report to Congress, the Office of Inspector General ("OIG") stated that it anticipated over $3.44 billion in expected recoveries during its reporting period, April through September 2023.[5] However, these large numbers indicate how much

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[1] *False Claims Act Settlements and Judgments Exceed $2 Billion in Fiscal Year 2022*, DEP'T OF JUST. (2023), https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-2-billion-fiscal-year-2022 (last visited Jan. 16, 2024).

[2] *Id.* ("Settlements and judgments under the False Claims Act exceeded $2.2 billion in the fiscal year ending Sept. 30, 2022... [t]he government and whistleblowers were party to 351 settlements and judgments, the second-highest number of settlements and judgments in a single year.").

[3] *Id.* ("Of the more than $2.2 billion in False Claims Act settlements and judgments… over $1.7 billion related to matters that involved the health care industry, including drug and medical device manufacturers, durable medical equipment, home health and managed care providers, hospitals, pharmacies, hospice organizations, and physicians. The amounts included in the $1.7 billion reflect recoveries arising only from federal losses…").

[4] *Id.*

[5] *Semiannual Report to Congress*, OFF. OF INSPECTOR GEN. at 5 (2023), https://oig.hhs.gov/reports-and-publications/archives/semiannual/2023/fall-sar-2023.pdf (last visited Jan. 16, 2024) (demonstrating in "At-a-Glance Highlights for Fiscal Year 2023" table that, between Oct. 1, 2022 and Sep. 30, 2023, OIG determined the expected audit recovery to be $283.5 million, and the expected investigative recovery to be $3.16 billion, adding to a total of more than $3.44 billion in overall expected recovery.); *See* Press Release, *HHS-*

the government has recovered, while not considering what the victims of the fraud and abuse have experienced and lost. The lasting impact of the harm patients experience at the hands of healthcare professionals who commit fraud and abuse is often lost in the conversation. A qui tam relator, or a private individual who brings an FCA action against an individual or corporation on behalf of the government, is able to recover some financial reward for their efforts, but the hidden victims are left with a multitude of issues.[6] There are easily identifiable physical and financial harms, such as a Medicare beneficiary experiencing health issues from unnecessary medical services or being billed for services they never received.[7] However, what is often missing from the discussion are the intangible harms that ultimately impact a beneficiary's healthcare access and overall experience with the U.S. health care system, which negatively impacts health equity. Because fraud and abuse practitioners ("FAPs") are most likely to target non-white, elderly, and underserved populations, damages recoupment is critical in filling the gap to improve health equity.[8] For these reasons, federal rules and regulations regarding damages penalties, such as the application of the Civil Monetary Penalties Law ("CMPL"), should include intangible, but

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OIG's Efforts Result in $3.44 Billion in Expected Recoveries, According to Latest Report, OFF. OF INSPECTOR GEN. GOV'T OVERSIGHT DEP'T OF HEALTH & HUM. SERVS., (Dec. 1, 2023) (https://oig.hhs.gov/newsroom/news-releases-articles/2023-fall-sar/) (last visited Mar. 8, 2024).

[6] 31 U.S.C § 3730(b)-(d); *See also*, *Semiannual Report to Congress*, OFF. OF INSPECTOR GEN. at 95 (2023) https://oig.hhs.gov/reports-and-publications/archives/semiannual/2023/fall-sar-2023.pdf (last visited Mar. 8, 2024).

[7] Lauren Hersch Nicholas et al., *Association Between Treatment by Fraud and Abuse Perpetrators and Health Outcomes Among Medicare Beneficiaries*, 180 J. AM. MED. ASS'N INTERNAL MED., 62, 63 (2020) (discussing fraud crimes by physicians resulted from billing for unnecessary services that jeopardized patient well-being; *See also* Federal Trade Commission, *Medical Identity Theft: FAQs for Health Care Providers and Health Plans*, at 1 (listing one of the consequences of medical identity theft as receiving bills for services never rendered to the beneficiary)

[8] Lauren Hersch Nicholas et. al., *Medicare Beneficiaries' Exposure to Fraud and Abuse Perpetrators*, 38 HEALTH AFF., 788, 791 (2019) https://www.healthaffairs.org/doi/epdf/10.1377/hlthaff.2018.05149.

quantifiable, harms to patient's interests as a way to further deter impact on vulnerable populations.

This article will explore the impact of fraud and abuse on vulnerable populations, highlight the intangible harms that arise from fraud and abuse, propose language that can be used in current legislation, and discuss how financial recoupment can improve health equity where fraud and abuse has caused a negative effect.

II. Overview of Healthcare Fraud and Abuse Regulations

Due to the increased incidence of fraud, Congress created the Health Insurance Portability and Accountability ("HIPAA") of 1996 and established the Medicare Integrity Program to combat fraud and abuse committed against private and public health plans.[9] Under HIPAA, funds were appropriated, not only for the Integrity Program, but also for the Department of Health and Human Services ("HHS"), Centers for Medicare and Medicaid Services ("CMS"), and the Department of Justice ("DOJ") to lead the charge on health care fraud and abuse control.[10] Furthermore, HHS acts and operates through its OIG to coordinate the Health Care Fraud and Abuse Control Program ("HCFAC") by engaging local, state, and federal law enforcement agencies to hold wrongdoers accountable for their offensive actions.[11]

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[9] Gov't Accountability Off., Centers for Medicare and Medicaid Services Needs to Ensure More Widespread U*se*, at 5 (Jun. 30, 2011) (hereinafter *GAO Report*), https://www.gao.gov/assets/gao-11-475.pdf.

[10] *Id.*

[11] *Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2022*, Dep't of Just. & Dep't Health & Hum. Servs. at 1 (2023) (hereinafter *HCFAC Annual Report FY 22*), https://oig.hhs.gov/documents/hcfac/1156/OIG-HCFAC-2022-Complete%20Report.pdf).

There are five main federal fraud and abuse laws that apply to all healthcare providers.[12] First, the FCA is a federal civil statute that protects the government from reimbursing providers that knowingly submitted fraudulent claims to the Medicare or Medicaid programs.[13] Fraudulent activity may include, but is not limited to, submitting multiple claims for the same service, submitting claims for unbundled services, or billing for services that a patient never actually received.[14] FCA violations include fines, that when aggregated, could add up to millions of dollars in damages owed to the government.[15] Because the FCA also includes provisions for qui tam relators, those private individuals are thus entitled to a percentage of what the government recovers from bad actors.[16] However, the statute does not include a provision where victims of the fraudulent services and subsequent claims are entitled to a percentage of the recovery.

Three additional fraud and abuse regulations include the Anti-Kickback Statute ("AKS"), the Physician Self-Referral Law ("Stark Law"), and the Exclusion Statute.[17] When considering both Stark Law and the AKS, healthcare providers who submit or cause to submit claims that violate these laws will be subject to severe monetary penalties.[18] The Exclusion Statute also aims to control fraud and abuse by requiring the OIG to exclude offending providers from billing, directly or indirectly, to Federal healthcare programs.[19]

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[12] *Fraud and Abuse Laws*, DEP'T OF HEALTH & HUM. SERVS. & OFF. OF INSPECTOR GEN. (HHS-OIG) https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/ (last visited Feb. 11, 2024)
[13] 31 U.S.C. § 3729-3733 (West).
[14] *Id.*
[15] Settlement Agreement at 2-3, U.S. ex rel. Lutz & Webster v. Lab'y Corp. of Am. Holdings, No. CV-9:14-3699-RMG, 2021 WL 7367200 (D.S.C Jun. 29, 2021) (determining that defendant must pay $19 million as part of settlement agreement for submitting several false claims between Jan. 2010 and Dec. 2014, and the relators must receive $5,605,000 as their share of the recovered amount).
[16] *Id.*
[17] HHS-OIG, *supra* note 12.
[18] *Id.*
[19] *Id.*

Finally, under the CMPL, OIG has authority to impose fines, assessments, and exclusions on an entity that engaged in prohibited conduct.[20] Depending on the violation, the offender's penalties can be up to $100,000 for each prohibited act, and the amount will be trebled.[21] The robust healthcare fraud enforcement system almost guarantees mass monetary recovery for the government; however, there is little to be said about compensation for injured beneficiaries.

III. Impact of Fraud and Abuse on Vulnerable Populations

A. Economic and Physical Harms

When providers engage in fraud and abuse, patients experience economic, physical, and intangible harms.[22] From an economic standpoint, Medicare beneficiaries who are FAP victims incur many financial costs due to the cost-sharing structure of the healthcare programs.[23] For example, beneficiaries must pay 20% of the charges for outpatient services, once the deductible is met, pursuant to Medicare Part B statutory guidelines.[24] Even though the government subsidizes the majority of healthcare costs for the beneficiaries, many still must pay co-insurance or co-payments for the services they receive.[25] As stated earlier, most victims of FAPs are non-white, low-income,

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[20] 42 U.S.C § 1320a-7a (West).
[21] HHS-OIG, *supra* note 12.
[22] Alanna M. Lavelle & Timothy L. Helms, *How Healthcare Fraud and Abuse Perpetuate Health Disparities in the U.S.*, MITRE, at 3 (2022), https://www.mitre.org/sites/default/files/2022-02/pr-21-3650-how-healthcare-fraud-abuse-perpetuate-health-disparities.pdf.
[23] United States v. Mazkouri, 945 F.3d 293 (5th Cir. 2019) (discussing defendant billed Medicare for more than $69 million, and Medicare paid more than $22 million on claims submitted for beneficiaries with severe dementia, and those patients should not have received those outpatient services due to their PHP program ineligibility).
[24] *Medicare Claims Processing Manual*, Pub 100-04, Ch. 5, Sec. 10. Ctrs. for Medicare & Medicaid Servs., (Rev. 11129, Nov. 22, 2021) https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c05.pdf.
[25] *Costs*, Medicare.gov, https://www.medicare.gov/basics/costs/medicare-costs (last visited Mar. 9, 2024) (outlining in table titled "Part B (Medical Insurance) Costs" that beneficiary

elderly, dually-eligible and/or disabled.[26] Furthermore, a beneficiary whose provider has been excluded from participating in a Federal health care program may incur costs finding a new Medicare provider. Thus, a beneficiary with limited financial resources likely experiences disproportionate impact from fraud and abuse conduct, that can negatively impact their overall health and access to healthcare.

The physical harms of healthcare fraud are the easiest to recognize because they demonstrate a direct consequence of a provider's prohibited conduct.[27] In other instances, the harm may not be physical itself; however, the impact of overtreatment, such as unnecessary diagnostic tests, can lead to a downpour of more unnecessary tests, false-positive results, and psychological repercussions.[28] Similarly, when a provider fails to provide adequate treatment, the patient will likely experience adverse outcomes because they involuntarily relinquish their ability to get more effective, safer treatments with another provider.[29]

B. Intangible Harms

While economic and physical harms are easily identified, there are a plethora of hidden— intangible harms—that deserve heightened acknowledgment. Intangible harms may be characterized as diminished trust in the provider or health system, emotional distress, fear, or anxiety related

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has premium to pay along with 20% of costs, while Medicare pays 80% of the costs for Part B-covered services).

[26] Nicholas et al., *supra* note 8.

[27] United States ex rel. Polukoff v. St. Mark's Hosp., 895 F.3d 730 (10th Cir. 2018) (discussing defendant's submission of claims where it was alleged that he submitted 861 claims for PFO closures which were all deemed to be medically unnecessary surgical procedures for his heart patients).

[28] Peter Franks et al., *Gatekeeping Revisited-Protecting Patients from Overtreatmen*t, 327 NEW ENG. J. MED. 424-25 (1992).

[29] United States v. Bachynsky, 949 F.2d 722, 735 (5th Cir. 1991) (concluding that "while relying on Dr. Bachynsky's ineffective course of treatment, his patients may have been foregoing more effective, safer, and legitimate treatments elsewhere. Neither is it mere speculation that at least some of the patients paid personally for portions of the costs of these bogus treatments by virtue of deductibles and co-payments.").

to conduct that resulted from healthcare fraud and abuse.[30] One of the most detrimental intangible harms stems from medical identity theft. When a provider inappropriately uses a Medicare beneficiary's number, the beneficiary can likely be compromised because false claims will be attached to their Medicare number indefinitely.[31] Furthermore, attached to the false claims is the imprint of false diagnoses.[32] As a result, they may be subsequently "denied Medicare benefits" due to the fraudulent activity.[33] Benefit denial will lead to reduced access to needed healthcare, which will ultimately lead to adverse health outcomes.[34] Additionally, the health charts of impacted beneficiaries are inaccurate, leading to inaccurate future treatment, and possible adverse health outcomes.[35]

Though the exclusion of FAPs from participating in Federal health care programs is a positive aspect of fraud control, there are also unintentional harms that arise. When a provider is excluded from participating in Medicare or Medicaid, that provider is essentially unable to serve program beneficiaries.[36] In a way, it can be viewed as if the provider is absent from

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[30] Anthony Kyriakakis, *The Missing Victims of Health Care Fraud*, 3 UTAH L. REV. 605, 623-35 (2015).
[31] Senior Medicare Patrol, *Consequences to Beneficiaries*, https://smpresource.org/medicare-fraud/consequences-to-beneficiaries/ (last visited Feb. 12, 2024).
[32] *Id.*
[33] *Id.*
[34] *Care Without Coverage: Too Little, Too Late, Ch. 3 Effects of Health Insurance on Health*, INST. OF MED. U.S. COMM. ON THE CONSEQUENCES OF UNINSURANCE, at 48-58 (2002), https://www.ncbi.nlm.nih.gov/books/NBK220636/ (finding that extensive health coverage is likely to result in greater use of preventive and screening services, which indicates regular source of care, increased likelihood of receiving care, and better health outcomes); *See also* Melissa Magerol et al. *The Uninsured: A Primer*, KAISER FAM. FOUND., at 1 (2015), https://files.kff.org/attachment/primer-the-uninsured-a-primer-key-facts-about-health-insurance-and-the-uninsured-in-the-era-of-health-reform ("Being uninsured affects people's access to needed medical care and their financial security. The access barriers facing uninsured people mean they are less likely to receive preventive care, are more likely to be hospitalized for conditions that could have been prevented, and are more likely to die in the hospital than those with insurance.").
[35] Kristen Peremore, *Medical Identity Theft and Its Impact on Healthcare*, PAUBOX (Sept. 13, 2023), https://www.paubox.com/blog/medical-identity-theft-and-its-impact-on-healthcare.
[36] HHS-OIG, *supra* note 12.

the healthcare system as a whole, at least for affected patient populations. When there is a shortage of physicians, there is decreased access to care.[37] As a result, beneficiaries will likely experience a delay in needed care and long wait times.[38] Further, finding a new provider that one trusts to treat them can be a time-consuming task.[39] Finally, fraudulent bills negatively impact a beneficiary's future treatment options.[40]

In many ways, the identified intangible harms may seem difficult to quantify, and thus be deemed unimportant. However, the effect of those intangible harms can be detrimental to one's access to health care and ultimately their health, which would create more health disparities. Therefore, it would be appropriate for victims of fraud and abuse to be able to recover some portion of damages assessed to an offending provider as a way to make the victim whole again.

IV. PURPOSE OF THE MEDICARE TRUST FUND

According to the Tax Policy Center, the Medicare Trust Fund was created to finance Medicare to ensure that beneficiaries are able to receive health services that are paid for by the government.[41] The Trust Fund is financed through multiple avenues, including payroll taxes, standard tax revenue, and the premiums that enrollees pay into the Medicare program.[42] In fiscal year

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[37] Thomas Bodenheimer & Hoangmai H. Pham, *Primary Care: Current Problems and Proposed Solutions*, 5 HEALTH AFF., 799, 801-802 (2010), https://www.healthaffairs.org/doi/10.1377/hlthaff.2010.0026.
[38] *Id.* at 801.
[39] Lindsay Hedden et al. *How Long Does it Take Patients to Find a New Primary Care Physician When Theirs Retires: A Population-based, Longitudinal Study*, HUM. RES. HEALTH, at 7 (2021) ("We found that while the vast majority of patients do go on to find a new MSOC, that process can take considerable time. Six percent of our sample had not found a family physician 36 months after the retirement of their original MSOC. Eighteen percent took between 18 and 36 months.")
[40] Joan H. Krause, *A Patient-Centered Approach to Health Care Fraud Recovery*, 2 J. CRIM. L. & CRIMINOLOGY, 579, 594 (2006).
[41] *Key Elements of the U.S. Tax System*, TAX POL'Y CTR., https://www.taxpolicycenter.org/briefing-book/what-medicare-trust-fund-and-how-it-financed. (last updated Jan. 2024).
[42] *Id.*

2022, HHS-OIG reported that the HCFAC transferred $1.2 billion of the $1.7 billion recovered money from settlements and judgments under the FCA.[43] Thus, it follows that the overall goal of controlling healthcare fraud and abuse at the Federal level is to ensure that the Trust Fund remains financed to accomplish its goals. As previously stated, if a whistleblower succeeds on an FCA claim, then they will receive a portion of the damages award.[44] Furthermore, funds that are not appropriated to the Trust Fund are directed to the HCFAC Program to financially support the anti-fraud enforcement efforts of the DOJ and OIG.[45] Thus, a limited amount of funds are available to be directed to beneficiaries impacted by FAPs.[46]

V. PROPOSED REGULATION FOR EXPANDING DAMAGES RECOVERY AND ALLOCATION

When money is fraudulently taken from the government, it has authority to recover that money.[47] It also may hold perpetrators accountable through sentencing and exclusion.[48] Under the Exclusion Statute, the amount of time that an offending provider is excluded from program participation is aggravated based on the financial, physical, and mental impact that their prohibited conduct had on beneficiaries.[49] Keeping that idea in mind, the HHS Secretary has authority under the Civil Monetary Penalties Law to "impose civil money penalties," program exclusion, and/or assessment against perpetrators for fraud and abuse conduct

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[43] *HCFAC Annual Report FY 22*, *supra* note 11, at 5.
[44] 31 U.S.C § 3730(b)-(d).
[45] *HCFAC Annual Report FY 22*, *supra* note 11, at 3-4.
[46] *Id.* at 7. ("FY 2022 Allocation of HCFAC Appropriation").
[47] Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191, Sec. 1128C(a)(1) (extending OIG authority to eliminate healthcare fraud and abuse in federal health care programs); 42 U.S.C § 1320a-7c(a)(1) (West).
[48] 42 U.S.C § 1320a-7a (West).
[49] 42 C.F.R. § 1001.102(b)(3).

concerning the Medicare and Medicaid programs.[50] Consequently, CMS has implemented a strategic plan to advance healthy equity as a way to address the health disparities that continue to plague our health system.[51] When considering HHS/CMS goals to protect public welfare, the various authorities, and guidelines for recovery outlined in federal fraud and abuse regulation, intangible harms should be included as part of the government's injury.[52] Specifically, the collective harms of Medicare patients, especially in the aggregate, result in overall harm to the government, and should thus be considered as part of the government's total injury. Therefore, this article proposes that the CMPL should be modified to include restitution for Medicare beneficiaries who were impacted by their provider's prohibited conduct. Under the CMPL, section (d) states:

"**(d) Amount or scope of penalty, assessment, or exclusion**

In determining the amount or scope of any penalty, assessment, or exclusion imposed pursuant to subsection (a) or (b), the Secretary shall take into account—

(1) the nature of claims and the circumstances under which they were presented,
(2) the degree of culpability, history of prior offenses, and financial condition of the person presenting the claims, and
(3) such other matters as justice may require."

The legislation should be modified by adding a new third prong, and a sub-section, with the proposed language as follows:

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[50] M.J. Gaynes, *Civil Monetary Penalties Law: Mistakes Could be (Very) Costly*, TEX. MED. (May 1989) https://pubmed.ncbi.nlm.nih.gov/2660314/.
[51] *CMS Strategic Plan* (infographic), https://www.cms.gov/about-cms/what-we-do/cms-strategic-plan (last updated Mar. 8, 2024) (The infographic outlines the six CMS strategic pillars along with several cross-cutting initiatives as a way to demonstrate the agency's dedication to serving the public "as a trusted partner and steward, dedicated to advancing health equity, expanding coverage, and improving health outcomes.").
[52] Krause, *supra* note 40, at 602. (contrasting with the author's contention that "The fact that such harm [physical and financial] is relevant, however, does not mean that it will be remedied separate from the government's own injury.").

> "(3) the intangible harms that arose as a result of conduct outlined in section (a)
>
> (a) Intangible harms may include, but are not limited to, financial cost accrued due to medical identity theft, financial cost due to payment for unnecessary medical services including co-payments and co-insurance, and emotional or mental distress resulting from a provider's prohibited conduct."

Similar to the statutory guidelines outlined in the FCA, if the government elects to bring a suit against the alleged FAP, it has the burden to "prove that the [claims] were false under any reasonable interpretation… by a preponderance of the evidence."[53] The government has a role in protecting the public's interest and welfare[54], thus, it follows that the government should protect the interests and welfare of its most vulnerable citizens. Furthermore, the government should take on this burden since it recognizes that the federal health care programs it created are highly susceptible to fraud, waste, and abuse.[55] Therefore, it should uptake the injury of its Medicare beneficiaries as its own injury in order to maximize recovery of funds.[56]

Modeled after the statutory language pertaining to a qui tam relator's entitled recovery and the Civil Injunction Statute[57], the legislation under section f(3) of the CMPL[58] should be modified by adding the proposed language as follows:

"Two to five percent of the amount recovered shall be allocated to Medicare beneficiaries who were directly impacted by a provider's

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[53] 31 U.S.C.A § 3731(c)-(d) (West).
[54] Jodi L. Short. *In Search of the Public Interest*, 40 YALE J. ON REGUL. 759, 764-655 & n.23 (2023).
[55] GOV'T ACCOUNTABILITY OFF., MEDICARE AND MEDICAID: CMS NEEDS TO FULLY ALIGN ITS ANTIFRAUD EFFORTS WITH THE FRAUD RISK FRAMEWORK, 8 GAO-18-88 (2017) (explaining the GAO conducted the study because HHS identified the Medicare and Medicaid programs as "high risk partly due to their vulnerability to fraud, waste, and abuse."), https://www.gao.gov/assets/gao-18-88.pdf.
[56] Kyriakakis, *supra* note 30, at 643.
[57] 31 U.S.C. §§ 3730(d) (West); *see also* 18 U.S.C. § 1345 (West).
[58] 31 U.S.C.A § 3731(f) (West).

prohibited conduct under paragraph (a) to promote the Secretary's efforts to prevent a continuing and substantial injury to the United States or any person or class of persons for whose protection the action is brought."

Because the proposed legislation falls under the CMPL, the added provisions will be enforced by the DOJ and HHS-OIG. The new statutory proposal will specifically cover Medicare beneficiaries who have been identified as victims of FAPs as part of the "Covered Conduct". Finally, the allocated portion will be quantified based on the trial judge and jury's final penalty calculation that is in line with how the calculations are customarily determined.

The proposed language should be adopted, not only to continue to protect the welfare of the nation's most vulnerable population – Medicare beneficiary patients of FAPs – but also because states have adopted similar initiatives to help victims get restitution for what has happened to them. For example, the Connecticut Attorney General on the *Dey Inc* healthcare fraud trial used his authority to employ a holistic approach to remedy the impact of fraud and abuse on victims, and/or similarly situated patients, in the community.[59] Ultimately, the goal of the proposed modification to current legislation should include allocations for intangible, but quantifiable, harms to protect Medicare beneficiary interests. Those interests may include maintaining their health, maintaining trust in the health system, and/or protecting their privacy as a way to further deter bad actors, and push back on possible inequity or disparity issues. Federal prosecutors should be empowered to consider and include harm against beneficiaries just as some State Attorneys General have exercised such power by including restitution to beneficiaries as part of settlement agreements. For example, the U.S. States Attorney for the Eastern District of Washington created a settlement

[59] Paul Brian Nolette, *Advancing National Policy in the Courts: The Use of Multistate Litigation by State Attorneys General*, BOS. COLL., at 497-98 & n.18 (Aug. 2011) (PhD dissertation, Boston College), http://hdl.handle.net/2345/bc-ir:104391.

agreement with Lincare Holdings where the company's Corporate Integrity Agreement would include it identifying and reimbursing Medicare Advantage plan beneficiaries for improper copayments under the Covered Conduct.[60] This case, and others, demonstrates that there is some level of authority at the state level, and it is reasonable to infer that similar settlement agreements are possible at the federal level.

VI. POSSIBLE CONCERNS OF PROPOSED LEGISLATION AND ITS EXECUTION

Presumptively, those that oppose the proposed legislation may assert that the statutory modification is unfeasible due to the arduous legislative process. A bill must be introduced and referred by a representative to the appropriate committee.[61] It must go through hearings, reports must be conducted, and legislators must debate on its measures.[62] If the proposed bill is passed by the House and Senate, and the bill is signed by the President, then it becomes public law.[63] The contents of the bill are codified in the U.S. Code, and the relevant agencies are tasked with implementation by proposing and finalizing regulations in the Federal Register.[64] Before presidential consideration, Congress would need to consider that funds currently recovered due to government injury, and appropriated to various programs, should also include appropriations to private citizens. Congress would be confronted

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[60] *See e.g.,* Settlement Agreement at 5, United States ex rel. Montgomery et al. v. Lincare Holdings, Inc., No. 2:21-cv-151-TOR (Aug. 9, 2023) (E.D. Wash.) https://www.justice.gov/usao-edwa/file/1311981/dl?inline; *See e.g.,* Settlement Agreement at 31-33, State of California v. Caremark Rx LLC, No. 37-2008-00077952-CU-MC-CTL (Feb. 14, 2008) (Cal. Sup.).

[61] William Keating, *The Legislative Process*, https://keating.house.gov/policy-work/legislative-process (last visited Mar. 8, 2024).

[62] *Id.*

[63] *Id.*

[64] *Federal Legislative History: Basics*, https://wcl.american.libguides.com/c.php?g=563252&p=3877952 (last updated Feb. 24, 2024, 12:51pm).

with determining and balancing the federal government's role "as a payor and a protector."[65] Reimbursement to beneficiaries may not be seen as the government's primary goal, likely because there are other legal alternatives for impacted individuals to utilize.[66] Accordingly, such legal alternatives "exist at the state level to redress direct patient harm,"[67] and the federal government offers some level of restitution for criminal claims as well.[68]

The concerns are acknowledged; however, Congress should move forward with implementing the proposed statutory language because, based on the public health socio-ecological model, federal-level policy imparts the broadest structural change in health equity.[69] The socio-ecological model consists of five successive levels with the fifth being policy impact.[70] Coupled with the National Institute on Minority and Health Disparities (NIMDH) framework, it is clear that proper public policy implementation has a positive impact on reducing health disparities and improving health equity.[71] The government can serve as payor *and* protector for its most vulnerable citizens by imparting lasting change at the federal level. that can apply to all entitled citizens in all states. Furthermore, the difficulty of

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[65] Joan H. Krause, *Healthcare Fraud and Quality of Care: A Patient-Centered Approach*, 37 J. HEALTH L. 161, 178 (2004).
[66] *Id.* at 183.
[67] *Id.*
[68] 18 U.S.C. § 3663A(c)(1) (West) (outlining guidelines for mandatory restitution to victims of certain crimes).
[69] *See* Kenneth R. McLeroy et al., *An Ecological Perspective on Health Promotion Programs*, 15 HEALTH EDUC. Q., 351, 355 (Winter 1988).
[70] Samantha E. Scarneo-Miller et al., *The Socioecological Framework: A Multifaceted Approach to Preventing Sport-Related Deaths in High School Sports*" 54 J. OF ATHLETIC TRAINING, 356, 357 fig. "The 5 Levels of the Socioecological Framework" (2019). (Socio-ecological model consists of five levels: intrapersonal or individual, interpersonal, organizational, environmental, and policy (including federal, state, and local) impact).
[71] Shelley White-Means et al., Editorial, *Intervention and Public Policy Pathways to Achieve Health Care Equity*, 16 INT. J. ENVIRON. RES. PUB. HEALTH, at 1-3, 3 tbl.1. (2019) (discussing NIMDH framework and other socio-ecological models include policy changes and interventions that affect health equity). *See e.g.,* Barry M. Straub, *A Role for Government: An Observation on Federal Healthcare Efforts in Prevention*, 44 AM. J. OF PREVENTIVE MED., S39, S39-S42 (2013) (explaining how the Affordable Care Act is a recent example of how federal-level policy can be successful in increasing access to healthcare) https://www.ajpmonline.org/action/showPdf?pii=S0749-3797%2812%2900631-9.

surviving the legislative process is not an appropriate reason to refrain from pursuing policy that will improve U.S. citizens' welfare.

VII. CONCLUSION

When healthcare providers engage in fraud and abuse activity, not only is the government injured, but also the actual patients of those practitioners.[72] Though there are several regulations to assist the government in recovering money lost from offending providers, the government should not fail to consider Medicare beneficiary FAP victims in its recovery efforts. Just as the ultimate damages reward is apportioned to whistleblowers and HCFAC program, so should a portion be allocated to beneficiaries who were victims of healthcare fraud. Adoption of the proposed language and proper execution would help dismantle systematic structures that promote healthy inequities in a way that efforts at the individual may not be able to do.

[72] Lavelle & Helms, *supra* note 22, at 3.

Intermediaries Uncovered: The Hidden Cost of Telehealth Innovation

Francisco Borrayo

I. THE RISE OF TELEHEALTH AND PRIVACY CONCERNS

Over the last two weeks, how often have you been bothered by any of the following problems?

1. *Little interest or pleasure in doing things.*
2. *Feeling depressed, down, or hopeless.*
3. *Feeling nervous, anxious, or on edge.*[1]

These mental health screening questions, which were once primarily answered on the Patient Health Questionnare-9 ("PHQ-9") and Generalized Anxiety Disorder scale ("GAD-7") questionnaires in a heath care provider's waiting room, are now asked by telehealth startups, newcomers in the healthcare space that offer the benefits of health care from the comfort of home.[2] Telehealth's benefits are readily apparent, saving both time and money compared to traditional provider visits.[3] Yet, there is a less apparent cost: the compromise of your personal health information.[4]

The substantial growth of telehealth, accelerated by the COVID-19 pandemic, has prompted concerns about data privacy gaps and potential

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[1] *Patient Health Questionnaire and General Anxiety Disorder (PHQ-9 and GAD-7)*, FLORIDA STATE UNIV. – UNIV. HEALTH SERV. (last visited Feb. 13, 2024), https://uhs.fsu.edu/sites/g/files/upcbnu1651/files/docs/PHQ-9%20and%20GAD-7%20Form_a.pdf.

[2] *Id.*; *See Welcome to Mindbloom*, MINDBLOOM, https://welcome.mindbloom.com (last visited Apr. 23, 2024), for an example of a telehealth startup's candidacy questionnaire.

[3] Dori Milburn, *How Telehealth is Helping Underserved Populations in Healthcare*, HEALTH RECOVERY SOLS. (last visited Feb. 12, 2024), https://www.healthrecoverysolutions.com/blog/how-telehealth-is-helping-underserved-populations-in-healthcare.

[4] Todd Feathers et al., *"Out of Control": Dozens of Telehealth Startups Sent Sensitive Health Information to Big Tech Companies*, THE MARKUP (last updated Dec. 22, 2022), https://themarkup.org/pixel-hunt/2022/12/13/out-of-control-dozens-of-telehealth-startups-sent-sensitive-health-information-to-big-tech-companies.

exploitation.[5] While the Health Insurance Portability and Accountability Act ("HIPAA") Privacy Rule introduced in 2003 aimed to protect individuals' health information, limitations within HIPAA's existing framework, especially the narrow definition of "business associate," pose challenges in safeguarding patient data.[6]

This article focuses on telehealth entities that act as intermediaries, connecting patients to affiliated providers and exploiting loopholes in HIPAA's "business associate" definition. This article advocates for the expansion of the definition of "business associate" under HIPAA. Such reform would strengthen regulatory frameworks and proactively address potential data privacy breaches in the evolving telehealth landscape.

II. CURRENT LEGAL LANDSCAPE OF DATA PRIVACY

A. Overview of HIPAA, HITECH, and the Inclusion of Business Associates

Signed into law in 1996, HIPAA is the primary federal law that protects health information.[7] HIPAA's objectives have expanded since its inception.[8] In 2003, the HIPAA Privacy Rule was added to protect the privacy and security of individuals' health information held by covered entities and their

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[5] Lisa M. Koonin et al., *Morbidity and Mortality Weekly Report (MMWR)*, CTRS. FOR DISEASE CONTROL & PREVENTION (last reviewed Oct. 30, 2020), https://www.cdc.gov/mmwr/volumes/69/wr/mm6943a3.htm; Feathers et al., *supra* note 4.
[6] *Summary of the HIPAA Privacy Rule*, HHS.GOV (last reviewed Oct. 19, 2022), https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html; Jordan Harrod & Dan Utter, *Health Data Privacy: Updating HIPAA to Match Today's Technology Challenges*, SCI. IN THE NEWS (May 15, 2019), https://sitn.hms.harvard.edu/flash/2019/health-data-privacy/.
[7] Heath Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, 110 Stat. 1936; Harrod, *supra* note 6.
[8] *See* Harrod, *supra* note 6 (discussing HIPAA's original intent to facilitate Americans' ease of transferring between doctors and ensuring affordable treatment for pre-existing conditions through insurance coverage)

business associates, giving individuals certain rights to access and control their information.[9]

A "covered entity" under 45 C.F.R. § 160 is a health plan, health clearinghouse, or a health care provider that electronically transmits health information.[10] A "business associate" under HIPAA is an entity managing protected health information ("PHI") for a covered entity, which provides services such as claim processing, data analysis, consulting, records management, and data transmission services. [11] A covered entity can also serve as a business associate for another covered entity. [12]

The HIPAA Privacy Rule permits the use and disclosure of health information without authorization for public interest and benefit purposes, such as public health, research, law enforcement, and health oversight.[13] It was enacted due to the rise of electronic health transactions.[14] The Secretary of Health and Human Services ("HHS") was tasked to set standards for protecting electronic health information and propose measures to secure the privacy of identifiable health information.[15]

The 2009 Health Information Technology for Economic and Clinical Health ("HITECH") Act and the 2013 final rule by the U.S. Department of Health and Human Services ("HHS") Office for Civil Rights ("OCR") addressed business associates' role in managing health information, making them directly liable for HIPAA violations stemming from impermissible PHI uses and disclosures.[16]

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[9] *Summary of the HIPAA Privacy Rule*, *supra* note 6.
[10] 45 C.F.R. § 160.103.
[11] *Id.*
[12] *Id.*
[13] *Summary of the HIPAA Privacy Rule*, *supra* note 6.
[14] Steve Alder, *The Comprehensive History of HIPAA to the Current Day*, THE HIPAA J. (last visited Feb. 12, 2024), https://www.hipaajournal.com/hipaa-history/.
[15] *Id.*
[16] Modifications to the HIPAA Privacy, Security, Enforcement, and Breach Notification Rules Under the Health Information Technology for Economic and Clinical Health Act and the Genetic Information Nondiscrimination Act; Other Modifications to the HIPAA Rules,

B. HIPAA's Limitations

Despite the inclusion of a "business associate" as a "covered entity" under HITECH, in its current state, HIPAA is limited in how it can protect PHI because of its narrow definition of "business associate" and weak enforcement mechanisms.

While HIPAA's "business associate" definition explicitly excludes certain entities, it fails to mention entities that function as intermediaries connecting patients to HIPAA-covered affiliated providers.[17] This omission raises the possibility that information collected by an intermediary, like a telehealth company's intake, may lack HIPAA protection.[18] Even though the same information would be protected if shared with a provider covered by HIPAA, an intermediary is not defined as a "business associate."[19]

OCR enforces the HIPAA Privacy Rule through the investigation of complaints and compliance reviews, as well as through education and outreach.[20] HHS states that if "a covered entity knows of a material breach or violation by [a] business associate," it must try to rectify the issue or terminate the agreement.[21] However, there is no guidance for situations where an intermediary, *not* defined as a business associate, commits a material breach or violation.

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78 Fed. Reg. 5566 (Jan. 25, 2013); *Direct Liability of Business Associates*, HHS.GOV (last reviewed July 16, 2021), https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/factsheet/index.html; 45 C.F.R. § 164.502(a)(3).

[17] *See* 45 C.F.R. § 160.103 (Outlining the exclusion of health care providers, plan sponsors under specific conditions, government agencies for authorized purposes, and covered entities participating in organized health care arrangements for specified activities from the "business associates" definition.).

[18] Feathers et al., *supra* note 4.

[19] *Id.*

[20] *How OCR Enforces the HIPAA Privacy & Security Rules*, HHS.GOV (last reviewed Nov. 20, 2023), https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/examples/how-ocr-enforces-the-hipaa-privacy-and-security-rules/index.html.

[21] *Business Associates*, HHS.GOV (last reviewed May 24, 2019), https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/business-associates/index.html.

III. ETHICAL CONCERNS AND PREDATORY PRACTICES

A. Telehealth's Increased Prevalence Within Vulnerable Communities

Telehealth, as defined by the Centers for Medicare and Medicaid Services ("CMS"), is the utilization of electronic information and telecommunication technologies for remote patient care.[22] These technologies include videoconferencing, imaging, streaming media, and both terrestrial and wireless communications.[23] Before the COVID-19 pandemic, "telehealth visits and remote patient monitoring had doubled" among physicians.[24] Subsequently, telehealth visits continued to surge by fifty percent in the first quarter of 2020 when compared with the same period in 2019.[25] Moreover, in the last week of March 2020, telehealth visits spiked 154% compared to the same week in 2019.[26]

Early adopters utilized telehealth to decrease emergency room visits, manage chronic diseases, and provide care to underserved and vulnerable populations, including those in rural areas with limited access to health professionals.[27] According to HHS, "underserved communities" face barriers to health care due to unfamiliarity with the healthcare system, access to fewer providers, and economic, cultural, and linguistic challenges.[28] Vulnerable populations are characterized by significant hardships, such as a

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[22] *Coverage to Care - Telehealth for Providers: What You Need to Know*, CTRS. FOR MEDICARE & MEDICAID SERVS. (May 2023), https://www.cms.gov/files/document/telehealth-toolkit-providers.pdf.
[23] *Id.*
[24] Len Strazewski, *Telehealth's Post-pandemic Future: Where Do We Go from Here?*, AM. MED. ASS'N (AMA) (Sept. 7, 2020), https://www.ama-assn.org/practice-management/digital/telehealth-s-post-pandemic-future-where-do-we-go-here (discussing the increase in remote patient monitoring among physicians from 14% to 28% between 2016 and 2019).
[25] Koonin et al., *supra* note 5.
[26] *Id*.
[27] Robert Pearl & Brian Wayling, *The Telehealth Era Is Just Beginning*, HARVARD BUS. REV. (May – June 2022), https://hbr.org/2022/05/the-telehealth-era-is-just-beginning.
[28] *Serving Vulnerable and Underserved Populations*, CTRS. FOR MEDICARE & MEDICAID SERVS. (last visited Feb. 12, 2024), https://www.cms.gov/marketplace/technical-assistance-resources/training-materials/vulnerable-and-underserved-populations.pdf.

higher risk for health care problems or pre-existing conditions, discrimination, or a limited ability to understand or give informed consent without language assistance.[29]

The National Rural Health Association reports that rural areas have only thirty specialists per 100,000 residents, compared to 263 in urban areas.[30] Before telehealth, the physician shortage in rural U.S. areas forced patients to travel long distances or forgo care, rendering them more vulnerable to serious illness.[31] Telehealth has mitigated this dilemma, providing access to necessary care and saving patients an average of 145 miles and 142 minutes per visit.[32]

Despite a decrease from its peak usage, telehealth continues to improve patient health, reduce costs, and provide more equitable and accessible care to 89% of U.S. adults, including those in medically underserved communities.[33]

B. Data Privacy Gaps Exploited

HIPAA's current "business associate" definition does not encompass telehealth entities acting "as middlemen connecting patients to affiliated providers," an omission exploited by some telehealth providers.[34]

A joint investigation by journalistic organizations STAT and The Markup found that forty-nine out of fifty telehealth websites shared sensitive health data with major ad platforms like Meta (formerly Facebook) and Google via trackers.[35] Without the users' knowledge, trackers collect user data,

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[29] *Id.*
[30] Hyacinth Empinado, *Treating Rural America: STAT Examines Health Care Disparities*, STAT (Nov. 2, 2023), https://www.statnews.com/2023/11/02/rural-health-telehealth-doctors-patients/.
[31] *Id.*
[32] Milburn, *supra* note 3.
[33] Pearl, *supra* note 27.
[34] Feathers et al., *supra* note 4.
[35] *Id.*

including browsing URLs and intake form responses, for advertising or other undisclosed purposes.[36]

The investigation highlighted Cerebral Inc.'s ("Cerebral") case.[37] Cerebral is a mental health company that connects patients with providers who prescribe antidepressants and other drugs.[38] A pixel, one of Meta's trackers on Cerebral's website, sent Meta users' detailed answers to intake questions about depression, anxiety, bipolar disorder, and insomnia, along with hashed identifiers of the users.[39] Hashing data is a process that transforms data, such as names or email addresses, into a string of letters and numbers that is difficult to reverse.[40] While HIPAA permits the sharing of health information once it has been de-identified, hashed identifiers can be matched to user profiles by tech platforms that receive them.[41]

Although Cerebral claims to be HIPAA-compliant, it also states that information shared with third parties is not PHI under HIPAA because it acts as a middleman between parties and providers, not as a business associate.[42] Patients seeking online treatment for opioid use and other addictions unknowingly had their intimate answers about drug use and self-harm sent to these platforms.[43]

IV. THE CASE FOR EXPANDING DATA PROTECTION

A. Strengthening Data Privacy Protections – "Business Associate"

In February 2023, the Federal Trade Commission ("FTC") took action against GoodRx, a digital health platform, filing a complaint and proposing

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[36] *Id.*
[37] *Id.*
[38] *Id.*
[39] *Id.*
[40] Andrew Zola, *What is Hashing and How Does It Work?*, TECH TARGET (last updated June 2021), https://www.techtarget.com/searchdatamanagement/definition/hashing.
[41] 45 C.F.R. § 164.514(a); Feathers, *supra* note 4.
[42] Feathers et al., *supra* note 4.
[43] *Id.*

an order for violating the FTC Act and the Health Breach Notification Rule.[44] The FTC accused GoodRx of deceiving users by sharing personal health information with third parties, including Meta, Google, and Criteo, for advertising purposes, contrary to its assurances.[45] Additionally, GoodRx targeted users with health-related ads on social media platforms.[46] GoodRx falsely claimed compliance with HIPAA and the Digital Advertising Alliance principles, while lacking sufficient policies to safeguard user data.[47]

The proposed order prohibits GoodRx from sharing health information for advertising without user consent, mandates deletion of shared consumer health data by third parties and requires informing users about breaches and the FTC's enforcement.[48] GoodRx must also limit data retention, implement a comprehensive policy program, and pay a $1.5 million civil penalty for Health Breach Notification Rule violations.[49]

The FTC's intervention is a positive step towards safeguarding telehealth users' PHI. However, it is important to note that this action was undertaken by the FTC, not the HHS.[50] This distinction is significant because GoodRx, despite not falling under the category of a HIPAA-covered entity, consistently portrayed itself as such, implying that its privacy and information practices adhered to HIPAA requirements.[51] Depending on the FTC to address misrepresentations by telehealth entities after the fact is a reactive and significantly delayed approach. This approach still permits

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[44] *FTC Enforcement Action to Bar GoodRx from Sharing Consumers' Sensitive Health Info for Advertising*, FED. TRADE COMM'N (Feb. 1, 2023), https://www.ftc.gov/news-events/news/press-releases/2023/02/ftc-enforcement-action-bar-goodrx-sharing-consumers-sensitive-health-info-advertising.
[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] *Id.*
[49] *Id.*
[50] *FTC Enforcement Action to Bar GoodRx from Sharing Consumers' Sensitive Health Info for Advertising, supra* note 44.
[51] *Id.*

telehealth entities not covered by HIPAA to share users' sensitive PHI with third parties, provided they can demonstrate that, unlike GoodRx, they did not portray themselves as HIPAA-covered.[52] This level of reliance is insufficient.

To proactively address telehealth users' PHI being shared to third parties without their knowledge, an expanded HIPAA definition of "business associate" is necessary. Currently, a "business associate" is defined as a person or entity engaging in functions or activities regulated by HIPAA on behalf of a covered entity, encompassing the creation, receipt, maintenance, or transmission of PHI.[53] However, the current definition fails to address entities that act as intermediaries linking patients to affiliated providers covered by HIPAA but are not themselves regulated by HIPAA.[54] This omission arises because, as per the current language of HIPAA, acting as an intermediary connecting patients to a HIPAA-covered entity does not meet the criteria for engaging in functions or activities regulated by HIPAA on behalf of a covered entity.[55]

B. Proposal to Include Telehealth Intermediaries in HIPAA's "Business Associate" Definition

To remedy this omission, I propose the following addition to the "business associate" definition in HIPAA's statutory text:

> (3) **Business associate** includes:
>
> (iv) Any entity that, on behalf of a covered entity or organized healthcare arrangement, functions as an intermediary for that covered entity or organized healthcare arrangement by facilitating the creation, receipt, maintenance, or transmission of protected health information via telehealth services, including but not limited to, platforms that provide direct-to-consumer health care-related services, digital health applications, and

[52] Feathers et al., *supra* note 4.
[53] 45 C.F.R. § 160.103.
[54] 45 C.F.R. § 160.103; Feathers, *supra* note 4.
[55] 45 C.F.R. § 160.103.

> entities that analyze or manage health data obtained from patients through such platforms.

Expanding the "business associate" definition to include telehealth entities serving as intermediaries will allow HIPAA's regulatory framework to effectively mitigate instances of telehealth users' PHI being shared with third parties without their knowledge.

As previously discussed, rural populations uniquely rely on telehealth services due to the scarcity of specialists in those areas, making them particularly susceptible to data privacy breaches.[56] This proactive approach would ensure telehealth companies serving rural areas, including those functioning as intermediaries for covered entities, are held to the same data privacy standards as traditional health care providers. Consequently, rural patients may be more willing to engage with telehealth services if they are confident that their PHI is protected, even when handled by a business associate functioning as an intermediary, leading to better health care outcomes and adherence to treatment plans. Privacy and security measures within the whole telehealth sector would therefore be enhanced, ultimately fostering a more comprehensive protection of patient data, and aligning with the evolving landscape of health care services.

V. REGULATORY CONSIDERATIONS & RESPONSES

Expanding the reach of the "business associate" definition in HIPAA would result in increased regulation, a stance not universally accepted: an October 2023 Gallup poll found that 54% of Americans believed the government is "trying to do too many things that should be left to individuals and businesses."[57] Such sentiments have remained consistent since the early

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[56] Empinado, *supra* note 30.
[57] Lydia Saad, *Public Firm in View Government Doing Too Much, Too Powerful*, GALLUP (Oct. 24, 2023), https://news.gallup.com/poll/512900/public-firm-view-government-doing-powerful.aspx.

1990s, maintained by the belief that deregulation helps improve economic efficiency and consumer choice while reducing prices.[58] Therefore, over-regulation is viewed as form of government interference that distorts market signals, creates artificial scarcity, and imposes unnecessary costs on producers and consumers.[59]

While skepticism towards increased regulation persists among a significant portion of the population, the unique nature of healthcare data demands nuanced consideration. In the context of telehealth entities acting as intermediaries and transmitting PHI to HIPAA-covered entities, factors beyond economics come into play. The intricacies of healthcare data privacy, especially in the rapidly expanding telehealth landscape, necessitate a careful evaluation of the potential consequences of minimal regulation. Unlike many sectors, healthcare involves highly personal and sensitive information; as demonstrated by companies like Cerebral Inc. and GoodRx, the data privacy landscape is uniquely susceptible to abuse if not properly governed.[60] Because of the widespread use and dependence on telehealth among vulnerable populations, they bear the brunt of this exploitation.[61]

Moreover, the argument that regulation interferes with innovation is not entirely supported. Deloitte, the largest professional services network globally, found regulation enables innovation by promoting the adoption of new technologies and approaches and encourages investment by providing certainty that risks are being mitigated to both regulators and entities.[62] Telehealth entities, especially those like the startups that thrived during the

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[58] *Id.*; Robert W. Crandall, *Extending Deregulation Make the U.S. Economy More Efficient*, THE BROOKINGS INST. (last visited Feb. 13, 2024), https://www.brookings.edu/wp-content/uploads/2016/06/pb_deregulation_crandall.pdf.
[59] Crandall, *supra* note 58.
[60] Feathers et al., *supra* note 4; *Fed. Trade Comm'n*, *supra* note 44.
[61] Pearl, *supra* note 27.
[62] William D. Eggers et al., *Regulation that Enables Innovation*, DELOITTE (Mar. 22, 2023), https://www.deloitte.com/global/en/our-thinking/insights/industry/government-public-services/government-trends/2023/regulatory-agencies-and-innovation.html.

initial phase of the COVID-19 pandemic, have a distinct opportunity to develop business models that are both scalable and compliant.[63] They can leverage the ongoing demand for telehealth services driven by factors such as the aging population, expanded insurance coverage, and a shortage of clinicians.[64]

As we explore the necessity of expanding the definition of "business associate" in HIPAA to encompass these intermediaries, it is clear that increased regulation is not merely about bureaucratic oversight but rather an essential safeguard for the integrity of the healthcare system as well as the trust and confidentiality of vulnerable patient populations.

VI. THE FUTURE OF TELEHEALTH AND PATIENT PRIVACY

Telehealth's convenience comes with a hidden cost – the compromise of personal health information. Although the HIPAA Privacy Rule aimed to protect such data, the current framework, hindered by a narrow definition of "business associate," presents challenges. This article has explored the ethical concerns and predatory practices in the expanding telehealth landscape, particularly its impact on vulnerable communities.

With telehealth's exponential growth, propelled by the COVID-19 pandemic, concerns about data privacy gaps and exploitation have risen. The focus on telehealth entities as intermediaries, exploiting the loopholes in HIPAA's definition, underscores the need for reform. This article advocates for an expanded definition of "business associate" under HIPAA. Proactively addressing potential data privacy breaches in the evolving telehealth

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[63] Nathaniel M. Lacktman & Jacqueline N. Acosta, *Telemedicine Startups Can Survive and Thrive under Renewed Regulation*, TECHCRUNCH (Jan. 24, 2022), https://techcrunch.com/2022/01/24/telemedicine-startups-can-survive-and-thrive-under-renewed-regulation/.

[64] *Id.*

landscape is essential for maintaining the integrity of healthcare systems and safeguarding the trust and confidentiality of vulnerable patient populations.

Expanding Required Reporting of Social Drivers of Health in CMS Inpatient Services

Malia Bott

I. INTRODUCTION TO SOCIAL DRIVERS OF HEALTH ("SDOH")

Experiences of fraud and abuse in the healthcare system are interconnected with healthcare inequity. The most vulnerable populations suffer disproportionate impacts of medical error due to implicit bias and discrimination.[1] When healthcare fraud and abuse occur, there is not only physical harm done to patients and their families, but also emotional and financial harm resulting in a degraded sense of trust in providers, government agencies, and the healthcare system.[2]

Health care coverage is a large barrier to accessing care for underserved populations. The Centers for Medicare and Medicaid Services ("CMS") is in the best position to understand how to eliminate health disparities due to the unique understanding they have of the patients they insure. CMS is a federal agency that provides health care coverage to more than 170 million people through Medicare, Medicaid, the Children's Health Insurance Program, and the Health Insurance Marketplace.[3] CMS is considered the nation's largest insurance provider, and, as such, released the CMS Framework for Health Equity in 2022,

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[1] Phoebe Jean-Pierre, *Medical Error and Vulnerable Communities*, 102 B.U.L. REV. 327 (2022).
[2] *The Challenge of Health Care Fraud*, NAT'L HEALTH CARE ANTI-FRAUD ASS'N, https://www.nhcaa.org/tools-insights/about-health-care-fraud/the-challenge-of-health-care-fraud/.
[3] *CMS Framework for Health Equity 2022-2032*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Apr. 2022).

which outlines five priorities to achieve health equity and eliminate disparities among underserved populations.[4]

This article proposes to require the reporting of "health literacy" as a sixth mandatory category of Social Drivers of Health ("SDOH") through CMS in the inpatient sphere. Currently, there are only five SDOH categories that are required to be reported, which include: 1) food insecurity; 2) interpersonal safety; 3) housing insecurity; 4) transportation insecurity; and 5) utilities.[5] Fraud and abuse violations through Medicare and Medicaid programs occur when there is a lack of oversight, oversight failure, and ambiguous norms.[6] Adding a sixth category would help decrease these issues, as providers will be aware of their patients ability to comprehend their care and any implicit bias asserted due to the patient's ability to understand their treatment or care.

II. MEDICARE FRAUD AND ABUSE CLAIMS

Fraud can take many forms in the Medicare space. Medicare fraud can occur when an individual, group, or organization knowingly submits false claims with misrepresentations of fact to obtain federal health care payments or remuneration in violation of the federal False Claims Act (FCA).[7] Common examples of FCA violations include knowingly billing for services that were not provided, ordering medically unnecessary services for patients, or even billing for the appointments

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[4] *Id.*
[5] *SDOH reporting to CMS mandatory in the inpatient sphere starting January 2024*, IND. STATE MED. ASS'N (Jan 4, 2024), https://www.ismanet.org/ISMA/Resources/e-Reports/1-4-24/SDOH.aspx.
[6] James M. DuBois, et al., *Serious Ethical Violations in Medicine: A Statistical and Ethical Analysis of 280 Cases in the United States from 2008-2016,* 19 PUBMED CENT. 1, 9 (2019).
[7] *Medicare Fraud & Abuse: Prevent, Detect, Report*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Jan. 2021).

that patients fail to keep.[8] Health care professionals who abuse these kinds of federal programs through fraudulent and abusive activities cost taxpayers billions of dollars.[9] In 2022, civil health care fraud settlements and judgments under the FCA were more than $1.6 billion.[10] Investigations by the Department of Health and Human Services' Office of the Inspector General ("HHS-OIG") in 2022 resulted in 661 criminal actions for those engaged in Medicare and Medicaid fraud, as well as 726 civil actions for false claims and unjust enrichment.[11]

III. MEDICARE-MEDICAID DUAL ENROLLEES & UNIQUE VULNERABILITIES AS PATIENTS

Fraud and abuse within CMS are significant due to the quantity of insured patients. As of January 31, 2023, 12.5 million people in the U.S. were jointly enrolled in Medicare and Medicaid, receiving their primary insurance coverage through Medicare with some assistance through Medicaid.[12] This population's unique health needs, combined with their demographics, demonstrate that they are especially vulnerable to healthcare fraud and abuse. Among enrollees receiving Medicare and Medicaid, 87% had an annual income of less than $20,000; nearly half were people of color; 48% had at least one limitation in activities of daily living; and 44% were in fair or poor health.[13] Four out of ten enrollees in both Medicare and Medicaid lived on an income of less than

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[8] *Id.* at 6.
[9] *Id.* at 5.
[10] *Annual Report of the Departments of Health and Human Services and Justice*, U.S. DEP'T OF JUSTICE & U.S. DEP'T OF HEALTH & HUM. SERVS. (Nov. 2023), https://oig.hhs.gov/publications/docs/hcfac/FY2022-hcfac.pdf.
[11] *Id.*
[12] Maria T. Peña, et al., *A Profile of Medicare-Medicaid Enrollees (Dual Eligibles)*, KAISER FAM. FOUND. (2023).
[13] *Id.*

$10,000.[14] One in four Medicare-Medicaid enrollees also had five or more chronic conditions, and 50% of enrollees had a mental health condition.[15] Thus, the Medicare-Medicaid enrollees are a population with challenging and diverse needs. They are in poorer health, are more racially diverse, have lower incomes, and have lower education overall.

Due to the fact that Medicare-Medicaid enrollees have unique health needs combined with challenging socioeconomic circumstances, this article proposes to require the reporting of "health literacy" as a mandatory sixth SDOH category through CMS in the inpatient sphere. CMS began requiring reporting of the SDOH factors in the inpatient sphere starting in January 2024, with a deadline to submit by May 15, 2025.[16] This reporting was voluntary for CMS in 2023.[17] For admitted patients, CMS will now require screening for five specific SDOH domains, including: 1) food insecurity; 2) interpersonal safety; 3) housing insecurity; 4) transportation insecurity; and 5) utilities.[18] However, these questions do not address the extremely important issue of health literacy.

Health literacy can be understood as the extent to which a patient has the ability to read, understand, or comprehend their medical care.[19] More than half of adults in the United States are classified as having intermediate health literacy, with 14% of adults below basic health

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[14] *Id.*
[15] *Id.*
[16] *SDOH reporting to CMS mandatory in the inpatient sphere starting January 2024*, IND. STATE MED. ASS'N (Jan 4, 2024) https://www.ismanet.org/ISMA/Resources/e-Reports/1-4-24/SDOH.aspx.
[17] *Id.*
[18] *Id.*
[19] *Patients with Low Health Literacy Make More Errors Interpreting Instructions and Warnings*, INST. FOR SAFE MEDICATION PRACS. (Nov. 30, 2023), https://www.ismp.org/resources/patients-low-health-literacy-make-more-errors-interpreting-instructions-and-warnings.

literacy, and only 12% of adults are regarded as having health literacy proficiency.[20] These statistics are significant because Medicare-Medicaid dually eligible or enrolled patients may have a limited understanding of what they have been told about their condition, treatment, or prescription, have little prior knowledge about their medications or prevention, or may lack the ability to navigate health services. Patients 65 and older, disabled or retired, with an income of less than $20,000 per year and an education level of some high school or less had the highest rates of inadequate health literacy.[21]

Health literacy is essential to individualized health care because patients with low health literacy are more likely to make errors when interpreting instructions for taking medications, understand warning labels, have decreased medication adherence, and are less likely to take medication as described.[22] Low health literacy is often not obvious through daily communication, as patients can suffer from embarrassment when disclosing such information, and often practitioners are unaware that patients need additional support to understand their health plan.[23]

Currently, education and health literacy are a code CMS has recently made available for physicians to use.[24] However, without mandatory reporting to fill out such information, this important SDOH need will likely not be adequately screened. While Medicaid accountable organizations and federally qualified health centers screen more for

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[20] *Id.*
[21] Rabia Shahid, et al., *Impact of low health literacy on patients' health outcomes: a multicenter cohort study*, 22 BMC HEALTH SERV. 1, 4 (2022).
[22] *Patients with Low Health Literacy Make More Errors Interpreting Instructions and Warnings, supra* note 19.
[23] *Id.*
[24] Vinita Magoon, *Screening for Social Determinants of Health in Daily Practice*, AM. ACAD. OF FAM. PHYSICIANS, 1, 10 (2022).

SDOH factors than other hospitals, most do not screen patients for key social needs.[25] Among U.S. hospitals and physician practices, only 24% of hospitals and 16% of physician practices reported screening for these five factors.[26] It was most common to screen for interpersonal violence.[27] Without accountability, screening for health literacy will likely not occur among providers. This is true especially in non-academic medical centers. Physician practices that were not in an academic medical center were more likely to screen for zero needs.[28] Since Medicare and Medicaid recipients frequently return to these inpatient centers for treatment of chronic health conditions, this increases the necessity for such screening and reporting to be performed.

IV. PROPOSED ADDITION OF "HEALTH LITERACY" AS A REQUIRED SDOH IN CMS

CMS should require the reporting of "health literacy" as a sixth mandatory SDOH category in the inpatient sphere. Once providers identify a vulnerable patient due to a low level of health literacy, providers need to remain accountable and aware of bias, stereotyping, or prejudice to create a lesser likelihood that patient harm does not occur. Fewer medically unnecessary surgeries and incorrect diagnoses among Medicare and Medicaid patients will result in decreased instances of provider fraud and abuse within CMS. Providers will be aware of the vulnerabilities of a patient through reporting these SDOH factors, involving documenting their ability to comprehend or self-advocate, which could result in differential treatment plans, diagnoses, or care.

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[25] Taressa K. Fraze et al., *Prevalence of Screening for Food Insecurity, Housing Instability, Utility Needs, Transportation Needs, and Interpersonal Violence by US Physician Practices and Hospitals*, 2 JAMA NETWORK 1, 1 (2019).
[26] *Id.* at 1.
[27] *Id.*
[28] *Id.* at 6.

The reporting of this sixth SDOH category should occur through the same reporting requirements of the collection period used through 2024. If patients are identified as potentially having low health literacy, screening in the form of asking questions related to health literacy should occur for this patient. The identification of patients with low health literacy will ultimately be at the discretion of the provider. However, key areas of interest that staff should be aware of include: when a patient struggles to engage with their provider about their care plan when needed; when a patient identifies that they are unable to access or find up-to-date resources on health information; when they do not fully complete forms when necessary due to a lack of comprehension; or when they indicate a lack of self-confidence in managing their own health care decisions.

Here, screening for health literacy should occur with patients ages 18 or older by asking five "yes" or "no" or short-answer questions to identify needs in this field. The codes CMS has created will be used by providers when patients answer "yes" to any of questions three through five below, their lowest level of education is high school or less, or they indicate they are a non-native English speaker. The codes CMS uses have already been created and can be used for this screening.

Therefore, when a patient demonstrates that they may struggle with health literacy verbally, or through nonverbal signals such as appearing confused during the visit, the following questions should be asked at the patient's visit to screen their level of health literacy:

1. Are you a native English speaker?

2. What is your highest level of education?

3. Do you ever have trouble reading your medical information (Ex. filling out forms, reading prescription labels, or medical records)?

4. Have you ever left a visit feeling confused about your health plan?

5. Do others help you stay up-to-date on your health information?

If a patient declines to answer a question, screening should occur within the same calendar year, at their next in-patient stay. If a patient is hospitalized more than once in a year, this screening should only be completed once per year, unless a patient identifies a change in their circumstances in which it would be appropriate to screen again. For example, if a patient identifies that they have recently struggled to understand their care plan or have recently asked for outside help to stay up to date on their care plan.

Screening for health literacy as a SDOH is essential because Medicaid and Medicare recipients are more likely to be frequent patients of inpatient care yet have the lowest health literacy levels and poorest health outcomes. For instance, one study found that patients with low health literacy levels were more likely to visit the emergency room within three months of their discharge date.[29] Given this statistic, fraud and abuse can be perpetuated due to frequent interactions with the healthcare system and inherent exposure due to receiving repeated treatments, or procedures for complex and chronic illnesses. In such repeated encounters, patients may even be treated by the same physicians, nurses, or staff. This is significant because patients who are vulnerable may lack the ability to self-advocate, and thus providers may be unaware they are

[29] Shahid et al., *supra* note 21, at 4.

struggling to understand their care plans. Yet even though these patients are more likely to revisit emergency rooms and receive more care, limited health literacy is still associated with worse health outcomes.[30] For instance, a study found that low health literacy independently predicts mortality and cardiovascular death among elderly people, suggesting that health literacy is a more powerful variable than general education.[31] In these instances, patients may lack the ability to self-advocate.[32] Health literacy documentation is important information and context for providers to have, as providers' attitudes toward patients can influence the quality of care in medical settings.

The frequency of such encounters, however, indicates a downside to using such screening questions. First, a central issue is time. The amount of time that is needed to complete a health assessment among professionals is already limited, given the amount of time providers have to complete patient assessments.[33] Providers have a constrained period of time for visits with patients, and some may argue that this is not enough time to provide the in-depth care for patients that is needed, particularly for those with chronic or complex conditions. There will likely be pushback from providers that such a screening is outside the scope of their role, such as their goals are not to serve as a social worker or community advocate but to give care. It would be

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[30] Carolyn Clancy, *Health Literacy Measurement Mapping the Terrain*, AGENCY FOR HEALTHCARE RSCH & QUALITY (2009).
[31] David W. Baker et al., *Health literacy and mortality among elderly persons*, 23 ARCH INTERN MED. (2007).
[32] Eliza Becze, *Promote Patient Self-Advocacy Across the Cancer Spectrum*, ONS VOICE (Aug. 9, 2022), https://voice.ons.org/news-and-views/promote-patient-self-advocacy-across-the-cancer-spectrum.
[33] Kriti Prasad, et al., *Time Pressure During Primary Care Office Visits: a Prospective Evaluation of Data from the Healthy Work Place Study*, 35 J. GEN. INTERNAL MED. (2020).

important for hospitals to hire staff whose specific duties are to screen for social determinants of health and provide information to physicians. This is timely and particularly relevant as the healthcare industry overall shifts towards value-based care. Yet, this indicates a short-term goal should be educating providers about health literacy and screening for this social determinant of health. Given that most providers want to serve their patients in good faith, a long-term goal for CMS should be to educate providers on the ongoing statistics of the patient populations they serve, for example, the number of patients they have identified who have challenges with health literacy. This will motivate providers to continue screening for these factors.

V. Education and Training Needed for Providers

The primary focus required for clear understanding in this SDOH area is clarifying what health literacy means. Education and training are necessary for this field to provide a comprehensive and standard understanding of health literacy. The definition of health literacy should be universal across CMS and read as the following: "the ability of a patient to comprehend and understand health-related benefits, risks, and rewards." Moreover, education should be given on what to do with the information identifying a patient with low health literacy. This is significant because when physicians recognize that certain patients lack the ability to voice concerns or opinions by screening for health literacy, providers can attempt to mitigate the effects of such implicit bias. A few examples of "activating" or engaging with a provider include empowering patients with information, educating patients on medical terminology, and encouraging patients to be vocal and engaged with their care plans. Screening and reporting for this SDOH factor will result in providers' awareness of the lesser ability of certain patients to self-advocate or articulate questions or concerns based on their care plan.

Awareness of health literacy by providers is also significant for instances of misdiagnosis. One study found that if a patient is female, a racial minority, or has an education level less than a high school degree, their chance of cerebral misdiagnosis was highest, with consequences as extreme as death or disability in the emergency department.[34] Reducing biased treatment among patients of minority groups is directly correlated with how they are perceived by their providers. By screening for this SDOH factor in inpatient care and adding the requirement to report this statistic to CMS, providers will be prepared to better engage with patients and recommend treatments to those who may lack the ability to self-advocate, ask questions, or voice concerns about their health care plans, therefore promoting better health outcomes. Providers will be aware of any implicit bias they are asserting due to differing levels of understanding or education, as well.

VI. AWARENESS OF PATIENT NEEDS WILL INCREASE ENFORCEMENT AND ACCOUNTABILITY

Schemes of healthcare fraud and abuse under Medicare or Medicaid can go beyond simple mistakes or the implicit bias of patients. Criminal schemes indicate a limit to what the education and screening requirements for health literacy can resolve in the short-term. The consequences, however, for those who fail to comply with requirements are relevant to fraud and abuse. Fraud and abuse schemes can operate under criminal enterprises who specifically target vulnerable patients. For example, a Florida doctor was reported to the police when he wrote oxycodone prescriptions to patients without a legitimate medical purpose

[34] Alexander Andrea Tarnutzer et al., *ED misdiagnosis of cerebrovascular events in the era of modern neuroimaging*, AM. ACAD. OF NEUROLOGY 1468, 1473 (2017).

by specifically recruiting Medicare and Medicaid patients.[35] In 2013, a dermatologist settled with the Department of Justice for $26.1 million after performing thousands of unnecessary biopsies and tissue transfers on Medicare patients for reimbursement.[36] He received more than $6 million in Medicare payments.[37] Here, reporting requirements of SDOH factors such as health literacy may inadvertently contribute to eliminating such bad actors by identifying those who fail to comply with basic requirements. This mandatory SDOH screening may disqualify criminal enterprises from CMS if they fail to screen for these required factors. Overall, this reporting requirement may be a catch-all for those organizations or providers who demonstrate a reckless disregard for fraudulent or abusive activities.

While CMS has not outwardly disclosed the consequences of failure to comply, failing to comply with past COVID reporting requirements resulted in the revocation of the providers' enrollment.[38] CMS should adopt similar standards for providers who fail to meet these reporting requirements to increase accountability. If a provider fails to make the required disclosures consistently, CMS may revoke the provider's enrollment. However, CMS should give providers the opportunity to come into compliance or even work with providers to develop a plan to successfully meet these requirements. Due to the unique demographics of this population as described, the low health literacy of these patients

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[35] *Two South Florida Doctors Arrested on Charges of Unlawfully Dispensing Opioids*, U.S. ATT'Y'S OFF., S. DIST. OF FLA. (Feb. 7, 2019), https://www.justice.gov/usao-sdfl/pr/two-south-florida-doctors-arrested-charges-unlawfully-dispensing-opioids.
[36] *Florida Physician to Pay $2.1 Million to Resolve False Claims Allegations*, OFF. OF PUB. AFFAIRS (Feb. 11, 2013), https://www.justice.gov/opa/pr/florida-physician-pay-261-million-resolve-false-claims-allegations.
[37] *Id.*
[38] *CMS Releases Interpretative Guidance on Mandatory COVID-19 Data Reporting for Hospitals*, AM. HOSP. ASS'N (Oct. 6, 2020), https://www.aha.org/special-bulletin/2020-10-06-cms-releases-interpretative-guidance-mandatory-covid-19-data-reporting.

only contributes to this population's ability to advocate for a procedure or practice that may be questionable but is often based on an implicit bias. Thus, CMS should emphasize education as well as accountability to teach providers the importance of screening for these categories. It may, in turn, improve their health outcomes through education, self-managed care, and increased health knowledge.

Others may argue that screening for health literacy is redundant and unnecessary because a patient's literacy is obvious to providers and can be indicated through their ability to orally communicate, or that the harms of low health literacy to patient safety are merely speculative. But fraud and abuse can occur when such vulnerable patients face challenges to self-advocacy, such as having less health knowledge in general. Thus, while social needs are generally not typically reported for patients with these key needs, screening for this factor and requiring reporting of this SDOH will help contribute to the awareness of vulnerabilities in this population by providers and ensure that there is oversight for the needs of such groups.

VII. Conclusion

Adding the reporting of "health literacy" as a sixth mandatory SDOH category through CMS in the inpatient sphere will combat patient fraud and abuse in the healthcare system. As previously stated, currently, there are only five SDOH categories that are required to be reported. Often, screening for these categories does not occur unless they are required to be reported to CMS. Screening and reporting are essential because the populations CMS serves are particularly vulnerable to healthcare fraud and abuse due to their chronic health conditions, low levels of education, and socioeconomic status. Low socioeconomic status is directly correlated with health care inequality, particularly among the poor,

uninsured, and elderly, who experience implicit bias and suffer greater risk for medical injury.[39] This shift to screen for health literacy levels will improve these issues by making providers aware of those patients who lack the ability to self-advocate, through education and training of the meaning of health literacy, and through the ongoing reporting requirements to CMS.

[39] Cassidy Visser, *The Economics of Injustice: Stratification in Medical Malpractice by Poor and Vulnerable Patients,* 29 THE GEO. J. ON POVERTY L. & POL'Y 274, 275 (2022).

Capitalizing Health: The Impact of Private Equity on Health Equity

Emma Goodman-Fish

I. PRIVATE EQUITY IN HEALTHCARE

Bain Capital (BC) is one of the largest private equity firms in the world, amounting to over $180 billion in asset value.[1] HCA Healthcare (HCA) is a for-profit healthcare facility that operates over 186 hospitals and approximately 2,000 care sites.[2] In 2006, BC acquired HCA in a transaction valued at $33 million.[3] At the time of the acquisition, BC claimed that the acquisition would maintain HCA's "patient first" culture and "focus on quality care and investing in substantial resources."[4] However, the focus quickly turned from quality to profit.[5] By January 2010, BC paid out significant dividends to its investors, totaling $1.75 billion.[6] The following year, they took the company public again, repricing its shares and earning a value of nearly $15.5 million.[7] When a private equity firm like BC acquires a healthcare system such as HCA, it typically makes changes such as streamlining processes, reducing administrative burdens, and focusing on advances in technology.[8] While these changes may sound beneficial, the impacts on patient outcomes are not always positive. In fact, patients treated at private equity-purchased hospitals show a 25% increase in hospital-acquired conditions and complications related to poor and inadequate care.[9]

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[1] Bain Capital, https://www.baincapital.com/ (last visited Feb. 10, 2024).
[2] HCA Healthcare, https://hcahealthcare.com/ (last visited Feb. 10, 2024).
[3] *HCA Completes Merger with Private Investor Group,* HCA HEALTHCARE (Nov. 17, 2006), https://investor.hcahealthcare.com/news/news-details/2006/HCA-Completes-Merger-With-Private-Investor-Group/default.aspx [hereinafter HCA Merger].
[4] *Id.*
[5] *Id.*
[6] Kevin Dowd, *This Day in Buyout History: KKR, Bain Capital Complete the Biggest LBO Ever,* PITCHBOOK (Nov. 16, 2017) https://pitchbook.com/news/articles/this-day-in-buyout-history-kkr-bain-capital-complete-the-biggest-lbo-ever.
[7] *Id.*
[8] Grace Niewijk, *New Findings Show Private Equity Investments in Healthcare May Not Lower Costs or Improve Quality of Care*, UCHICAGO MED. (July 25, 2023), https://www.uchicagomedicine.org/forefront/research-and-discoveries-articles/private-equity-investments-in-healthcare-may-not-lower-costs.
[9] Tara Bannow, *Complications Spiked 25% in Hospitals Bought by Private Equity,* STAT (Dec. 26, 2023), https://www.statnews.com/2023/12/26/hospitals-private-equity-complications/.

Since BC's acquisition of HCA, private equity in healthcare has only grown. In the last decade, such deals have grown six-fold, increasing from 75 deals in 2012 to 484 deals in 2021.[10] Healthcare deals now make up the majority of private equity deals.[11] A recent analysis in 2019 displayed that private equity deals in healthcare amounted to $79 billion, which made up 18 percent of the private equity deals worldwide.[12] There are three reasons for private equity's dominance in the healthcare sector. One reason is the "recession-proof nature" of healthcare or the lower cost of capital in the healthcare economy.[13] A second reason is the increasing commercialization of healthcare, which has allowed firms to treat healthcare and the health industry solely as a business rather than with altruistic intent.[14] Third, America's health systems have continually failed patients, providers, and all those who are a part of healthcare.[15] With no current improvements coming to fruition, hospitals and health systems, and sometimes even patients, may believe that private equity firm funds and resources will help to improve their systems and therefore seek out the involvement of private equity firms.[16]

II. PRIVATE EQUITY'S NEGATIVE IMPACT ON HEALTH EQUITY

BC and HCA's deal exemplifies a private equity acquisition strategy in which firms secure investor funding through borrowing, leveraging acquired

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[10] Richard Scheffler et al., *Monetizing Medicine: Private Equity and Competition in Physician Practice Markets*, AM. ANTITRUST INST. (July 10, 2023), https://www.antitrustinstitute.org/wp-content/uploads/2023/07/AAI-UCB-EG_Private-Equity-I-Physician-Practice-Report_FINAL.pdf.
[11] Anaeze Offodile, et al., *Private Equity Investments In Health Care: An Overview of Hospital and Health System Leveraged Buyouts, 2003-17*, HEALTH AFF. (May 2021), https://www.healthaffairs.org/doi/10.1377/hlthaff.2020.01535.
[12] *Id.*
[13] David Blumenthal, *Private Equity's Role in Health Care,* THE COMMONWEALTH FUND (Nov. 17, 2023), https://www.commonwealthfund.org/publications/explainer/2023/nov/private-equity-role-health-care.
[14] *Id.*
[15] *Id.*
[16] *Id.* (explaining that private equity firms offer a "hope for change" to physicians who are being failed by the U.S. healthcare system).

assets as collateral, aiming for short-term profit that compromises patient care and improvement of the healthcare system. [17] In fact, a private equity company can still make a profit off of an investment even if that healthcare entity goes bankrupt, which is ten times more likely to occur when a company is owned by a private equity firm.[18]

Carlyle Group (Carlyle)'s acquisition of HCR Manor Care (Manor) in 2007 illustrates the pitfalls of aggressive private equity practices. Carlyle borrowed funds to finance the purchase, then sold Manor's property, forcing Manor to rent a new property with significant annual expenses.[19] Ten years after the acquisition and thousands of layoffs and health code violations later, Manor Care was forced to file for bankruptcy.[20] Carlyle profited off Manor, while patients, employees, and providers suffered.[21] Carlyle and Manor is just one example of how profit-driven strategies used in private equity can harm communities and compromise patient care, particularly for those already marginalized in the healthcare system.[22]

Private equity currently owns at least 130 rural hospitals, which are characterized by limited access to care, poor health outcomes, and relatively low acquisition costs.[23] The acquisition of such hospitals by private equity poses a significant threat to patient care, particularly for those already

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[17] Jake Miller, *What Happens When Private Equity Takes Over a Hospital*, HARV. MED. SCH. (Dec. 26, 2023), https://hms.harvard.edu/news/what-happens-when-private-equity-takes-over-hospital#:~:text=A%20private%20equity%20firm%20raises,to%20pay%20down%20that%20debt; Atul Gupta, *Webinar on Understanding the Growth & Influence of Private Equity in Health Care*, U. PA. (June 6, 2023), https://www.youtube.com/watch?v=O_sxWQxCk2k.

[18] Brendan Ballou, *When Private Equity Firms Bankrupt Their Own Companies*, THE ATLANTIC (May 1, 2023), https://www.theatlantic.com/ideas/archive/2023/05/private-equity-firms-bankruptcies-plunder-book/673896/.

[19] *Id.*

[20] *Id.*

[21] *Id.*

[22] *See* U.S. Anesthesia Partners Complaint, FTC v. U.S. Anesthesia Partners Inc. (Sept. 21, 2023).

[23] Anastasia Gliadkovskaya, *Private Equity Owns at Least 130 Rural Hospitals, and Other Revelations in a Sweeping New Report on PE in Rural Healthcare,* FIERCE HEALTHCARE (Jan. 26, 2023), https://www.fiercehealthcare.com/finance/new-report-private-equity-stakeholder-project-ownership-rural-healthcare; Blumenthal, *supra* note 13.

impacted by the social determinants of health.[24] Residents living in rural areas who rely on these health facilities face a higher likelihood of encountering certain social determinants of health that adversely affect quality and access to care.[25] Factors such as low income, inadequate community infrastructure, poor access to education, transportation, and more, are social determinants of health that impede access to equitable care limiting individuals' resources and access to essential services.[26] These factors create barriers to healthcare, exacerbate health disparities, and perpetuate unequal health outcomes across different socioeconomic groups.[27] Given the greater need of rural healthcare providers for resources and capital, they often will either seek out or concede to private equity ownership.[28]

Private equity firms can engage in such behavior unnoticed because they often operate without official oversight.[29] By taking public companies private, the actions of private equity firms are not under public watch.[30] There are currently no laws that allow for antitrust or financial regulatory agencies to adequately monitor private equity activity.[31] Operating discreetly

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[24] *Social Determinants of Health for Rural People,* RHI HUB, https://www.ruralhealthinfo.org/topics/social-determinants-of-health (last visited Feb. 11, 2024) (describing certain social determinants of health such as income, employment, race, educational attainment, health literacy, adequate community infrastructure, access to transportation, food, healthcare services, and more).
[25] *Id.*
[26] *Id.* (highlighting how rural residents who have limited access to health services face barriers to good healthcare which can exacerbate already high-risk conditions in the community).
[27] *Id.*
[28] Gliadkovskaya, *supra* note 23.
[29] Richard Scheffler, Laura Alexander & James Godwin, *Soaring Private Equity Investment in the Healthcare Sector: Consolidation, Accelerated, Competition Undermined, and Patients at Risk*, AM. ANTITRUST INST. 2 (May 18, 2021),https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3860353.
[30] Troy Segal, *Understanding Private Equity (PE)*, INVESTOPEDIA (Feb. 9, 2024), https://www.investopedia.com/articles/financial-careers/09/private-equity.asp#:~:text=By%20taking%20public%20companies%20private,to%20improve%20the%20company's%20fortunes.
[31] Jim Parker, *Regulators Taking Aim at Hospice PE Backers*, HOSPICE NEWS (June 23, 2022), https://hospicenews.com/2022/06/23/regulators-taking-aim-at-hospice-pe-backers/ (emphasizing that private equity firms operate under the public and regulatory radar because "private equity acquisitions in healthcare are not reportable to antitrust or other financial regulatory authorities under current law").

and without public or regulatory scrutiny, private equity firms often engage in healthcare acquisitions that fall outside the reporting requirement of antitrust, as well as financial regulatory authorities.[32] Currently, when an FCA action is pursued against a health system or hospital, a hospital will be at fault and responsible for settlement charges that can amount to treble damages.[33] For example, a recent settlement with Silver Lake Hospital led the hospital to pay $18.6 million to resolve the government allegation that the hospital had presented fraudulent bills to the government.[34] Silver Lake Hospital had private equity investors at the time, who were responsible for $12 million because they violated of the Fair Debt Collection Practices Act.

Practices that involve fraud and abuse present a severe impact on health equity.[35] Fraud and abuse within the healthcare sector can exacerbate health inequities, particularly in the poor rural communities where private equity companies often make investments.[36] Vulnerable low-income communities are routinely taken advantage of and receive substandard, medically unnecessary, and inadequate care.[37] The case of Ancor's fraudulent practice in healthcare private equity underscores a broader issue of private equity firms operating without sufficient oversight in the healthcare industry. The potential for unchecked and illegal activities, driven by profit, poses a significant threat to general patient care and health equity. Vulnerable populations continue to be exploited, which exacerbates health disparities

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[32] *Id.*
[33] False Claims Act, 31 U.S.C.A. § 3729(1)(A)(2009).
[34] *Poten*tial *Liability of Investors in the Healthcare Industry Heightens as Hospital Investors Enter into Novel Settlement*,
SIDLEY AUSTIN (Jan. 24, 2024), https://fcablog.sidley.com/2024/01/24/potential-liability-of-investors-in-the-healthcare-industry-heightens-as-hospital-investors-enter-into-novel-settlement/.
[35] *See generally* John Dube, *The Anti-Kickback Statute and the False Claims Act: How Statutory Interpretation Affects Access to, and Protects Against Fraud in, the Public Healthcare Sector*, 19 J. HEALTH & BIOMED. L. 360 (2023).
[36] *Id.*
[37] *Id.*

and highlights the need for increase transparency and oversight of private equity investments in healthcare.

III. Preventing Private Equity Fraud and Abuse by Enhanced Regulation and Increase Enforcement

In response to the growing concerns surrounding private equity's involvement in healthcare and the potential for fraud and abuse, this proposal seeks to outline strategic measures aimed at preventing such misconduct. There has been some recent action against private equity firms' investment into healthcare entities and the fraud that follows, but not enough. Regulation of private equity firms, including those involved in healthcare, must involve a combination of federal and state regulatory bodies. This can be done in two ways. First, the regulation of private equity investments should be enhanced by new congressional legislation, and second, increased enforcement by the Department of Justice (DOJ) should be implemented through modification of the FCA language, allowing the DOJ to target private equity firms.

The first part of this solution enhances the regulation of transactions and transparency in private equity investment with new legislation. This should be done by expanding the evaluation and review of private equity companies that invest in healthcare and requiring additional notice of material transactions before private equity investments are closed. In August of 2023, the SEC issued new rules regarding their management of private equity companies.[38] These rules require private firms to provide quarterly statements about fees, expenses, and performance. However, these rules do not address how private equity investments impact the companies in which they invest, such as hospitals and physician practices. Neither do they consider how private equity investments and management may impact

[38] *SEC Issues New Private Fund Rules*, FTI Consulting, https://www.fticonsulting.com/insights/articles/sec-issues-new-private-fund-rules (last visited Feb. 11, 2024).

patients and health equity. Therefore, Congress should implement legislation that enhances the regulation of private equity companies, not only to protect investors but also to maintain and protect an efficient and fair healthcare market.

The legislation that Congress should implement would require notice of material transactions before closing private equity investments in healthcare.[39] The New York state legislature has implemented a similar model rule, but transitioning a rule such as this to the federal level will be more beneficial and have a larger impact. New York's new legislation notes how private equity in healthcare is largely unregulated and requires private equity firms to give thirty-day notice of material transactions that involve healthcare entities to the New York State Department of Health.[40] Material transactions include mergers, acquisitions, joint ventures, management services organizations, and more.[41] Congress should mimic the New York legislation at the federal level. Additionally, this federal legislation should incorporate part of the earlier drafted legislation, which was broader and would be a greater tool for promoting health equity.[42] The New York Legislation is Part L of the Health and Mental Hygiene Article VII draft legislation.[43] The legislation states the following:

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[39] Arthur Fried, Gary Herschman, & Randall Lee, *New York State Enacts New Notice Requirements Targeting Private Equity Health Care Transactions* (July 12, 2023), https://www.healthlawadvisor.com/new-york-state-enacts-new-notice-requirements-targeting-private-equity-health-care-transactions.

[40] FY 2024 New York State Executive Budget, *Health and Mental Hygiene*, Article VII Legislation https://www.budget.ny.gov/pubs/archive/fy24/ex/fy24bills.html [hereinafter, NY Budget].

[41] *New York Enacts New Requirement for Prior Notice of Certain Healthcare Transactions*, SIDLEY AUSTIN (May 8, 2023), https://www.sidley.com/en/insights/newsupdates/2023/5/new-york-enacts-new-requirement-for-prior-notice-of-certain-healthcare-transactions.

[42] Fried, *supra* note 39 (explaining that the earlier draft of the legislation would have provided the Department with the authority to review and approve material transactions regarding "impact on cost, quality, access, health equity and competition in the health care service market").

[43] FY 2024 New York State Executive Budget, *supra* note 40.

> *"A healthcare entity shall not consummate a material transaction without obtaining approval from the department for such material transaction"*

The NY statute requires the NY Department of Health to publish the information of the material transaction to the public, who can then become more informed about who is investing in the entity that is providing their treatment. The federal legislation should do the same but require transactions to be published by the federal Department of Health and Human Services (DHHS) instead. The language for this legislation would mimic the NY statute and would require the healthcare entity's transaction to be reported to each state's Department of Health, who would then report it federally to DHHS. It is also essential that DHHS take special care to note the impacts PE has in rural and low-income communities. To do this, the initial language of the NY statute which allows the "Department the authority to review and approve material transactions regarding impact on cost, quality, access, health equity and competition in the health care service market" should be added into the federal legislation, so that health equity is at the forefront of considerations.[44]

Additionally, after the close of the material transaction, DHHS should still retain the ability to review and evaluate substantial changes to the entity, such as the loss of reduced or free clinical services or a substantial increase in the number of employees laid off since the acquisition. This notice and continued monitoring would give the federal government the ability to review and approve material transactions and assess the negative impact it could have on patients before the deal goes through and throughout the PE's management of the healthcare entity. While some may argue that this level of review would result in "closing delays, unwanted publicity, and increased costs," it would add a necessary level of additional regulation of private equity in healthcare that can minimize the negative impacts these transactions

[44] Fried, *supra* note 39.

pose to health equity.[45] New levels of transparency will prevent PE from taking advantage of the healthcare market.

The second part of the solution should be increased enforcement of the False Claims Act (FCA) by the Department of Justice (DOJ) against not only healthcare entities but also the private equity companies that manage them.[46] FCA actions are one of the most effective ways to combat fraud in the healthcare industry. 80-90% of FCA claims against companies arise from healthcare fraud and abuse.[47] However, the government cannot always charge the private equity firm for the fraud that took place because they are not the ones who are directly submitting the false claims and, therefore, do not qualify under the FCA.[48] Congress should, therefore, amend the FCA to incorporate private equity firms under DOJ enforcement of the FCA. Despite a private equity company not being directly involved in the misconduct, the DOJ should pursue claims as it did with Ancor and Alliance,[49] finding private equity firms who acquire a hospital or health system and allow fraud to continue for profit are equally as liable as the health system itself. As of now, the FCA has the following language:

> *"any person who…(a)(1)(A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval"*[50]

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[45] *New York Seeks Regulatory Review of Health Care Transactions with Private Equity Investment*, ROPES & GRAY (Feb. 7, 2023), https://www.ropesgray.com/en/insights/alerts/2023/02/new-york-seeking-new-approval-right-over-material-health-care-transactions.

[46] Jonathan Ferry, *False Claims Act Risk to Private Equity Healthcare Investors*, 42 HEALTH L.. 30, 33 (Oct. 2020).

[47] Taylor Chenery & Angela Humphreys, *FCA Risks for Private Equity Investment in Healthcare for Mergers & Acquisitions Magazine*, BASS BERRY + SIMS (Oct. 4, 2023), https://www.insidethefalseclaimsact.com/false-claims-act-risk-private-equity-investment/.

[48] *Private Equity Put on Notice: The False Claims Act and Investor Liability*, V CHECK (Dec. 20, 2021) https://vcheckglobal.com/private-equity-put-on-notice-false-claims-act-and-investor-liability/ (explaining that private equity firms are usually considered "passive investors that aren't liable for misconduct by the companies that they own").

[49] *DOJ Hands Down Fines for FCA, Kickbacks, and Failure to Stop Kickbacks*, FREEMAN L., https://freemanlaw.com/kickbacks-and-failure-to-stop-kickbacks/ (last visited Feb. 11, 2024).

[50] False Claims Act, 31 U.S.C.A. § 3729(1)(A) (2009).

This language only implicates the person who knowingly presented the claim. "Knowingly" under the FCA means that a person, with respect to information, has actual knowledge, acts in deliberate ignorance, or acts in reckless disregard.[51] Congress should make an addendum here in order to clarify that private equity companies are equally liable for such fraud and misconduct. While it may be difficult to make individual investors at a firm liable, the company as an entire entity should face discipline for their involvement in the fraud and abuse. Because the vast majority of FCA actions are in the healthcare sector, it would make sense that an additional addendum is added for healthcare claims. This addition would be under the "definitions" section. The language should look as follows:

> *"(5) the term "a person," in healthcare-specific claims, applies not only to the "person" but additionally to any private firms that have ownership, management, or investments in the healthcare entity or practice."*

This addition will encourage responsible investments and provide an incentive for private equity firms to increase oversight and reduce fraud and abuse in the healthcare systems in which they are investing. Rather than purchasing rural hospitals that already run a risk for fraud and therefore endanger patients while liquidating the hospital, firms will be more wary about hospitals or practices that are involved in fraud if they know that they could be held liable. Additionally, the government will be on the watch for private equity firms that are involved in any kind of fraud and abuse that would perpetuate health inequities and be able to prosecute them adequately. While it could be argued that private equity firms will be deterred from investing in hospitals altogether, resulting in certain struggling hospitals closing, the benefits of this risk outweigh the concerns. Unmonitored private equity investments are only a band-aid for struggling hospitals, and the benefits of regulation would have a greater impact on patients than the potential loss of financial backing by a private equity firm.

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[51] *Id.*

Once Congress amends the language of the FCA, the DOJ will be responsible for the increased enforcement of FCA claims against private equity owned healthcare entities. Considering that FCA claims are predominantly in the healthcare sector, a separate task force that targets only FCA claims in the healthcare sector would help to improve enforcement and reduce fraud and abuse. While some medical associations, such as the American Medical Association and the American Hospital Association, argue that expansion of the FCA's scope could lead to dangerously increased scrutiny of hospitals and health systems,[52] such enforcement is intended to protect patients and is the best way to reduce fraud and abuse. With private equity companies so heavily involved in the healthcare sector, the only way to moderate this behavior is to put punishments in place that apply to the firms and not only to the hospitals. This creates an overall incentive to establish honest care and, therefore, supports patients equitably.

IV. DECAPITALIZING HEALTH FOR A MORE EQUITABLE FUTURE

In conclusion, while private equity investment has played a significant role in shaping the landscape of healthcare, its impacts on hospitals and health systems raise serious concerns for health equity need for the adaptation of new and informed approaches to private equity involvement in healthcare to mitigate these negative impacts and protect equitable access to quality health services. Regulation of private equity firms, specifically those investing in healthcare, must involve a combination of federal and state regulatory bodies. As noted, the solution that would best solve this problem requires two actions by Congress. First, Congress enhanced the regulation and reporting of private equity investments, and second, increased enforcement by the

[52] *Supreme Court's False Claims Act Opinion Raises Stakes for Physician Billing,* MEDSCAPE (June 13, 2023), https://www.medscape.com/viewarticle/993129?form=fpf.

DOJ coupled with adaptation of the FCA by Congress. Both of these actions by Congress, coupled together with the work of federal and state agencies, will lead to increased targeting and regulation of private equity firms, therefore reducing fraud and eliminating the barriers that private equity creates to health equity.

Bandaging an Open Wound: How Preventative Governmental Action Against Fraud and Abuse Protects Patients

Zahrah Khan

I. INTRODUCTION TO FEDERAL REGULATORY ACTION AGAINST FRAUD AND ABUSE

In 2022, the Department of Justice ("DOJ") brought forth the highest number of "new DOJ-initiated False Claims Act ("FCA") matters since 1994".[1] The government and *qui tam* relators also obtained the second-highest number of settlements and judgments in any one year since the enactment of the FCA.[2] This data raises questions as to the efficacy of the Office of Inspector General's ("OIG") Compliance Program Guidelines ("CPGs") and its penalties that are intended to deter entities from committing fraud when healthcare organizations are found to have violated federal fraud and abuse law.[3] It also points to the success (or lack thereof) of corporate compliance programs that are established for the purpose of identifying this kind of fraud within their organization.

Litigating fraud and abuse matters is both costly and time-consuming, with the federal government often taking three or more years to litigate a fraud matter after conducting an investigation.[4] While the government has

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[1] Perkins Coie, *The Number of False Claims Act Cases Reaches Record High, but DOJ's Recoveries Drop to $2.2. Billion in Fiscal Year 2022* (2023), https://www.perkinscoie.com/en/news-insights/false-claims-act-cases-reach-record-high-but-dojs-recoveries-drop-to-dollar22-billion-in-fiscal-year-2022.html.

[2] *Id.*

[3] *General Compliance Guidance*, U.S. DEP'T OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN. (Nov. 2023), https://oig.hhs.gov/compliance/general-compliance-program-guidance/.

[4] Ralph C. Mayrell, *Digging Into FCA Stats: Part I – In-House Litigation Budget Insights,* KRAMER LEVIN (July 13, 2021), https://www.kramerlevin.com/en/perspectives-search/digging-into-fca-stats-part-i-in-house-litigation-budget-insights.html (finding that the Department of Justice is 50% more likely to intervene in a *qui tam* complaint under the False Claims Act three or more years after a case has been sealed).

increased the number of settlements for fraud actions, consumers still face issues of overbilling and unnecessary treatments.[5] Furthermore, fraud and abuse threaten patient health and safety, particularly for minority populations.[6] A 2019 John Hopkins study found that non-White and dually enrolled Medicare beneficiaries are more likely to be treated by fraud and abuse perpetrators ("FAPs").[7] This can lead to dangerous outcomes for those entities or individuals that fraudulently conduct unnecessary services and treatments to receive reimbursements.[8] These issues only further compound the historical mistreatment of minority patients in the healthcare industry.

This article begins with evaluating the current framework of the FCA, CPGs, and how the OIG addresses offending entities. Next, a discussion of how certain patient populations are more impacted by fraud and abuse than others, through both financial and nonfinancial harm. Lastly, a proposal that the Federal Regulatory Oversight system should reinstate its compliance consultant and update its set of compliance metrics to current healthcare industry standards. Doing so can guide both healthcare entities when identifying fraud and the federal government when determining how to penalize offending entities.

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[5] Perkins Coie*, supra* note 1; *see also* Markian Hawryluk, *Why It's So Tough to Reduce Unnecessary Medical Care,* CBS NEWS (Nov. 9, 2023), https://www.cbsnews.com/news/unnecessary-medical-care-treatments-costs/ (finding that of the $3 trillion spent on health care, 10% to 30% of costs are attributed to treatments that raise costs and lead to health complications.)

[6] Alanna M. Lavelle & Timothy L. Helms, *How Healthcare Fraud and Abuse Perpetuate Health Disparities in the U.S.*, MITRE 1 (Jan. 2022), https://www.mitre.org/sites/default/files/2022-02/pr-21-3650-how-healthcare-fraud-abuse-perpetuate-health-disparities.pdf.

[7] Nichols, et. al, *Association Between Treatment by Fraud and Abuse Perpetrators and Health Outcomes Among Medicare Beneficiaries,* 180 JAMA INTERN. MED. (2019) (discussing how avoidance of FAPs may be associated with improvements in beneficiary health and longevity).

[8] *Id.*

II. OVERVIEW: CURRENT FRAMEWORKS OF THE FEDERAL REGULATORY SYSTEM

Although considered to be the federal government's most potent tool in combatting fraud, the healthcare industry continues to account for the lion's share of monies recovered by the federal government under the False Claims Act.[9] The healthcare industry tends to be more susceptible to fraud and abuse in comparison to other industries due to a number of factors. First, certain types of healthcare fraud and abuse, including billing, can be difficult for the government to identify and are therefore attractive to FAPs.[10] Additionally, the spike in cybersecurity issues have plagued the healthcare industry and spiked the incidents of medical identify theft across the country.[11] Most pointedly, a lack of oversight by hospitals and other large healthcare entities breed unnecessary services and treatments and kickback schemes.[12] Although fraud may be unintentional at times, patients' difficulty with medical literacy is also intentionally taken advantage of by FAPs when they falsely bill patients for unnecessary services and treatments.[13] Without clear guidelines to measure and detect fraud, it naturally follows that healthcare

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[9] *False Claims Act Settlements and Judgments Exceed $2 Billion in Fiscal Year 2022,* U.S. DEP'T. OF JUST., OFF. OF PUB. AFF. (Feb. 7, 2022), https://www.justice.gov/opa/pr/false-claims-act-settlements-and-judgments-exceed-2-billion-fiscal-year-2022 (discussing how of the $2.2 billion reported by the DOJ for FCA settlements and judgments, $1.7 billion of that was attributed to healthcare fraud and abuse).

[10] Nicole Forbes Stowell et al., *Investigating Healthcare Fraud: Its Scope, Applicable Laws, and Regulations,* 11 WILLIAM & MARY BUS. L. REV. 479, 484 (2020).

[11] *Id.* at 487 (noting that medical identity theft is one of the fastest-growing areas of healthcare fraud).

[12] *Id.* at 490 (explaining that an overly complex system creates pressure for medical providers to meet financial goals and create additional revenues generated through billing for unnecessary procedures).

[13] Jane Antonio, *Seeing the connection between health insurance literacy and fraud*, FIERCE HEALTHCARE (Oct. 1, 2014), https://www.fiercehealthcare.com/antifraud/seeing-connection-between-health-insurance-literacy-and-fraud.

facilities are unable to control fraud within their organizations and establish programming aimed at fraud prevention.[14]

A. Pre-Fraud Compliance Guidelines

For years, the DOJ experienced challenges in determining how to penalize corporate misconduct.[15] With notice that the U.S. Sentencing Commission (USSC) had amended its guidelines to reduce fines for corporate firms that showcased effective compliance programs, firms jumped to finetune their compliance training programs.[16] However, these efforts did not necessarily decrease their chances of prosecution. During her tenure as the Compliance Counsel Expert, until her resignation in 2017, Hui Chen discovered that while many corporate firms had scores of procedures regarding compliance, they were taking little to no action to test that these policies were effective in properly training their employees to prevent fraud and misconduct.[17] In an effort to rectify this discrepancy, Chen drafted a set of compliance metrics that the government could utilize when prosecuting fraud matters.[18]

Corporations then began to use these metrics themselves to structure their internal compliance groups, but these kinds of actions ultimately presented a challenge for corporations and prosecutors. Corporations treated these metrics as a "checklist" rather than simply guidelines to refer to when individualizing their fraud and abuse prevention methods and as a result, the metrics failed to substantiate the information that was being collected by

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[14] *Id.*
[15] Hui Chen & Eugene Soltes, *Why Compliance Programs Fail—and How to Fix Them*, HARV. BUS. REV. (Mar.-Apr. 2018), https://hbr.org/2018/03/why-compliance-programs-fail.
[16] *Id.*
[17] *Id.*
[18] *Id.*

these organizations.[19] Metrics that do not provide clear guidance present a lack of meaningful measures for the effectiveness of a compliance program. For example, rather than measuring the level of understanding employees have about company policies and procedures through surveys or other forms of data, firms evaluated this metric by how many employees had "agreed" to compliance policies through signature.[20] Unclear metrics also fail to provide direction to companies to understand that simply checking items off the "list" of metrics laid out by the Compliance Consultant Expert is not sufficient to maintain an effective compliance program.[21]

In November of 2023, the OIG released an updated General Compliance Program Guidance ("GCPG") specifically for healthcare entities.[22] The GCPG is intended to be a "reference guide for the health care compliance community and other health care stakeholders."[23] However, the GCPG is still ambiguous as to the guidelines it lays out for organizations to follow when implementing their own compliance programs, paralleling the same issues that arose due to the compliance metrics set by Chen. For example, the GCPG encourages healthcare entities to impose consequences on employees for "noncompliant actions".[24] It does not specify what kinds of consequences an employer should take and fails to substantiate how

[19] *Id.* (noting that one of the questions of the evaluation document asked if a company has ever terminated or disciplined an employee for the type of misconduct at issue, but firms would simply list the employees that have been fired or denied promotions as a result of "compliance related transgressions" and did not indicate how many employees had *not* been disciplined).
[20] *Id.*
[21] *Id.*
[22] OIG-HHS, *supra* note 3.
[23] *Id.*
[24] *Id.*

employers should consider the severity of a noncompliant offense in determining the proportionality of the consequence.

B. Post-Fraud Action by the Federal Government

Good faith efforts to control fraud, even when fraud does occur within an organization, do not go unnoticed by the federal government. Most FCA cases are resolved through settlement agreements and depending upon the context of the cases, the OIG will pursue different methods of penalization while settling a fraud case, rather than jumping to the closure of a facility.[25] Instead, as part of these settlements, the OIG negotiates corporate integrity agreements ("CIAs") that set out a number of requirements organizations must follow when they have been found liable for defrauding the government, including hiring a compliance officer and developing comprehensive programs and policies.[26] However, it is important to note that these compliance requirements are only imposed upon an organization *after* fraud and abuse are detected. Rather, the GPCG, as discussed above, is currently the federal government's only tool that provides direction to healthcare entities when forming compliance guidelines.[27]

Additionally, ambiguity surrounding what an offending organization will be subjected to presents a challenge to healthcare facilities; without guidance from the government, an organization may find difficulty in following

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[25] *Fraud Risk and Heightened Scrutiny,* U.S. DEP'T. OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN. (Jan. 26, 2024), https://oig.hhs.gov/fraud/fraud-risk-spectrum/; Harsha, Dan, *How Do Hospital Closures in the United States Impact Patient Care?*, HARV. KENNEDY SCH. (Apr. 12, 2022), https://www.hks.harvard.edu/faculty-research/policy-topics/health/how-do-hospital-closures-united-states-impact-patient-care.

[26] Jim Moye, *Are We Bulletproof ?: A Defensive Business Strategy to Protect Health Care Companies from False Claims Act Litigation and Corporate Integrity Agreements,* 41 UNIV. BALT. L.F. 24, 30 (2010).

[27] *Corporate Integrity Agreements,* U.S. DEPT. OF HEALTH & HUM. SERVS., OFF. OF INSPECTOR GEN. https://oig.hhs.gov/compliance/corporate-integrity-agreements/index.asp (last visited March 30, 2024).

compliance standards. When an organization refuses to comply with the integrity agreement, the OIG will subject that organization to heightened scrutiny, a restriction just below total exclusion from federal health care programs.[28] However, the OIG has not been clear as to what the heightened scrutiny would consist of. Given that the implementation of listing offending entities on the OIG's public website was established in 2018, little data exists as to whether it has acted as a strong enough deterrent to prevent organizations from violating federal fraud and abuse laws again.[29] In fact, there is little evidence about the overall effectiveness of federal penalties against fraud and abuse.[30] The seven elements the federal government has established to ensure an effective compliance program do not address these issues, and do not provide specific directions to entities.[31]

III. Impact of Fraud and Abuse on Patient Health and Safety

Patients that belong to minority groups have historically been vulnerable to mistreatment in the healthcare industry.[32] Racial and economic disparities exacerbate poor health outcomes and leave minority patients vulnerable to fraud and abuse that can cause both physical and financial harm.[33]

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[28] *Heightened Scrutiny,* U.S. Dep't of Health & Hum. Servs., Off. of Inspector Gen. https://oig.hhs.gov/compliance/corporate-integrity-agreements/heightened-scrutiny.asp; HHS-OIG, *supra* note 25.
[29] OIG-HHS, *supra* note 28.
[30] Rashidian et al., *No Evidence of the Effect of the Interventions to Combat Health Care Fraud and Abuse: A Systematic Review of Literature,* Nat'l Libr. Med. (Aug. 2012), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3427314/.
[31] Steve Alder, *The Seven Elements of a Compliance Program*, The HIPAA J., https://www.hipaajournal.com/seven-elements-of-a-compliance-program/.
[32] Lavelle, *supra* note 6 (explaining that racial and ethnic disparities are associated with significantly worse health outcomes).
[33] *Id.; see also, Serving Communities of Color: A Staff Report on the Federal Trade Commission's Efforts to Address Fraud and Consumer Issues Affecting Communities of Color* Fed. Trade Comm'n 1-3 (2021) (describing how in 2021, the Federal Trade

Healthcare fraud translates into higher premiums and out-of-pocket expenses for consumers and unfortunately, minority patients are often those most likely to be exploited by healthcare entities or medical professionals who are looking to receive more reimbursements from the federal government through overcharging or false coding.[34] Even more concerning are patients who are subjected to unnecessary services and low-quality care by medical providers seeking to defraud the government. As recent as 2023, a doctor in Georgia was ordered to pay almost $2 million to the federal government after it was discovered that she had performed unnecessary cataract treatments on a number of patients and caused injury to some.[35] Indeed, the government recognizes the need for vulnerable populations to be protected, as noted by the DOJ's nationwide enforcement action against twenty-four medical professionals who were among seventy-eight persons charged for healthcare fraud that specifically targeted the elderly and disabled.[36] This enforcement action emphasizes an ongoing issue that resources are expended in both the fraud that occurs and litigation that ensues afterwards.[37]

Commission ("FTC") published a report that found that Black and Latino consumers are more likely to experience fraud and that Latino consumers are more likely to underreport such fraud).

[34] *Id.*

[35] *Conyers Doctor Pays $1,850,000 to Resolve Allegations That She Performed and Billed for Medically Unnecessary Cataract Surgeries and Diagnostic Tests,* U.S. ATT'Y'S OFF., N. DIST. OF GA. (Jan. 9, 2023), https://www.justice.gov/usao-ndga/pr/conyers-doctor-pays-1850000-resolve-allegations-she-performed-and-billed-medically.

[36] Harley Moyer, *Communities of Color, Fraud, and Consumer Protection Agencies*, NAT'L ASS'N OF ATT'YS GEN. (Feb. 1, 2022), https://www.naag.org/attorney-general-journal/communities-of-color-fraud-and-consumer-protection-agencies/.; Nat'l Health Care Anti-Fraud Ass'n, *The Challenge of Healthcare Fraud,* https://www.nhcaa.org/tools-insights/about-health-care-fraud/the-challenge-of-health-care-fraud/ (last visited March 9, 2024).; Off. of Pub. Affairs, *National Enforcement Action Results in 78 Individuals Charged for $2.5B in Health Care Fraud,* DEP'T JUST., (June 28, 2023), https://www.justice.gov/opa/pr/national-enforcement-action-results-78-individuals-charged-25b-health-care-fraud.

[37] Chen et al., *Recommendations to Protect Patient and Health Care Practices from Medicare and Medicaid Fraud,* 60 J. OF AM. PHARM. ASS'N 61 (2020).

The need for the government to prevent such fraud is not only to alleviate the physical and financial impacts of fraud on patients, but also to prevent further erosion of patient trust. Trust is a core tenet of successful health outcomes, because "it encourages patient[s] to volunteer intimate facts about their lives…and experience the doctor-patient relationship itself as empowering and comforting."[38] However, due to historical mistreatment and structural racism, studies show that minority patients and patients from low-income communities are less likely to trust their medical providers.[39] Unfortunately, current enforcement frameworks by the federal government are not designed to improve patient trust, particularly within these communities.[40] This discrepancy, coupled with the difficulty in detecting the intent to commit fraud needed to penalize FAPs, threatens the necessity of patient trust and ultimately puts patients in danger of fraud and abuse.[41] As such, preventative action is a necessary tool the federal government should utilize to maintain quality care and ensure patients have equal access to health care.

IV. Looking Forward: Revised Compliance Metrics to Provide Additional Guidance to Healthcare Entities

It is clear that more action should be taken by the federal government to guide healthcare organizations and prevent fraud and abuse that will

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[38] M. Gregg Bloche, *Trust and Betrayal in the Medical Marketplace*, 55 Stan. L. Rev. 919, 924 (2002).
[39] *Id.*
[40] Katrice Bridges Copeland, *Health Care Fraud and the Erosion of Trust*, 118 Nw. L. Rev. 89, 103 (2023) (explaining how because the Anti-Kickback Statute and Physician Self-Referral Law are enforced by the civil FCA, the government's autonomy in making enforcement decisions is largely driven by *qui tam* relators and thus, the focus is less on promoting trustworthy conditions and more on recovery of federal funds).
[41] Lavelle et. Al., *supra* note 6.

ultimately impact the individual patient. Accordingly, the DOJ should reinstate its Compliance Consultant Expert and improve their compliance metrics to assist healthcare entities that are looking to refine their compliance groups. The reinstated Compliance Counsel Expert would serve to oversee that the compliance metrics aligns with current healthcare industry standards. This proposal does not suggest that the government start anew, but rather build upon pre-existing metrics to encourage entities to substantiate data that they are collecting. As noted by the previous compliance metrics, the updated compliance metrics should ask whether 1) a corporation designates sufficient resources for their compliance programs and 2) whether those resources are being used not only in the hiring of a compliance officer, but also in providing tools for officers to conduct their duties efficiently, including training for employees and auditing of the organization, if necessary.[42] Rather than instructing corporations to quantify how many employees have completed compliance training, the corporation should implement follow-up protocols that can determine whether the employees 1) understood the training they completed and 2) are able to detect instances where fraud is occurring.[43]

The updated compliance metrics should also suggest that corporations conduct internal auditing. Doing so would achieve the purpose of ensuring corporations are allocating sufficient resources to their compliance programs. Auditing would identify additional Board oversight and resources that may be required, as well as evaluate whether current risk management functions are adequate to prevent fraud within the organization.[44] While the OIG's

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[42] *The FCPA's Jurisdictional Hooks – How Far Do They Reach –Who Can They Ensnare*: *11th Annual National Security Institute*, AM. BAR ASS'N (2017).
[43] Chen & Soltes, *supra* note 15.
[44] *Practical Guidance for Health Care Governing Boards on Compliance OVERSIGHT,* OFF. OF INSPECTOR GEN., U.S. DEP'T. OF HEALTH & HUM. SERVS. 14-17 (Matos et. al. eds., 2015).

heightened scrutiny standard may already require auditing when an organization has refused to comply with a CIA, an organization that undergoes its own internal auditing can prevent such action from being taken by the federal government if they can show that they did their own due diligence.[45]

Internal auditing should not only identify whether the organization is following federal guidelines but should also collect information that can inform a healthcare organization's board about improvements that should be made to their management systems and whether these objectives will benefit the consumer. As such, the auditors should be encouraged to visit the organization in person to review its management and survey its patients and employees outside of the entity's management chain.[46] These actions would emphasize a more "democratic process" of auditing that will go beyond simply interviewing relevant stakeholders of an organization.[47]

The compliance metrics should also encourage entities to work with third-party auditing companies rather than finding someone within the organization. This third-party auditing should be led by predesignated organizations selected by the federal or state governments. If members of the organization fail to comply with the auditing, the compliance metrics shall indicate how its internal compliance officer(s) can discipline such employees based upon a sliding scale of severity set by the Board. Therefore, if an organization is found to have violated a federal statute, the government

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[45] U.S. GOV'T ACCOUNTABILITY OFF., DEP'T. OF HEALTH & HUM. SERVS., OFFICE OF INSPECTOR GENERAL'S USE OF AGREEMENT TO PROTECT THE INTEGRITY OF FEDERAL HEALTH CARE PROGRAMS 6-7 (GAO-18-322 2018).
[46] Christine Parker, *Regulator-Required Corporate Compliance Program Audits*, 25 LAW & POL'Y 223, 236 (2003).
[47] *Id.*

can use the discipline, or lack thereof, of offending employees to evaluate whether the corporation did enough to prevent such fraud and abuse. This evidence can then be used to determine which penalties they should be subjected to: mitigating factors such as implementing best practices, no prior offenses, resources allocated to corporate compliance can assist the government in determining whether an organization is lower risk and therefore should only be subjected to "lighter" penalties of self-disclosure or no further action.[48] This proposal aims to follow the government's approach in penalizing entities and prevent further exclusions. The first quarter of 2024 indicates that the government has primarily utilized the "no further action" approach in penalizing entities, and this proposal aims to continue that trend and prevent further exclusions.[49]

Once the audits are complete, beyond simply laying out what kinds of information should be reported to a board, the compliance metrics should also provide guidance as to who should be receiving such compliance-related information, how often it is reported to the board, and which formats would be most efficient for the board to receive the information. Too much information may result in important data being overlooked and therefore, the government should encourage compliance groups to consider what tools would be most effective in communicating concerns to the board, such as through dashboards that include key operational indicators that provide a

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[48] OIG-HHS, *supra* note 25.

[49] *Id.*; *see also Criteria for Implementing Section 1128(b)(7) Exclusion Authority,* OFF. OF INSPECTOR GEN., U.S. DEPT. OF HEALTH & HUM. SERVS. (April 18, 2016), https://oig.hhs.gov/exclusions/files/1128b7exclusion-criteria.pdf (explaining how the OIG evaluates fraud on a continuum, typically designating an organization as low risk where this is an absence of egregious conduct, such as intentional fraud, or where the person the OIG is resolving a fraud case is a successor owner and the new owner has an existing compliance program and does not have a prior history of wrongdoing or fraud settlements with the federal government. Where a person self-discloses fraud in good faith, the OIG may release exclusion without requiring integrity obligations).

"general snapshot" of what areas need improvement.[50] These compliance metrics should align with the OIG's heightened scrutiny standard so that penalties or restrictions an offending healthcare organization would be subjected to after a refusal to comply with a CIA, would already be included in the compliance metrics.

Without clear compliance standards, healthcare organizations may have difficulty preventing fraud and abuse, particularly where there are no officers designated to ensure that the organization remains in compliance. Updated compliance metrics will be instructive for the federal government both in assisting corporations and in considering the level of heightened scrutiny an organization shall be subjected to if they violate a CIA. The OIG can utilize the reinstated compliance metrics to subject a violating organization to third-party auditing and to ensure that they will not re-offend. Additionally, the reinstated compliance metrics will set the stage for how closely an offending organization will be evaluated by the government.

The compliance metrics should also recommend that healthcare organizations have at least one neutral board member from the predesignated auditing companies to oversee fraud and abuse red flags raised in the course of their tenure and report findings to the federal government, if necessary. While a neutral board member may not be required for every healthcare organization, organizations that have struggled to maintain effective compliance programs would benefit from this metric. Doing so would also allow the government to pinpoint whether this particular metric is effective in preventing fraud, as they have an individual, they can turn to during an

[50] OIG-HHS, *supra* note 49.

investigation to determine what went wrong that allowed fraud and abuse to occur to begin with.

Although the existence of a neutral board member and auditing would not necessarily eliminate fraud and abuse, these metrics can still provide guidance to the government and healthcare organization to evaluate whether: 1) this approach is worthwhile to continue enforcing and 2) more precisely identify what occurred within the hospital that allowed this kind of fraud to occur. Given that the fraud and abuse issues raised by the federal government are widespread in the healthcare industry, the ability for the government to identify which issues are most prevalent throughout the industry is valuable in continuing to refine the proposed compliance metrics that are targeted to resolving those particularized issues.

A. Setbacks to Increased Governmental Oversight

While increased governmental oversight can assist in preventing fraud, too much of a strong hold over healthcare industries may raise concerns about stifling innovation and autonomy. Members that sit on the board of a healthcare organization exercise control over strategic decisions of the entity. They would likely push back on the government's attempt to overly enforce compliance metrics, including the suggestion of including a board member from a neutral third-party organization.[51] However, these concerns would not necessarily arise with healthcare companies that comply federal statutes. Further, compliance metrics are simply suggested guidelines that do not mandate corporations to follow any specific metric so long as they are in general compliance with already issued federal statutes.[52] Therefore, the

[51] Don L. Arnwine, *Effective Governance: the Roles and Responsibilities of Board Members*, 15 BAYLOR U. MED. CTR. 19, 20 (2022).
[52] OIG-HHS, *supra* note 3 (noting that the GCPG is voluntary guidance that discusses general compliance risks and programs).

federal government could not penalize a corporation for not following what the government is suggesting. Additionally, fraudulent organizations tend to allocate their resources to projects and incentives that are less risky.[53] If an organization has been able to "successfully" defraud its consumers, they are likely to continue to invest in those endeavors rather in ones that they are unfamiliar with or that they do not believe would provide them with the biggest payoffs.[54]

V. CONCLUSION

The federal government's current approach to fraud and abuse, while effective in prosecuting claims, does not address the need to prevent fraud to begin with. Patients are often the silent victims of fraud. While patients do not receive the generous compensation afforded to whistleblowers under the FCA, they fall victim to manipulation by medical providers during the course of fraudulent action, especially if they belong to a minority ethnic or economic group. By refining current compliance standards that provide more guidance to healthcare facilities and set out clear expectations that entities should adhere to in order to have effective compliance groups, the likelihood of fraud will decrease. Ultimately, patients will be protected, specifically those who are already vulnerable to medical mistreatment, from the inequities that result due to fraud and abuse.

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[53] Wang et. al, *Fraud and Innovation*, 66 ADMIN. SCI. Q. 268, 270 (2021).
[54] *Id.*

The Limitation of the Application of FCA to Inadequate Care Cases

Siya Mahesh

I. INTRODUCTION

The FCA allows the United States government to combat fraud by allowing private individuals to bring forth civil actions. The False Claims Act (FCA) should not be used in allegations of inadequate care by hospitals and nursing homes. This is because there are federal statutes and state actions in place that specifically target claims of inadequate care.[1] In a healthcare setting, the FCA holds an individual or entity liable when a false or fraudulent medical claim is submitted for reimbursement to a federal healthcare program.[2] This includes FCA claims based on regulatory violations or inadequate care.[3] Currently, there is no clear standard in the language of the statute to determine the level of inadequate care that results in FCA liability by entities.[4] This paper will discuss the application of the FCA to inadequate care cases and analyze how courts determine FCA liability due to inadequate care. Further, this paper will argue that state specific statutes, medical malpractice actions and the use of the Social Security Act is better suited for inadequate care violations.

II. THE CURRENT ROLE OF THE FCA IN INADEQUATE CARE CASES

Presently, the False Claims Act focuses on holding individuals or entities liable when they, 1) knowingly submit a claim to the federal government for payment, 2) the claim was false or fraudulent, and 3) the claim was submitted

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[1] Robert Salcido, *The Use of the False Claims Act in Quality of Care Cases*, 3 SEDONA CONF. J. 143, 145 (2002).
[2] Goldberg v. Rush Univ. Med. Ctr., 929 F. Supp. 2d 807, 815 (N.D. Ill. 2013).
[3] *See generally* Salcido, *supra* note 1 at 144 (discussing case law on the FCA and its application to the Standard of Care).
[4] *Id.*

with the knowledge that it was false.[5] In 2023, the Supreme Court held that this standard is objective and proving specific intent of fraud is not required.[6] Any deliberate ignorance of the truth or reckless disregard from a reasonable person standard is sufficient for FCA liability.[7] A finding of deliberate ignorance includes consciously disregarding conduct that results in fraud.[8] The reasonable person standard is an objective standard and assesses the amount of care and caution that an ordinary person would use in a given situation.[9] Under the FCA, private individuals, called *qui tam* relators, are allowed to bring *qui tam* actions against any individual or entity.[10]

In a healthcare setting, the FCA holds an individual or entity liable when a false or fraudulent medical claim is submitted to Medicare or Medicaid for reimbursement.[11] FCA claims can be based on regulatory violations or inadequate care.[12] Regulatory violation claims specifically arise when non-compliance with federal regulations for services is tied to billing for those services.[13] Inadequate care violation claims occur when there is rendering of poor-quality care connected to payment that is inconsistent with the quality of care.[14] For example, in *Swan*, the court held that the defendant, Covenant Care, violated the FCA due to inadequate care because the services provided

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[5] False Claims Act, 31 U.S.C.A. § 3729.
[6] *See* United States *ex rel.* Schutte v. SuperValu Inc., 143 U.S. 1391, 1404 (2023).
[7] *Id.*
[8] *Id.*
[9] *Id.*
[10] United States *ex rel.* Swan v. Covenant Care, Inc., 279 F. Supp. 2d 1212, 1215 (E.D. Cal. 2002).
[11] Goldberg v. Rush Univ. Med. Ctr., 929 F. Supp. 2d 807, 815 (N.D. Ill. 2013).
[12] United States *ex rel.* Swan v. Covenant Care, Inc., 279 F. Supp. 2d 1212, 1215 (E.D. Cal. 2002).
[13] *Swan*, 279 F. Supp 2d at 1215.
[14] *Id*.

to their residents and billed to Medicare were equivalent to no services at all.[15]

Currently, the use of the FCA to impose liability due to inadequate care is most prevalent in cases against nursing homes and intermediate care facilities regarding their Medicare and Medicaid patients.[16] To successfully claim FCA liability under the inadequate care theory, the Department of Justice allows the government to allege wrongdoing under a two-pronged approach.[17] First, the government must show that the provider failed to provide the necessary quality of care to its Medicare or Medicaid patients.[18] Second, when the provider submits the request to Medicare or Medicaid for reimbursement, the provider must certify that it has complied with the standards of care.[19] The standard of care varies between different states but the majority of states specify that in a health care setting, medical professionals must use the same degree of knowledge, skill, and ability as an "ordinarily careful" professional would exercise under similar circumstances.[20] In current cases regarding FCA liability and inadequate care allegations, there is a circuit split on theories of liability.[21] Thus, there are currently three theories of liability under the FCA for quality-of-care violations.[22]

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[15] *Swan*, 279 F. Supp 2d at 1215.
[16] *See* Constantinos I. Miskis & William F. Sutton, Jr., *Enforcing Quality Standards in Long-Term Care: The False Claims Act and Other Remedies*, 73, FLA. BAR J., 108, 111 (1999).
[17] John R. Munich & Elizabeth W. Lane, *When Neglect Becomes Fraud: Quality of Care and False Claims*, 43 ST. LOUIS UNIV. L. J. 27, 36 (1999).
[18] *Id.*
[19] *Id.*
[20] *Id.*
[21] *See generally*, *supra* note 17.
[22] Veronica Finkelstein, *Searching for Bright-Lines in the Darkness: Enforcing Quality of Care Standards Using the False Claims* Act *Healthcare Fraud*, 64 U.S. DEP'T. OF JUST. EXEC. OFF. FOR U.S. ATT'YS 73, 74-76 (2016).

Under the first theory, the worthless services theory, plaintiffs can allege that the services are so deficient that they are virtually worthless.[23] Courts have recognized this theory in a variety of cases, such as when a long-term care facility was so severely understaffed that the patients were not receiving basic care such as feeding, bathing, and repositioning.[24] Alternatively, plaintiffs can claim FCA violation under the false certification theory.[25] Express false certifications attach liability under the FCA when a party expressly certifies compliance with a statute, regulation or government program in connection with a claim.[26] Under the third theory, implied false certification, liability attaches without expressly certifying compliance with a specific statute or regulation.[27] For example, under the express certification theory, a plaintiff can successfully allege violation of Medicare's listed standard of care for a Medicare patient if the provider has expressly certified that they have complied with Medicare's standard of care in their reimbursement form.[28] In contrast, under the implied certification theory, a provider can be found liable without expressly certifying compliance with Medicare's standard of care.[29] Under the implied certification theory, there is an inherent assumption that Medicare's standard of care is followed when

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[23] *Id.* at 74.
[24] United States. *ex rel.* Swan v. Covenant Care, Inc., 279 F. Supp. 2d 1212, 1215 (E.D. Cal. 2002).
[25] Farrell Fritz, *Implied Certification Theory Allowed Under False Claims Act*, JD SUPRA (Feb. 15, 2017), https://www.jdsupra.com/legalnews/implied-certification-theory-allowed-16110/.
[26] Christian Roux & John Hanover, *Implied False Certification Liability Under the False Claims Act: How the Materiality Standard Offers Protection after Escobar*, ESCOBAR https://www.alston.com/zh-hant/-/media/files/insights/publications/2018/01/implied-false-certification-liability-under-the-fa.pdf.
[27] *Id.*
[28] *Id.*
[29] *Id.*

the provider bills for patient's services.[30] These theories provide courts a way to determine whether defendants are liable and different courts use different approaches to find liability.[31] However, none of these theories are clear enough to establish liability for inadequate care violation due to how subjective the analysis is.

III. THE LACK OF A CLEAR STANDARD FOR FCA INADEQUATE CARE APPLICATION

Under the worthless services theory, it is extremely difficult for plaintiffs to succeed in asserting FCA liability because there has to be a *complete* lack of service to a patient for the provider to be liable.[32] Under the implied certification and express certification theories, there is a clearer standard in assessing liability for billing purposes.[33] However, there remains the question of whether a provider is following federal statutes and regulations that guide the standard of care is subjective.[34] A subjective standard is not useful because there is no brightline rule to determine how deficient services have to be to cause inadequate care liability. A subjective standard allows differences in courts' definitions of adequate care and, in turn, makes it hard for hospitals to assess whether their standard of care is deficient.

Currently, the government uses a variety of federal laws and regulations, such as the Nursing Reform Act and the Social Security Act.[35] The Nursing Reform Act states that providers "must care for the residents in such a manner

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[30] *Id.*
[31] *Id.*
[32] United States *ex rel.* Swan v. Covenant Care, Inc., 279 F. Supp. 2d 1212, 1215 (E.D. Cal. 2002).
[33] *Id.*
[34] *Id.*
[35] *Id.*

as will promote maintenance or enhancement of the quality of life of each resident."[36] The Social Security Act requires facilities to meet an "acceptable" nutritional status for residents and psychological wellbeing to be eligible for Medicare/Medicaid status.[37] The language of these Acts do not clearly guide the court into deciding what exactly is "maintenance" or "enhancement" of a quality of life of the patient. The vague language can cause a variety of subjective applications and its legal meaning is at the court's discretion. Further, while these Acts are looked at by courts to determine whether fraud has occurred, they are not created for the purpose of determining billing fraud but rather to improve the lives of residents.[38] Since Congress intended the FCA purely as an anti-fraud statute rather than a statute to "police compliance," there is a genuine question raised as to whether the FCA should be used in cases alleging inadequate care at all.[39]

IV. LIMITING THE USE OF THE FCA IN INADEQUATE CARE CASES

Currently, there is no clear standard in determining the minimum quality of care a provider requires in either the FCA or any other statute or regulation. Therefore, the FCA should no longer be utilized as a vehicle to allege inadequate care fraud. Rather, it should only be used for assessing regulatory compliance issues. An alternative way for plaintiffs to receive relief for issues of inadequate care is to claim a cause of action based on violations of state specific laws or medical malpractice actions. The first option is to allege violation of the Social Security Act or the Nursing Reform Act itself.

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[36] 42 U.S.C. §1395(i)-3 (1987).
[37] 42 U.S.C. §301 to 1397f (1994).
[38] Julie Rivers, *Nursing Home Reform Act*, NURSING HOME ABUSE JUST. https://www.nursinghomeabuse.org/resources/nursing-home-reform-act/.
[39] *Goldberg,* 929 F. Supp. 2d at 823-24.

Instead of going through the FCA, plaintiffs can directly allege a violation of standard of care that is outlined in these acts, enacted for the purpose of the cause of action – assurance of quality care of the residents and making sure they have a high physical and mental wellbeing.

Under the Social Security Act, both civil and criminal penalties can be imposed on providers.[40] More so, liability under the Social Security Act is broad and encompasses imposing liability for violations when filing an improper claim or reimbursement.[41] Further, the Social Security Act allows the government to exclude providers who violate the Act in situations where the provider has been accused of abuse or neglect.[42] The use of this Act in comparison to the FCA allows more leeway for plaintiffs to claim a violation as well. Courts that use the worthless services theory of liability may not find liability when there is evidence of mere abuse or neglect under the FCA due to the standard being so high.[43] However, it is much more likely that they will be able to find liability under violation of the Social Security Act. This act specifically addresses concerns of abuse, neglect and related fraud while imposing civil and criminal remedies.[44]

Similarly, the Nursing Home Reform Act of 1987 was designed to protect quality of living for the elderly.[45] Courts have recognized that there are federally mandated mechanisms, such as this Act, for regulating nursing

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[40] Michael Mustokoff, *The Government's Use of the Civil False Claims Act to Enforce Standards of Quality of Care: Integrity or the Heavy Hand of the 800-Pound Gorilla*, 6 ANNALS OF HEALTH L. 137, 143 (1997).
[41] *Id.*
[42] *Id.*
[43] *Swan*, 279 F. Supp. 2d at 1215.
[44] *Id*.
[45] *Assuring Nursing Home Quality: The History and Impact of Federal Standards in OBRA-87*, THE COMMONWEALTH FUND (Dec. 1, 1996), https://www.commonwealthfund.org/publications/fund-reports/1996/dec/assuring-nursing-home-quality-history-and-impact-federal.

home operations and identifying the standard of care required to implement a certain quality of care under the Acts.[46] Rather than using the FCA as a mechanism, it is preferable for individuals to use other regulatory compliance acts as a basis for quality of care violations because they are in a better position to assess quality of care in comparison to the FCA. This is because other acts, such as the Nursing Home Reform Act are specifically created to assess quality of care.[47] In contrast, the FCA was created to target billing issues, not quality of care issues.[48]

Further, the FCA requires private citizens to initiate suits against providers on behalf of the government.[49] In many instances, courts have decided that the government must allege injury for a *qui tam* actor to bring forth an FCA claim.[50] This means that unrelated relators are allowed to bring inadequate care allegations. Due to the subjective nature of quality of care and the potential lack of a relationship between the relator and the suffering patient, it can be very difficult to determine whether the allegations of the relator are accurate enough to find liability. A better option is for private citizens to be able to bring a medical malpractice action against the provider. When a medical malpractice action is brought, there is also a higher chance of success for the plaintiff because they do not need to prove a complete lack of services like plaintiffs do under the worthless services theory for FCA liability. Instead, the plaintiff must only provide evidence of abuse or neglect.

When there is an issue of regulatory compliance violations, less gray area exists in the application of the false certification theory of liability. When

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[46] *Id.*
[47] THE COMMONWEALTH FUND, *supra* note 45.
[48] False Claims Act, 31 U.S.C.A. § 3729.
[49] False Claims Act, 31 U.S.C.A. § 3729.
[50] *Id.*

there is a regulatory violation under the FCA, the court can easily determine whether certain statutory requirements are met by physicians, such as the supervision of an assisting physician or the falsification of the number of hours the physician has billed for. However, when it comes to the subjective issue of assessing quality of care, courts are tasked with determining what is the minimum requirement for the quality of care to be met. Further, due to this subjective assessment, the FCA can be a very harsh punishment for providers who may not realize that they are not meeting the minimum requirement of care. Moreover, the FCA has a significant threat of monetary damages, so many nursing and long-term care facilities can suffer huge losses.[51] Since the FCA does not require the *qui tam* plaintiff to prove any loss to the government, it is very easy for unrelated *qui tam* parties to allege inadequate care violations on behalf of the government without having to prove any quantitative loss.[52] Currently, the required burden of proof is much lower for *qui tam* plaintiffs alleging violations under the FCA.[53] Further, standard of care is not carefully outlined in federal statutes and regulations.[54] Due to this, there is an imbalance in the system which makes it much easier for plaintiffs to succeed in quit tam actions while nursing homes and long term facilities have to pay significant damages.[55]

Further, the FCA should not be used for inadequate care violations because of the statutory "knowingly" requirement.[56] Under the FCA, there is no requirement for the *qui tam* plaintiff to allege a specific intent to defraud

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[51] *Id.*
[52] *Id.*
[53] *Id.*
[54] *Id.*
[55] *Id.*
[56] False Claims Act, 31 U.S.C.A. § 3729.

in order for the provider to be liable.[57] Rather, only the standard of "deliberate ignorance" needs to be met.[58] Again, this is much more assessable for providers when they must comply with regulatory violations. Medicare and Medicaid regulations outline specific requirements for certain providers with regard to how many hours they are required to work and how many patients they must treat in order to avoid FCA liability.[59] However, the "deliberate ignorance" standard is much harder to avoid when patients allege lack of adequate care. Currently, there is no clearcut standard of patient safety because of the subjectivity of procedures.[60] Hospitals and facilities across the country may have inconsistent treatment decisions for similarly situated patients and many of these inconsistent decisions are equally rooted in science.[61] This would make it unreasonable for courts to impose liability based on a federal statute where there is no bright line rule of assessment.

V. COUNTERARGUMENTS: ALTERNATIVE SOLUTIONS

The FCA is often preferred by plaintiffs as a cause of action, as opposed to medical malpractice actions, because there is a significant threat of monetary damages more likely to yield a settlement.[62] Individuals who support the usage of the FCA for inadequate care claims argue that the FCA should be a route for individuals to allege inadequate care because it is unfair

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[57] *See* United States ex re. Schutte v. SuperValu Inc., 143 U.S. 1391, 1404 (2023).
[58] 31 U.S.C.A. § 3729.
[59] *See e.g.* Physician Fee Schedule Payment or Services of Teaching Physicians, 42 C.F.R. § 415.172 (2021); Centers for Medicare and Medicaid Services, Medicare Benefit Policy Manual, CMS Pub. 100-02, Chap. 15, Sec. 30.2 (Rev. 11426, May. 20, 2022).
[60] False Claims Act, *supra* note 49.
[61] *Id.*
[62] Jeff Ifrah, *The Viability of Expanding Quality of Care Cases Under the Federal False Claims Act*, 16 HEALTH L. J., 26, 28 (2004).

for the government to be funding care that does not meet a certain level.[63] However, the threshold for determining whether there is inadequate care is a fact specific claim. Additionally, the high bar that is required to prove that there were no services provided makes it very difficult for plaintiffs to succeed. Opponents may further argue that there should be a change to the standard that courts assess quality of care (i.e., the worthless service theory should be replaced with an easier standard for plaintiffs). However, this would also likely not solve the issue because it would create another problem where it is hard to draw the line of exactly what quality of care is enough to avoid liability, resulting in providers being held liable under the FCA for mere negligence.

Another argument for supporting the FCA for inadequate care claims is that the government should not be estopped from pursuing fraud claims just because a state regulatory system exists.[64] While this may be true, Congress has never intended for the FCA to be used for inadequate care claims.[65] There is nothing in the FCA that discusses inadequate care or how it would apply to these kinds of claims.[66] Further, there is more bad than good that comes out of using these claims due to the amount of damages providers can be liable for when violating the statute. Additionally, there are much more applicable, thorough laws and regulations in place that specifically target quality of care and allow causes of actions for violations of them such as the Social Security Act and the Nursing Home Reform Act. The Nursing Home Reform Act has caused the nursing home industry to become one of the most

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[63] *Roux*, *supra* note 26.
[64] *Id.*
[65] *Id.*
[66] *Id.*

regulated industries due to the clear standards that are given for nursing home to follow.[67] Therefore, it is much more useful to allege a cause of action under these Acts.

Lastly, Congress has noted the FCA should not be a vehicle to police compliance.[68] The FCA is only to be used to detect fraud and allow relators to bring actions on behalf of the government.[69] Inadequate care violations require analyzing whether medical professionals have complied with the standard of care required for individuals or complied with medical bylaws of an organization. The FCA was not created to address compliance issues but rather only to address fraud.[70] The use of the FCA for inadequate care makes it very difficult for courts to assess the quality of care without looking at other acts and state statutes addressed above which do police compliance. Therefore, the FCA should be limited to use for fraud allegations under regulatory compliance issues.

VI. CONCLUSION

While the FCA is useful for the government to allow private citizens to allege fraud on behalf of the government, the application of the FCA should not be extended to cases of inadequate care. Since the assessment of inadequate care is a subjective issue and there is a circuit split on the theories that can be used to impose FCA liability in these cases, it is better for quality-of-care issues to be litigated under laws and regulations that address the quality of care required for individuals in long-term care facilities. While individuals argue that the government has a right to be able to target fraud

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[67] THE COMMONWEALTH FUND, *supra* note 45.
[68] *Goldberg*, 929 F. Supp. 2d at 823-24.
[69] *Id.*

through the FCA, the benefits of using the FCA for inadequate care cases are outweighed by the cost of doing so. Due to the subjective standard and, currently, the high burden of proof *qui tam* relators needs to meet, there is a high chance of providers getting away with neglect and *qui tam* relators being unsuccessful. Rather, it is more beneficial for plaintiffs to pursue private action through medical malpractice actions or alleging violations under the Social Security Act or the Nursing Home reform Act. These Acts are targeted towards compliance regarding quality of care and do not bear the high penalty that the FCA carries.

What You Don't Know May Hurt You: Addressing the Lack of Longitudinal Research on Oocyte Donors and Their Health Outcomes Post-Oocyte Donation

Antonella Maneiro

I. INTRODUCTION

In 1932, Aldous Huxley's *Brave New World* discussed the concept of fertilization occurring outside the womb as science fiction, a surreal procedure only possible in a dangerous dystopian future.[1] Less than 50 years later, in a general hospital in Manchester, science fiction became reality. The world's first "test-tube baby" Louise Brown was born through in vitro fertilization ("IVF").[2] Since then, the use of IVF and other forms of Assisted Reproductive Technology ("ART") have exploded.[3] ART is defined as "all treatments and procedures which involve manipulating eggs and sperm in vitro to help a woman become pregnant."[4] Today, approximately 2.3 percent of all babies born in the United States each year are born through ART. [5] There are currently about 500 clinics helping fertility-challenged patients through ART in the United States.[6] Globally, in 2022, the ART market was

[1] Aldous Huxley*, Brave New World*, (Doran & Co., 1932*)* (" . . . 'And this', said the Director opening the door, 'is the Fertilizing Room . . . . These are the week's supply of ova kept at blood heat; whereas the male gametes . . . they have to be kept at thirty-five instead of thirty-seven. Full blood heat sterilizes.").
[2] Katharine Dow, *Looking into the Test Tube: The Birth of IVF on British Television*, 63 MED. HIST. 189, 208 (Apr. 2019), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6434648/.
[3] Vitaly A. Kushnir, et al., *The Future of IVF: The New Normal in Human Reproduction*, 29 REPROD. SCI. 849-856, (Jan. 2022) (explaining statistical and societal trends which indicate IVF use will continue to expand in the U.S.A., Europe, Australia, New Zealand, and China).
[4] *Oversight of Assisted Reproductive Technology*, AM. SOC'Y FOR REPRODUCTIVE MED., https://www.asrm.org/advocacy-and-policy/media-and-public-affairs/oversite-of-art/ (last visited Feb. 11, 2024).
[5] *ART Success Rates,* CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/art/artdata/index.html (last visited Feb. 11, 2024).
[6] *National ART Surveillance*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/art/nass/index.html (last visited Feb. 11, 2024).

valued at $25.7 billion.[7] What was once science fiction is now commonplace, highly profitable, and even the subject of a recent controversial Alabama Supreme Court decision. [8]

Though ART is portrayed to be "among the most regulated procedures"[9] in the United States, the scope of federal efforts to collect ART-related data is limited to data pertaining to (1) the success rate of an oocyte[10] transfer (also referred to as an oocyte cycle) and (2) the physical wellbeing of an oocyte donor *before* oocyte retrieval.[11] Furthermore, there is no federal legislative effort requiring that the physical or mental health of an oocyte donor be recorded and reported over time *after* the completion of a cycle of oocyte retrieval.[12] As it currently stands, the national regulatory framework for ART is designed to accurately inform the expectations of intended parents[13]

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[7] *Assisted Reproductive Technology Market Size, Share & Trends Analysis Report By Type (IVF, Artificial Insemination), By End-use (Fertility Clinics & Other Facilities, Hospitals & Other Settings), By Region, And Segment Forecasts, 2023 – 2030*, https://www.grandviewresearch.com/industry-analysis/assisted-reproductive-technology-market (last visited Feb. 11, 2024).

[8] LePage v. Ctr. for Reprod. Med., P.C., 2024 Ala. LEXIS 60 (Ala. Feb. 16, 2024) (holding Alabama's Wrongful Death Act applied to frozen embryos which were unsecured by a fertility clinic and consequently irretrievable); See also *In Wake of Alabama Supreme Court IVF Decision, U.S. Health and Human Services Secretary Xavier Becerra Visits Birmingham*, HHS, https://www.hhs.gov/about/news/2024/02/29/wake-alabama-supreme-court-ivf-decision-us-health-and-human-services-secretary-xavier-becerra-visits-birmingham.html (last visited Apr. 25, 2024).

[9] *Oversight of Assisted Reproductive Technology, supra* note 4.

[10] The term "oocyte" is defined as "an egg before maturation; a female gametocyte; also called an ovocyte." MERRIAM-WEBSTER, https://www.merriam- webster.com/dictionary/oocyte (last visited May 9, 2024).

[11] *Oversight of Assisted Reproductive Technology*, *supra* note 4 (noting that federal legislation on ART requires that the CDC annually report data including "the patients' infertility diagnoses, clinical information pertaining to the ART procedure, and statistics on resulting pregnancies and births" and therefore is geared towards would-be parents, impliedly leaving out data relevant to prospective donors).

[12] *Oversight of Assisted Reproductive Technology*, *supra* note 4; Sandra G. Boodman, *Health effects of egg donation not well studied,* KAISER FAMILY FOUND (June 2016), https://kffhealthnews.org/news/health-effects-of-egg-donation-not-well-studied/ ("Studies of the long-term impact of egg donation on donors have never been done, even though the practice dates back more than 30 years,").

[13] The term "intended parents" is used by ART scholars and egg donation agencies alike to refer to those who are seeking and receiving egg donation(s) to plan their family. See *Egg Donor Recipient Information for Intended Parents*, EGG DONOR AM., https://www.eggdonoramerica.com/parents, (last visited Mar. 8, 2024); D.A. Greenfield, *The evolving world of ART: who are intended parents and how are their children doing?,* 6 MINERVA GINECOLOGIA 455, 460 (2012).

receiving an oocyte donation and is *less* focused on informing the expectations of the women donating their reproductive cells.[14] Consequently, this gap in longitudinal research means that young women interested in donating their oocytes have no way of truly understanding the potential long-term physiological and psychological risks that may accompany such a contribution.[15] As a result, their ability to obtain informed consent is severely limited. [16]

First, this Article provides an overview of the potential long-term health risks to oocyte donors, the current regulatory landscape for ART, and examines an existing model for collecting and publicly presenting longitudinal data of similar subjects. Then, it proposes a two-pronged solution to the issue: first, an amendment to existing agency legislation dictating fertility clinics' ART-data collection and, second, a new federal legislative initiative to create an agency-operated center or institute to present the data in a public online database. Finally, it addresses potential limitations to implementing this two-pronged solution.

II. BACKGROUND

A. Potential Long-term Health Risks Oocyte Donors Face

Despite the lack of longitudinal data, there is no shortage of concerning anecdotal evidence of women who fell ill after donating their oocytes.

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[14] *Oversight of Assisted Reproductive Technology, supra* note 4 (explaining entirety of federal ART oversight illustrates total lack of data collection concerned with oocyte donor health after oocyte donation).

[15] Jennifer Schneider, et al., *Long-term breast cancer risk following ovarian stimulation in young egg donors: a call for follow-up research and informed consent*, 34 REPROD. BIOMED ONLINE 5, 480-485, (May 2017); Jane Ridley, *Being an Egg Donor Gave me Terminal Cancer*, https://nypost.com/2015/12/03/being-an-egg-donor-gave-me-terminal-cancer/ (last visited Feb. 10, 2024).

[16] Boodman, *supra* note 12, (explaining that oocyte donor data after retrieval is simply not collected, and that oocyte donors are sent home with "little to no follow up,").

Instances of oocyte donors reporting ovarian cancer,[17] breast cancer,[18] and colon cancer[19] not long after donation are frequently found in news reports and social media posts. The case of Jessica Grace Wing ("Ms. Wing") is proffered to illustrate one of the numerous previously healthy women who received a fatal diagnosis after oocyte donation.[20] Ms. Wing was physically fit and a gifted music student at Stanford University when she chose to start donating her eggs to pay for her education.[21] She completed three oocyte retrieval cycles resulting in the successful births of five children.[22] Four years after her last oocyte donation, Ms. Wing was diagnosed with colon cancer and passed away a few years later at age thirty-one.[23] The fatal diagnosis initially came as shock since Ms. Wing carried no genetic predisposition to cancers of any kind and lived a healthy lifestyle.[24] A separate 2017 case series delved into five individual cases of oocyte donors who, similar to Ms. Wing, were diagnosed with cancer after oocyte donation despite having no genetic risk for the disease.[25] The report noted that long-term hormone replacement therapy ("HRT") is a recognized contributing factor for breast cancer.[26] With this, researchers surmised that the hormone treatment oocyte donors undergo to stimulate oocyte development — which is similar to HRT — *may* be a contributing factor in the unexpected cancer

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[17] Dariush D. Farhud, et al., *Strong Evidence of the Ovarian Carcinoma Risk in Women after IVF Treatment: a review article*, 48 IRAN J. PUB. HEALTH, 2124, 2132 (Dec. 2019).
[18] Schneider, *supra* note 15; Jane Ridley, *Being an Egg Donor Gave me Terminal Cancer*, https://nypost.com/2015/12/03/being-an-egg-donor-gave-me-terminal-cancer/ (last visited Feb. 10, 2024).
[19] K.K. Ahuja & E.G. Simons, *Cancer of the colon in an egg donor: policy repercussions for donor recruitment*, 13 HUM. REPRODUCTION 227-231 (1998).
[20] Jane E. Brody, *Do Egg Donors Face Long-Term Risks?,* N.Y.TIMES, https://www.nytimes.com/2017/07/10/well/live/are-there-long-term-risks-to-egg-donors.html (last visited Feb 13., 2024).
[21] *Id*.
[22] *Id.*
[23] *Id.*
[24] *Id.*
[25] Schneider, *supra* note 15.
[26] *Id.*

diagnoses found in the group.[27] However, the lack of effort to further research this correlation means that it cannot yet be confirmed whether and to what degree hormone therapy for oocyte donors may increase the risk of cancer.

Until substantial longitudinal research on the matter is prioritized, oocyte donors will continue to be ill-informed of the true breadth of risks they may face.[28] The notion that the ART industry is currently protecting oocyte donors with complete informed consent [29] is objectively misleading.

B. The Federal ART Regulation Framework

Presently, there are three federal agencies that regulate ART: the Centers for Disease Control and Prevention ("CDC"), the Food and Drug Administration ("FDA"), and the Centers for Medicare and Medicaid Services ("CMS"), with the scope of latter two being limited to standardizing and regulating laboratory practices. [30] In 1992, Congress passed The Fertility Clinic Success Rate and Certification Act ("FCSRCA") to require fertility clinics to report two specific ART-data points to the CDC: (1) the pregnancy success rates of ART programs, and (2) the identity of each participating embryo laboratory and whether they are certified as a laboratory under federal law.[31] Furthermore, of the five modifications made to the FCSRCA since its inception, none call for change that would mandate the tracking of data related to oocyte donor health.[32] Evidently, the federal government's

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[27] *Id.* at 484. (stating "[u]ntil epidemiological studies on the safety of egg donors are available, cases can provide the only guidance for safe recruitment").
[28] *Id.*
[29] *The Belmont Report*, U.S. DEPT. OF HEALTH & HUM. SERVS. https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html (last visited Feb. 12, 2024) (listing protection of oocyte donors as a main objective of the department).
[30] *Oversight of Assisted Reproductive Technology, supra* note 4.
[31] 42 U.S.C §263a-1 (1992); *see also The Fertility Clinic Success Rate and Certification Act,* CTRS. FOR DISEASE CONTROL & PREVENTION https://www.cdc.gov/art/nass/policy.html (last visited Feb. 12, 2024) (demonstrating the Fertility Clinic Success Rate and Certification Act of 1992 ("FCSRCA") which federally mandated fertility clinics to report certain ART-related data to the State).
[32] *Id.*

regulatory framework is singularly focused on the early ART stage of oocyte retrieval and whether a cycle results in a successful live birth. A system which grossly overlooks how ART can impact women donors in the long run is of national importance.

C. The National Organ Donor Registry as an Instructive Database Model

The Organ Procurement and Transplantation Network ("OPTN") is a federally created public-private partnership established in 1984 to alleviate organ procurement issues.[33] Chief among its many purposes is the national organ registry.[34] The organ registry collects the long-term health outcome information of organ recipients, as well as organ donors, both living and deceased.[35] Registry data is published in an online database specifically designed for this purpose.[36] The database contains information regarding every organ donation and transplant in the United States since 1987.[37] Its data archival is so expansive and accessible that a prospective kidney donor could, for instance, peruse the database and discover that out of more than 51,000 living kidney donations that took place during 1998 to 2008, only thirty-nine donors died within twelve months after donation.[38] Thus, for its breadth and accessibility, the OPTN's online database serves as an attractive logistical model for publishing long-term health outcomes of oocyte donors.

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[33] *About data,* ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, https://optn.transplant.hrsa.gov/data/about-data/ (last visited Mar. 8, 2024); *History & NOTA*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, https://optn.transplant.hrsa.gov/about/history-nota/ (explaining that Congress passed the National Organ Transplant Act (NOTA; P.L. 98-507) in 1984 to establish the OPTN and in 2000, HHS implemented a final rule on how the OPTN is to be regulated).

[34] 42 C.F.R. §121.1(a); See also Organ Procurement & Transplantation Network, 63 C.F.R §16332 (1998).

[35] *National data*, ORGAN PROCUREMENT & TRANSPLANTATION NETWORK, https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/ (last visited Feb. 12, 2024).

[36] *About data, supra* note 33.

[37] *Id.*

[38] Connie L. Davis & Matthew Cooper, *The State of U.S. Living Kidney Donors*. 10 CLIN J AM. SOC'Y NEPHROL. 1873–80. (Oct. 2010).

III. PROPOSAL: IMPLEMENTING NEW RULES AND REGULATIONS

With a demonstrated need for longitudinal tracking of oocyte donors' health, this Article proposes two long-term goals to fulfill this gap in data and reporting at a federal level. First, the CDC must expand national ART data collection to include data that records the physical wellbeing of oocyte donors after their completion of oocyte retrieval. Second, Congress must enact new law to create a center or institute within the CDC [39] to report oocyte donor health outcomes on a public online database, thereby bolstering oocyte donors' informed consent. Specifically, this Article proposes that its first goal would best be achieved through an amendment of the CDC's aforementioned FCSRCA of 1992, allowing it to efficiently add pertinent data points for certified fertility clinics to collect. Because of the CDC's "informal rulemaking" authority[40] to make such an amendment, and because it already implements data reporting requirements upon certified fertility clinics,[41] the CDC is the ideal agency to implement the new rule. This Article's second goal would best be achieved through the federal legislative process to create a new CDC center or research institute with the purpose of carrying out publication of this data. Such legislation would benefit from mirroring the OPTN's federal organ registry system.

A. Goal 1: Implementing Data Collection Through the CDC's Informal Rulemaking Process

Regarding the first goal of amending data collection rules, the CDC must first address that the absence of oocyte donor health outcome data, which is

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[39] *CDC Organization*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/about/organization/cio.htm (demonstrating the various CDC Centers and Institutes, all of which carry out specific community health purposes but none of which address oocyte donor wellbeing) (last visited Apr. 23, 2024).

[40] *CDC Regulations*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/regulations/index.html (explaining CDC's informal rulemaking process, beginning with a rule proposal, then a public comment period, then a final rule period, then an implementation plan, and finally a retrospective review period.) (last visited Apr. 23, 2024).

[41] *The Fertility Clinic Success Rate and Certification Act*, *supra* note 31.

unacceptable and entirely antithetical to the HHS's efforts to enhance the health and well-being of all Americans. Next, to comply with the steps provided by the informal rulemaking process (also known as notice-and-comment rulemaking), the CDC must draft the proposed rule, then publish notice of it in the Federal Register and allow for a public comment period of at least thirty days before it becomes the "final rule." [42] The public comment period is particularly of interest because it ensures that vital perspectives of affected parties are considered. The proposed amendment to the FCSRCA should, at a minimum, add two new data points for fertility clinics to report annually: (1) the annual amount of participating oocyte donors and (2) the state of their physical health *after* the completion of a donation cycle. This would enable federal and private researchers to more accurately understand the long-term health risks associated with ART for oocyte donors over time. In turn, the anecdotal correlation between oocyte donation and an increased risk of cancer diagnoses could be either confirmed as causation or denied.

A sample of what the proposed rule's language for the CDC's notice summary in the Federal Register is as follows:

> "The Centers for Disease Control and Prevention (CDC), located within the Department of Health and Human Services (HHS) announces revised plans for additional data fields and modified reporting requirements for Assisted Reproductive Technology (ART) programs pursuant to the Fertility Clinic Success Rate and Certification Act of 1992 (FCSRCA), as well as the creation of an online database to publish such data. The additional information to be collected is listed below. (i) For current oocyte donors: total annual amount of oocyte donors who begin and or complete a cycle of oocyte retrieval, (ii) For former oocyte donors: total annual amount of former oocyte donors who have obtained a cancer diagnosis since completing oocyte retrieval; if cancer diagnosis exists, type of cancer must be noted (may include but is not limited to breast cancer, ovarian cancer, cervical cancer, colorectal cancer)." [43]

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[42] *CDC Regulations, supra* note 40.

[43] *See also* 87 FED. REG. NO. 112, *Reporting of Pregnancy Success Rates from Assisted Reproductive Technology (ART) Programs; Proposed Additional Data Collection Fields and Modified Reporting Requirements; Final Notice*, https://www.govinfo.gov/content/pkg/FR-2022-06-10/pdf/2022-12528.pdf (illustrating how reporting requirements are modified through the CDC and then reported as a final rule in the federal register).

B. Goal 2: Publishing the New Longitudinal Oocyte Donor Data to Bolster Informed Consent

Regarding the second goal of publishing new ART data points for the public to access in an online database, Congress must address how the lack of such public data severely limits HHS' ability to ensure oocyte donors are providing truly informed consent. Only a single member of Congress' sponsorship is needed to bring this objective to the docket. The Senate Committee on Health, Education, Labor and Pensions, ("Committee") for example, is a congressional committee for which this matter would be relevant.[44] In the past, sitting members of the Committee have led legislative efforts to address ART industry reform.[45] Given that reproductive rights and reproductive technology are topical subjects both in the U.S. Supreme Court and the court of public opinion, it is likely that a Committee member would take interest in sponsoring a bill to better inform the experiences of women who donate their oocytes. Moreover, such a bill could take inspiration from the OPTN, using its online database as a model for presenting ART-related data. As with the creation of the OPTN in 1984 and later, its national online database, this kind of initiative is spurred by necessity. Accordingly, the federal government has a vested interest in protecting its citizens from unrestrained private medical service providers (such as fertility clinics) who stand to benefit financially from the distribution of human genetic material.

IV. ADDRESSING POTENTIAL LIMITATIONS OR BARRIERS TO IMPLEMENTATION

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[44] *Senate Health, Education, Labor, and Pensions Committee*, https://www.congress.gov/committee/senate-health-education-labor-and-pensions/sshr00, (listing the Committee's most recent activity and demonstrating its sway in women's health) (last visited Apr. 23, 2024).

[45] *Murray, Duckworth, Wild Introduce Bill to Protect Right to Build a Family Through IVF as Extreme Republican Abortion Bans Threaten Access,* https://www.murray.senate.gov/murray-duckworth-wild-introduce-bill-to-protect-right-to-build-a-family-through-ivf-as-extreme-republican-abortion-bans-threaten-access/ (last visited Apr. 23, 2024).

Increasing the CDC's authority to amend its enforcement of the FCSRCA comes with limitations to consider regarding fertility clinics' abilities to capture data on oocyte donors' health, post-oocyte retrieval. As with any large-scale human data collection effort, accuracy relies on the likelihood of its participants to agree to share their data and to take the time to do so. For simple aggregate data of total of women who participate in oocyte donation, this should be easier for fertility clinics to collect and report.

There are many factors that determine whether former oocyte donors may be willing and available to discuss their health with the certified fertility clinics they worked with. First, former oocyte donors may not even have health updates to report each year, because doing so requires individuals to take advantage of preventative screening health services, and research indicates that preventative care is not a priority of many young American women.[46] Given that oocyte donors are typically healthy young women with no medical history of serious illness,[47] they may be less likely to ask their primary care physicians for cancer screenings. In general, people have reported avoiding medical care because they do not perceive a need; they cannot bypass traditional barriers like cost, lack of insurance, or scheduling difficulties; or they have had negative past experiences which deter them.[48] A 2022 Gallup Poll found that thirty-eight percent of Americans put off treatment due to cost, and women, younger adults, and lower-income adults

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[46] Julia Ries, *Nearly 50% of Women Skip Preventative Health Appointments—Here Are the Checkups to Prioritize*, HEALTH (Mar. 9, 2023) https://www.health.com/womens-annual-checkups-important-7229213 (last visited Apr. 24, 2024); See also Edward Winstead, *Why Are Many Women Overdue for Cervical Cancer Screening?,* NAT'L INST. HEALTH, https://www.cancer.gov/news-events/cancer-currents-blog/2022/overdue-cervical-cancer-screening-increasing ("[r]esearchers found that the percentage of women overall who were not up to date on screening jumped from 14% in 2005 to 23% in 2019").

[47] Brody, *supra* note 20.

[48] Jennifer M. Taber et al., *Why do People Avoid Medical Care? A Qualitative Study Using National Data*, 30 J. GEN. INTERN MED. 3, 290-97 (2015), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4351276/.

were consistently more likely to delay medical care for serious conditions.[49] Eradicating common barriers to seeking healthcare is a task for the entire healthcare system at large; however, fertility clinics and primary care physicians alike must do their part to emphasize (and not downplay) the importance of oocyte donors consistently seeking preventative screening tests for at least a few years after completing the oocyte retrieval cycle. The CDC's proposed rule on the matter should suggest such communication between fertility clinics and oocyte donors. Greater incentive to do so would be ensured if states legislatures made this a requirement for fertility clinics to acquire state licensure — a deep dive into this is beyond the scope of this Article but is recommended for future research.

One barrier to congressional efforts to create a CDC center or research institute responsible for implementing and maintaining an online database is that such a proposed bill may be seen as controversial, and crucial bipartisan support may be difficult to achieve. For instance, Senate Republicans recently blocked a Democrat-sponsored bill proposed to protect national access to IVF.[50] As current Senate Republicans seemingly conflate secure access to ART with pro-abortion policy,[51] it is foreseeable that even a simple data-collection initiative for ART could be regarded as a partisan issue. To combat this, the language and the publicity backing the proposed bill must carefully separate itself from the abortion discussion, and instead underscore the notion that a national oocyte donor registry database protects life and embryos by placing a higher burden on fertility clinics to protect child-bearing women. The bill may also benefit from sponsorship by members of

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[49] Megan Brenan, *Record High in U.S. Putting Off Medical Treatment Due to Cost, 2001-2022,* https://news.gallup.com/poll/468053/record-high-put-off-medical-care-due-cost-2022.aspx (last visited Apr. 23, 2024).
[50] Mary Clare Jalonick & Stephen Groves, *Republicans Block Senate Bill to Protect Nationwide Access to IVF Treatments*, AP NEWS, (Feb. 28, 2024), https://apnews.com/article/congress-ivf-access-abortion-alabama-bill-ruling-7f68248f36900d4583d9b181f3b4e380 (last visited Apr. 23, 2024).
[51] *Id.*

both political parties. Looking to the legislative history OPTN as an example, the federal law which created the organization was entirely sponsored by Senate Republicans.[52] If today's Senate members could liken the proposed CDC center or institute to the OPTN's organ registry, then perhaps fatal bipartisan stigma against the bill could be avoided. Additionally, in a time of increasing bipartisanship tension, the passage of this Article's proposed initiative would reflect favorably on participating Senate members.

V. CONCLUSION

Federal consideration of women's health has long been abysmal, and the results can even be fatal.[53] In the case of ART, this pattern shows itself to be true once more. The breadth and popularity of ART beckons stronger regulation that considers the women who provide their limited reproductive material to help others plan their families — simply cataloging success rates of oocyte retrieval is not enough. [54] If there is an increased risk of contracting cancer or other serious disease in the long run, then patients must be fully informed. The current regulatory system and data tracking in place for ART now is insufficient. True informed consent, therefore, does not exist in the ART industry. [55]

Through unified efforts between the CDC and Congress, a better understanding of how oocyte donation affects the health of women who donate in the long-term is possible, and likewise, the ability for those women to obtain genuine informed consent in the process is strengthened. The CDC, through its informal rulemaking authority, must amend its regulation of

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[52] National Organ Transplant Act of 1984, Pub. L. No. 98-507, 98 Stat 2339. https://www.congress.gov/bill/98th-congress/senate-bill/2048/cosponsors (noting that all eight of the Senate cosponsors for the bill that created the OPTN in 1984 were Republicans).
[53] Gilma Bernal, *The FDA and the Fem-Tech Revolution: A Feminist Healthcare Perspective,* 31 ANNALS OF HEALTH L. ADVANCE DIRECTIVE, 131, 134 (2023).
[54] Schneider, *supra* note 15.
[55] *Id.*

fertility clinic data reporting to reflect the interests of oocyte donors. To reinforce the impact of this large-scale data collection, Congress must enact legislation that creates a center or institute within the CDC which would be responsible for presenting the data in the form of an online public database. The OPTN's organ donor registry online database is an instructive model for the logistics and goals of such an endeavor.

Protect Grandma and Grandpa: Eliminate Abusive and Unfair Mandatory Arbitration Clauses in Nursing Home Contracts

Payton Moore

I. INTRODUCTION

Growing older and aging can result in vastly different experiences for everyone. Some aging individuals are no longer able to care for themselves in their own home, or their family members are not able to care for them, and they must resort to living in a short- or long-term care facility.[1] These facilities, such as nursing homes, are there to care for aging individuals. To become a resident in a nursing home, residents must enter into a contractual relationship with the nursing facility.[2] Most nursing home contracts include standard provisions such as identification of parties, the promise to pay, billing and changes in rates, notice about leaving the facility, medical treatment plans, visitor policies, and more.[3] These contracts may also include, and often do include, mandatory pre-dispute arbitration clauses, which can be worrisome.[4]

It is important to first understand the role of nursing homes and long-term care facilities. Additionally, it is necessary to note and be aware of the current use of mandatory pre-dispute arbitration clauses in nursing home contracts. Then, various counterarguments will be addressed, which support the use of mandatory arbitration clauses in nursing home contracts. Finally, attention will center on a proposal to implement federal legislation focused on eliminating mandatory pre-dispute arbitration agreements to protect the

[1] Taylor Burnett, *Arbitration Agreements and Nursing Homes: A Regulatory Compromise*, 4 ADMIN. L. REV. ACCORD 19, 22 (2018).
[2] Amy Mathieu, *Note: Nursing Homes and Mandatory Arbitration Clauses*, 34 J. L. & COM. 355, 358 (May 2016) ("Most, if not all, nursing homes require a contractual relationship with individuals before they can become residents.").
[3] *Id.*
[4] Burnett, *supra* note 1.

nursing home population from unwanted and abusive side effects of these agreements.

II. ROLE OF NURSING HOMES

Broadly speaking, nursing homes, which are also referred to as skilled nursing facilities or long-term care facilities, are residential facilities where members of the aging population can receive medical care services.[5] These services range from health to personal care and may include nursing care, twenty-four-hour supervision, three meals a day, assistance with everyday activities, and rehabilitation services.[6] An individual may turn to nursing home care when they can no longer care for themselves on their own or need increased medical help.[7] In fact, one-third of aging, older adults will spend time in a nursing home in their lives, whether that is for short- or long-term care.[8]

Often, nursing home residents must pay for their stay at a skilled nursing facility themselves.[9] Although Medicare may pay for related costs of certain services or medical supplies, it will not cover the resident's long-term stay at a nursing care facility.[10] To receive certain Medicare and Medicaid funding for various services, nursing homes must be licensed within the state that they operate in and follow all state regulations.[11] While following these state regulations is a requirement for nursing home facilities, they are often overlooked by some institutions.[12] Therefore, nursing home facilities are

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[5] *Long-Term Care Facilities: Assisted Living, Nursing Homes, and Other Residential Care*, NAT'L INST. ON AGING (Oct. 12, 2023), https://www.nia.nih.gov/health/assisted-living-and-nursing-homes/long-term-care-facilities-assisted-living-nursing-homes.
[6] *Id.*
[7] Burnett, *supra* note 1.
[8] *Id.*
[9] NAT'L INST. ON AGING, *supra* note 5.
[10] *Id.* (stating that Medicare coverage varies from state to state and can depend on whether the individual is eligible for coverage).
[11] Burnett, *supra* note 1.
[12] *Id.* at 23.

riddled with neglect and abuse, which may be the result of a lack of regulation or cutting corners.[13]

Both the patient and their loved ones find the nursing home admission process exhausting, stressful, and emotional because the admission process often takes place under emergent or unplanned circumstances.[14] Likewise, admission to a nursing care facility tends to require as quick and smooth of a transition as possible.[15] Due to this, prospective residents or loved ones may overlook some of the provisions or clauses, including arbitration clauses, in the paperwork.[16]

III. ARBITRATION AND CURRENT PROBLEMS WITH MANDATORY ARBITRATION

Arbitration is "an alternative dispute resolution method where the parties in dispute agree to have their case heard by a qualified arbitrator out of court."[17] Decisions made through arbitration are binding and, therefore, cannot be appealed.[18] Arbitration decisions are thus more final than the decision from a trial judge or court, which can be appealed to a higher court.[19] Additionally, once a claim is brought to arbitration, the parties are then precluded from also bringing that claim to a trial court.[20] An arbitrator is the

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[13] *Id.* at 22.
[14] Andi Alper, *Seeking Justice for Grandma: Challenging Mandatory Arbitration in Nursing Home Contracts*, 2016 J. DISP. RESOL. 469, 471 (2016) ("Typically, a worried child or spouse must find a safe refuge that can provide the immediately necessary care for a physically or mentally frail family member. The decision to admit a loved one is a stressful one, whether it is temporary or permanent.").
[15] *Id.* (stating that an elder individual may need immediately necessary care from a nursing home when physically or mentally frail).
[16] *Id.* at 472.
[17] *Arbitration*, CORNELL L. SCH.: LEGAL INFO. INST. (June 2022), https://www.law.cornell.edu/wex/arbitration.
[18] *Id.*
[19] Mathieu, *supra* note 2, at 360.
[20] CORNELL L. SCH., *supra* note 17.

person who declares the final judgment from the arbitration proceedings.[21] Usually, the institution, a party in the suit, hires the arbitrator.[22] The party who hired these hand-picked arbitrators may influence them to find in their favor, without being impartial to both sides.[23] Therefore, the arbitration decision is greatly dependent on the arbitrator and their potential biases.[24]

A. The Federal Arbitration Act

The United States Congress originally enacted the United States Arbitration Act in 1925.[25] Then, in 1947, Congress codified the Act as the Federal Arbitration Act ("FAA").[26] The FAA declared that arbitration "shall be valid, irrevocable, and enforceable" and is applicable both in state and federal courts.[27] From this language and the use of the Act, arbitration agreements are enforced under the FAA.[28] Interestingly enough, courts had not looked favorably at the FAA until the 1980s.[29] In 1983, the Supreme Court expanded the scope of the FAA through their decision in *Moses H. Cone Memorial Hospital v. Mercury Construction Corporation*.[30] Here, the Supreme Court endorsed the FAA as favoring arbitration agreements and further endorsed these agreements over litigation.[31]

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[21] *Id.*
[22] Mathieu, *supra* note 2, at 360.
[23] *Id.*
[24] *Id.* (discussing that there is an obvious incentive for arbitrators to continue with cases, despite their potential biases).
[25] Alper, *supra* note 14, at 470.
[26] 9 U.S.C. §§ 1-16 (2012).
[27] *Id.*; Alper, *supra* note **Error! Bookmark not defined.**, at 470.
[28] Burnett, *supra* note 1, at 26.
[29] Alper, *supra* note 14, at 470.
[30] Ann E. Krasuski, *Mandatory Arbitration Agreements Do Not Belong in Nursing Home Contracts with Residents*, 8 DEPAUL J. HEALTH CARE L. 263, 271 (2004); Moses H. Cone Mem'l Hosp. v. Mercury Constr. Corp., 460 U.S. 4, 29 (1983) ("The Arbitration Act calls for a summary and speedy disposition of motions or petitions to enforce arbitration clauses…[u]nder these circumstances, the court acted within its authority in deciding the legal issues presented in order to facilitate the prompt arbitration that Congress envisaged.").
[31] Moses, 460 U.S. at 29; Alper, *supra* note 14, at 471.

Along with this, Congress enacted the FAA under the Commerce Clause and, therefore, the FAA preempts any state law that prohibits arbitration agreements.[32] The Supreme Court determined the basis for this preemption in *Marmet Health Care Center, Inc. v. Brown*.[33] Here, the Supreme Court determined that any state law regarding arbitration was preempted and there were no exceptions for personal injury or wrongful death claims in the context of nursing homes.[34] Therefore, state courts are unable to invalidate arbitration agreements "solely based on laws specific to arbitration or laws that undermine the strong federal policy favoring arbitration."[35]

B. Mandatory Arbitration

Mandatory pre-dispute arbitration is a type of arbitration clause where "parties contracting with each other agree to submit any future dispute to arbitration rather than to a court of law."[36] These types of arbitration agreements are mandatory and, therefore, binding on both parties.[37] In the context of nursing homes, mandatory arbitration clauses can be problematic for residents and their loved ones.[38] Similar to regular arbitration clauses, mandatory arbitration clauses also involve the problems of biased arbitrators and the finality of judgments.[39] Furthermore, after various Supreme Court decisions, state legislatures are unable to restrict the use of mandatory arbitration clauses when dealing with personal injury or wrongful death cases

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[32] Mathieu, *supra* note 2, at 362.
[33] *Id.*; Marmet Health Care Ctr., Inc. v. Brown, 565 U.S. 530, 533 (2012) (finding that "West Virginia's prohibition against predispute agreements to arbitrate personal-injury or wrongful-death claims against nursing homes is a categorical rule prohibiting arbitration of a particular type of claim, and that rule is contrary to the terms and coverage of the FAA.").
[34] Marmet, 565 U.S. at 533.
[35] Alper, *supra* note 14, at 471.
[36] CORNELL L. SCH., *supra* note 17.
[37] Burnett, *supra* note 1, at 25.
[38] *Id.*
[39] Mathieu, *supra* note 2, at 360.

in nursing homes.[40] Due to these mandatory arbitration clauses, nursing homes tend to suffer from problems relating to the standard of care of residents.[41] This lower standard of care in the nursing home context can result in an increase in abuse, neglect, sexual assault, personal injury, and wrongful death.[42] When there is a mandatory pre-dispute arbitration clause in a nursing home contract, the nursing home is thus shielded from meaningful liability and public accountability, even in the circumstances of abuse, neglect, or worse.[43]

When a mandatory pre-dispute arbitration clause is signed, residents and their families are precluded from taking their case to court and seeking justice outside of the arbitration system.[44] Along with this, nursing homes incorporate these clauses into their contracts to make it less likely for residents to receive large amount of damages from a jury verdict.[45] This is true even for residents who have been victims of abuse or neglect in nursing homes.[46] In fact, the average amount of damages for victims of nursing home abuse and neglect has gone down from $226,000 in 1999 to $146,000 in 2006 as a direct result of implementing mandatory pre-dispute arbitration clauses.[47]

C. Nursing Home Abuse and Arbitration

Unfortunately, abuse and neglect are common issues that residents endure during their time living in a nursing home. In 2000, the National Center on

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[40] *Id.* at 362.
[41] Burnett, *supra* note 1, at 28.
[42] *Id.* at 21.
[43] *Id.*
[44] *Id.* at 25.
[45] Anthony P. Torntore, *"...And Justice for All": An Analysis of the Fairness in Nursing Home Arbitration Act of 2008 and Its Potential Effects on the Long-Term Care Industry*, 34 SETON HALL LEGIS. J. 157, 157-180 (2009).
[46] *Id.* ("Nursing homes use pre-dispute arbitration clauses in the admissions process in order to make it less likely that a victim of abuse or neglect will receive a large amount of damages, and to prevent such victims from pursuing their rights in court.").
[47] *Id.*

Elder Abuse ("NCEA") conducted a study and found that 44% of nursing home residents who were interviewed stated they had been abused and 95% stated they had been neglected or witnessed another resident being neglected.[48] The types of abuse that the NCEA considered in their study included "physical abuse (29%), resident-to-resident abuse (22%), psychological abuse (21%), gross neglect (14%), financial exploitation (7%), and sexual abuse (7%)."[49] Further, in 2010, the NCEA reported that over 50% of nursing home staff, through self-reporting, admitted to mistreating their nursing home residents.[50] This number is likely to be considerably higher because not all nursing home staff would admit to mistreating residents through self-reporting.[51]

The prevalence of this abuse and neglect in nursing homes has led some to declare that nursing home residents are "one of the nation's most vulnerable populations."[52] Abuse and neglect in this environment, unfortunately, is largely unnoticed and unreported for the most part.[53] When the abuse and neglect go unreported, nursing homes cannot be held accountable by residents or their loved ones, especially when there is an arbitration clause in effect.[54] Nursing homes can escape liability and the cycle of abuse and neglect to continue.

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[48] Mathieu, *supra* note 2, at 364 (reporting that, in addition, the NCEA, in 2012, found that "33% of nursing homes were cited for violations of federal standards from 1999-2001.").
[49] *Id.*
[50] *Id.*
[51] *Id.*
[52] Torntore, *supra* note 45, at 160.
[53] *Id.*
[54] *Id.* at 160-61.

D. Opposing Mandatory Pre-Dispute Arbitration

There are multiple arguments opposing the implementation of mandatory pre-dispute arbitration clauses in nursing home contracts. One main argument focuses on the prospective nursing home residents and their loved ones.[55] The decision to move into a nursing home or long-term care facility is a greatly emotional experience for both the resident and their loved ones.[56] It often arises due to an emergency or an urgent and sudden need to help an elderly, ill, or incompetent individual.[57] As a result of this health crisis, families are given limited time to find a nursing facility and fill out all of the required paperwork to admit their loved one to the facility.[58] With this limited time, families may be unable to consult an attorney to help them with all of the required paperwork and may be unable to "shop around" for other facilities.[59] Therefore, critics of mandatory pre-dispute arbitration clauses often believe it is disingenuous for a nursing home facility to claim the resident or family member "consciously, knowingly and deliberately accepted an arbitration clause in the contract" for the various reasons stated above.[60]

The second main argument focuses on how these arbitration clauses favor the nursing home facilities over the resident. Unfortunately for the families, most of these contracts are offered on a "take-it-or-leave-it" basis, where residents are unable to negotiate the terms of the contract.[61] Due to not having the same bargaining power as the nursing home facilities, residents

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[55] *See* Alper, *supra* note 14, at 476 (stating that nursing home residents and their families may be at a disadvantage when dealing with nursing home facilities' arbitration clauses).
[56] *Id.*
[57] *Id.*
[58] Paula Span, *Arbitration Has Come to Senior Living. You Don't Have to Sign Up.*, THE NEW YORK TIMES (Sept. 24, 2022), https://www.nytimes.com/2022/09/24/health/assisted-living-arbitration.html.
[59] *Id.*; Alper, *supra* note 14, at 476.
[60] Alper, *supra* note 14, at 476.
[61] Burnett, *supra* note 1, at 28; Krasuski, *supra* note 30, at 292.

and their families are unable to negotiate and, therefore, are treated unfairly.[62] With this inherent bias favoring the long-term care facilities, there is little protection offered for the resident.[63] Arbitration clauses may also bind the resident themselves and the resident's heirs, estate, and assigns.[64] Lastly, because arbitration outcomes are kept private and confidential, nursing home facilities benefit by avoiding public attention for not being required to disclose the claims or outcomes.[65]

IV. ARGUMENTS IN FAVOR OF MANDATORY ARBITRATION

Although there are a multitude of reasons to eliminate mandatory pre-dispute arbitration clauses in contracts, there are various arguments that emphasize the advantages of arbitration. These arguments include, but are not limited to, judicial efficiency, flexibility and informality, lower costs, and a fast finality of decision. Further, changing a process that is already restrictive, like arbitration, can be a challenge and cause issues for lawmakers.

The arbitration process can allow for a streamlined and efficient judicial system.[66] Since jury trials are long and drawn out, the efficiency of arbitration is one reason why long-term care facilities favor this process.[67] Even so, arbitration can "[ease] the burden on clogged court dockets" and "[offer] parties an opportunity to submit disputes to one experienced in that field."[68] Proponents of arbitration agreements argue that arbitration benefits residents and their loved ones because it provides an inherent expediency in

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[62] Burnett, *supra* note 1, at 28 ("[T]hese benefits largely favor the nursing home industry").
[63] *Id.* at 29.
[64] *Id.*
[65] Span, *supra* note 58, at 2.
[66] Alper, *supra* note 14, at 473.
[67] Torntore, *supra* note 45, at 167.
[68] Alper, *supra* note 14, at 473.

coming to a resolution to their problem.[69] Lastly, proponents of arbitration argue that the informality of arbitration is vital to reducing the cost for all parties involved.[70] This flexibility and informality of arbitration "enables it to function as an efficient, inexpensive, and expeditious means for dispute resolution."[71]

V. RECOMMENDATION

There are currently no federal laws aimed at reducing or eliminating the use of mandatory pre-dispute arbitration agreements in the realm of nursing homes and long-term care facilities. To protect the elderly population that lives in nursing homes and skilled nursing facilities, Congress should enact legislation that eliminates the unfair and abusive mandatory pre-dispute arbitration clauses in nursing home contracts. A proposed Act is as follows:

> Nursing Home Fairness Act
>
> §1: Purpose
> This Act aims to eliminate mandatory pre-dispute arbitration clauses in long-term care facility resident contracts.
>
> §2: Invalidity of Pre-Dispute Arbitration Agreements
> A pre-dispute arbitration agreement between a long-term care facility and a resident of such facility (or person acting on behalf of such resident, including a person with financial responsibility for such resident) shall not be valid or specifically enforceable.
>
> §3: Application to Agreements
> This section shall apply to any pre-dispute arbitration agreement between a long-term care facility and a resident of such facility (or a person acting on behalf of such a resident, including a person with financial responsibility for such resident), and shall apply to a pre-dispute arbitration agreement entered into either at any time during the admission process or at any time after the admission process.

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[69] Burnett, *supra* note 1, at 27 ("Advocates for the nursing home industry claim that arbitration is cost-efficient because its streamlined procedure and limited discovery process lowers attorney's fees. This reduction of attorney's fees potentially enables residents and family members to keep a larger portion of their financial settlement award.").
[70] Alper, *supra* note 14, at 473.
[71] *Id.*

> §4: Validity and enforceability
> An issue as to whether this chapter applies to an arbitration agreement shall be determined under Federal law. The applicability of this chapter to an agreement to arbitrate and the validity and enforceability of an agreement to which this chapter applies shall be determined by a court, rather than an arbitrator, irrespective of whether the party resisting arbitration challenges the arbitration agreement specifically or in conjunction with other terms of the contract containing such agreement.

This proposed law has been developed from a combination of provisions from The Arbitration Fairness Act of 2013 and the Fairness in Nursing Home Arbitration Act. The Arbitration Fairness Act of 2013 aimed to limit the scope of the FAA in disputes between commercial entities and consumers.[72] The Fairness in Nursing Home Arbitration Act has been introduced multiple times but has never moved further along in the legislative process.[73] This Act would invalidate mandatory pre-dispute arbitration clauses in the nursing home context.[74]

The Nursing Home Fairness Act will limit the scope of the FAA to govern disputes between long-term care facilities, such as nursing homes, and their residents or those acting on their behalf. Additionally, it will prohibit the enforcement of mandatory pre-dispute arbitration clauses. Sections 2 and 3 do not prohibit nor eliminate arbitration clauses in general, but only prohibit these causes if contracted to prior to a dispute arising. Since this Act does not wholly eliminate arbitration, it will not invalidate the various advantages of arbitration, such as judicial efficiency, flexibility, informality, and lower costs. Parties will continue to have the ability to both request and participate in arbitration disputes.

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[72] Mathieu, *supra* note 2, at 373.
[73] Fairness in Nursing Home Arbitration Act of 2009, H.R. 1237, 111th Cong. (1st Sess. 2009); Fairness in Nursing Home Arbitration Act, H.R. 2812, 117th Cong. (1st Sess. 2021).
[74] Torntore, *supra* note 45, at 159.

Section 3 is geared toward long-term care facilities in particular because, as mentioned, mandatory pre-dispute arbitration clauses in contracts are unfair and can be hurtful to prospective and current residents of nursing home facilities. These facilities are often at a greater bargaining advantage than their residents when dealing with arbitration, highlighting the need for balancing legislation. The specific wording of "shall apply to a pre-dispute arbitration agreement entered into either at any time during the admission process or at any time after the admission process," is particularly important. Residents and those acting on their behalf are at a specific disadvantage when arbitration is agreed to prior to a dispute arising. The Nursing Home Fairness Act, and specifically Section 3, is aimed at providing a more equal playing field for nursing home residents and those acting on their behalf.

Furthermore, Section 4 should be implemented to further protect equal bargaining power between nursing home facilities and residents. This section requires a court to determine the validity and enforceability of an arbitration agreement, rather than an arbitrator. Further, this section is important to show the value that all voices have in a dispute, regardless of whether they are the one to advocate that a claim be moved to arbitration. This Act would continue to allow a nursing home or long-term care facility to request that a dispute go through the arbitration process. However, Section 4 of The Nursing Home Fairness Act includes that an institution must first seek a determination by a court on the applicability of arbitration. This one small addition to the process ensures fairness on both sides of a dispute. Judicial efficiency can still be protected through this implementation of court decision prior to arbitration. Additionally, even if a court determines that arbitration is not valid for a dispute, parties can agree to a settlement instead of progressing to a trial, allowing for judicial efficiency, flexibility, and a fast finality of decision.

In sum, this Act would deter the issues of abuse and neglect of residents because the long-term care facility would not be able to shield themselves behind their pre-dispute arbitration agreements. From this, nursing home staff will, hopefully, increase the quality of the care they provide residents. Without mandatory pre-dispute arbitration clauses in nursing home contracts, residents or those acting on their behalf will not need to worry about accidentally signing away their rights to a trial by jury.

VI. CONCLUSION

Despite proponents of arbitration providing multiple arguments for its implementation in contracts, it is imperative to eliminate mandatory pre-dispute arbitration clauses to protect the population of those living in long-term care facilities and protect their families. The proposed Nursing Home Fairness Act would help to protect this vulnerable population and their families. This law would eliminate the unfair and abusive mandatory pre-dispute arbitration clauses found in nursing home contracts.

As noted, mandatory pre-dispute arbitration comes with great challenges to residents and their families. They are given little bargaining power in the contract process and if their claim goes through arbitration, they are disadvantaged even further. The proposed Nursing Home Fairness Act will not wholly eliminate the use of arbitration in nursing home claims. It only eliminates pre-dispute arbitration to create fairness and equity between the nursing home and the resident. With this effort, the residents of long-term care facilities will be offered protection during one of the most stressful times of their lives.

The Provider & The Law: Combating Opioid Epidemic with Healthcare Professionals and Legislature

Alexis Njoku

Since the 1990s, the opioid epidemic has overwhelmed the United States healthcare system.[1] Not only has this epidemic created an influx of patients requiring a very niche type of care but it has also proven to have serious ramifications on healthcare outcomes for the populations that it impacts.[2] Historically, the opioid epidemic has been characterized as a health crisis affecting predominately white, working-class Americans who illegally purchase opioids for recreational use. However, the true nature of this epidemic is far more complex; it disproportionately targets low-income black and brown communities[3] and exacerbated through overprescribing by healthcare providers.[4] Despite the expectation of empathy embedded into the role of the healthcare provider, many practitioners take advantage of their title in order to financially benefit beyond their ethical boundaries—particularly in the over-prescription of controlled substances. Coined with the name "pill mills", these healthcare providers play a role in the opioid epidemic by prescribing large amounts of highly addictive prescription drugs to their patients for use or to sake.[5] This brings us to the stereotypical image

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[1] *See generally Opioid Analysis and Resources,* CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/opioids/data/analysis-resources.html (providing nationwide overview of opioid epidemic (last visit August 23, 2023) (providing nationwide overview of opioid epidemic).

[2] Hsien-Yen Chang et al., *Impact of Prescription Drug Monitoring Programs and Pill Mills on High-Risk Opioid Prescribers: A Comparative Interrupted Time Series Analysis*, 165 DRUG & ALCOHOL DEPENDENCE 1, (Jan. 2, 2016).

[3] Melba Newsome & Gioncarlo Valentine, *The Opioid Epidemic Is Surging among Black people because of Unequal Access to Treatment*, SCI. AM. (Dec. 1, 2023), https://www.scientificamerican.com/article/the-opioid-epidemic-now-kills-more-black-people-than-white-ones-because-of-unequal-access-to-treatment/.

[4] *See generally* Khary K. Rigg, et al., *Prescription Drug Abuse & Diversion: Role of the Pain Clinic*, 40 J. OF DRUG ISSUES 681, 681-84 (Jan. 28, 2011).

[5] *Id.*

of the opioid epidemic, a back-alley drug exchanges conducted by a credentialed professional.[6]

In order to stay close to their target demographic, pill mills are often centralized in low-income areas, operating as on-site pharmacies or pain clinics that prescribe large amounts of pain medications to virtually any patient who asks for it.[7] Healthcare providers have the privilege and responsibility of improving the health outcomes of their resident populations. They also hold significant financial and educational privilege that many Americans are never privy to.[8] With this in mind, it is astonishing that some providers could complete years of schooling and extensive training on the importance of medical empathy and then abuse their power at the expense of the populations that they are supposed to protect. The exploitation of these vulnerable populations is especially dangerous when pill mills monopolize low-income areas, causing disastrous population health outcomes.[9]

In this article, I will discuss the significant negative effects that pill mills have on low-income communities and analyze their impact on worsening healthcare disparities. Furthermore, I will provide three methods to end pill mills by increasing the scope of regulation on providers to eliminate their role contributing to the opioid epidemic.

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[6] *Id.*
[7] *The Ugly Truth About Pill Mills In the United States,* NORTH POINT RECOVERY, (August 16, 2022) https://www.northpointrecovery.com/blog/ugly-truth-pill-mills-united-states/.
[8] Kevin Keith, *5 Things I Wish I Knew as a Premed About How to Pay for Medical School*, AMCC, https://students-residents.aamc.org/premed-navigator/5-things-i-wish-i-knew-premed-about-how-pay-medical-school.
[9] Marjorie C. Gondré-Lewis et al., *The Opioid Epidemic a Crisis Disproportionately Impacting Black Americans and Urban Communities*, 10 J. OF RACIAL & ETHNIC HEALTH DISPARITIES 2039, (Sept. 6, 2022), https://link.springer.com/article/10.1007/s40615-022-01384-6.

I. CURRENT STRUCTURE OF PILL MILL FACILITIES

Pill mills are "operations that prescribe drugs with no legitimate or medical purpose."[10] They are small, often solo-run health facilities that operate by prescribing large volumes of controlled substances, typically with pain medications and other narcotics.[11] Under federal law, "any drug that is a controlled substance listed in schedule II, III, IV, or V of the Federal Controlled Substances Act or implementing regulations must be dispensed by prescription only as required by section 503(b)(1) of the Federal Food, Drug, and Cosmetic Act unless specifically exempted."[12] Currently, the irresponsibly prescribing of controlled substances is a criminal offense that the Drug Enforcement Administration (DEA) and Federal Bureau of Investigation (FBI) investigate and litigate in federal court.[13] Due to the professionalism and medical empathy standards healthcare providers are required to uphold, the DEA and FBI alike have a "no-nonsense" attitude for greedy practices that could potentially hurt their patients.[14] Likewise, the criminal penalties for illegally prescribing controlled substances are serious, with providers facing imprisonment and exceedingly large fines exceeding $100,000.[15] Like many other fraud and abuse laws overseen by federal agencies, such as the Department of Health and Human Service's (DHHS)

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[10] United States v. Evans, 892 F.3d 692, 696 (5th Cir. 2018).
[11] *See generally* Amirreza Sahebi-Fakhrabad, et al., *Evaluating State-Level Prescription Drug Monitoring Program (PDMP) and Pill Mill effects on Opioid Consumption in Pharmaceutical Supply Chain*, 11 HEALTHCARE 437, 437 (Feb. 3, 2023), https://www.mdpi.com/2227-9032/11/3/437.
[12] 21 C.F.R. § 290.1.
[13] *Federal Prescription Drug Fraud and Pill Mills Charges – 21 U.S.C. 841,* EISNER GORIN, LLP, https://www.thefederalcriminalattorneys.com/federal-drug-offenses/federal-prescription-drug-fraud.
[14] *See*, Mitch Betses & Troyen Brennan, *Abusive Prescribing of Controlled Substance – A Pharmacy View*, 369 NEW ENG. J. MED. 989, 991 (2013) ("As we noted, pharmacists have an ethical duty, backed by both federal and state law, to ensure that a prescription for controlled substances is appropriate."); *See, e.g.*, Daniel C. Comeaux, *Physician Sentenced for $1.2 Pill Mill Scheme*, U.S DRUG ENF'T ADMIN. (2023), https://www.dea.gov/press-releases/2023/12/04/physician-sentenced-12m-pill-mill-scheme.
[15] 21 U.S.C. § 841(b).

Office of the Inspector General (OIG) investigates fraud and abuse in in the sale of opioids.[16] However, for many pill mill providers, the financial payoff still outweighs these penalties, and a doctor's empathy for their patients can only go so far.

When examining the social determinants of health (SDOH) specifically, low-income communities have generally experienced worse health care outcomes across various areas of health. Defined as "conditions in the environment where people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks" SDOHs are used to closely analyze the best medical practices for positive, population-based health outcomes.[17] Currently, the five SDOH domains are: (1) Economic Stability, (2) Education Access and Quality, (3) Health Care Access and Quality, (4) Neighborhood and Built Environment, and (5) Social and Community Context.[18] Many of the SDOH have a unique impact on people of color who already face resource and service gaps.[19] For example, there is a large and well-documented racial disparity in accessibility to maternal health services that exist regardless of income or education level.[20] Because Black and Brown communities make up a majority of these low-income areas, the disparity in access creates medical desserts that mirror the historically racist systems that exist in the

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[16] Nabarun Dasgupta, et al., *The Opioid Crisis: No Easy Fix to Its Social and Economic Determinants*, 108 AM J. OF PUB HEALTH 182, (2010).
[17] *Social Determinants of Health,* OFF. OF DISEASE PREVENTION & HEALTH PROMOTION: U.S. DEPT. OF HEALTH & HUM. SERVS, https://health.gov/healthypeople/priority-areas/social-determinants-health (Last Visited March 18, 2024).
[18] *Id.*
[19] *Id.*
[20] Latoya Holl, et al., *Racial Disparities in Maternal and Infant Health: Current Status and Efforts to Address Them*, KAISER FAM. FOUND. (Nov. 1, 2022), https://www.kff.org/racial-equity-and-health-policy/issue-brief/racial-disparities-in-maternal-and-infant-health-current-status-and-efforts-to-address-them/.

United States.[21] Because health facilities are so sparse in these areas, pill mill operations can thrive without the suspecting eye of other providers to report them. The issue is especially damaging when these facilities overwhelm such medically vulnerable locations.[22]

However, solutions can be made to combat this issue legislatively, through federal courts and among government agencies. In order to educate providers on pill mill operations, federal agencies should revise their compliance and education programs to be focus more on opioid drug operations in relation to the social and political determinants of health. Lastly, the utilization of technology to properly track and report highly addictive prescriptions would create a system that helps providers hold one another accountable. As a result, given the level of risk that these operations pose on both patients and providers, multiple solutions that examine both long-term and short-term effects from implementation should be considered when putting these incentives in place.

II. SOLUTION 1: LEGISLATIVE AMENDMENTS & ALTERNATIVE LITIGATION APPROACHES

Consider the following scenario: Betty is a family nurse practitioner (FNP) who is offered a part-time position at a small health clinic. This clinic is in a predominately black and Hispanic area that is well-known for its high opioid use. It is a solo-run facility operated by Dr. Smith, who sends his prescriptions to a neighboring pharmacy right across the street. On her first day, Betty sees an 18-year-old experiencing pain from a previous, sports-related injury. He is a Medicaid recipient, and it is his third time visiting this clinic. He lives an hour and a half away from the facility and his chart shows

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[21] *See* Darrell J. Gaskin, et al., *Residential Segregation and Availability of Primary Care Physicians*, 47 HEALTH SERV. RSCH. 2353 (Dec. 2012).
[22] Sean F. Altekruse, et al., *Socioeconomic Factors for Fatal Opioid Overdose in the United States: Findings from the Morality Disparities in American Communities Study (MDAC)*, PLOS ONE, (Jan. 17, 2020).

that he has received oxycodone, a schedule II-controlled substance.[23] Betty knows that the pain that the patient is experiencing is from slight swelling that could be treated with over-the-counter pain medications. However, Dr. Smith prompts Betty to prescribe large amounts of hydrocodone to the patient. This shocks Betty, but Dr. Smith assures her that the patient's pain can often become debilitating, and that the prescription is much needed. Unsure of what to do, Betty decides that it is best to not argue with her new employer and sign the prescription despite the lack of medical purpose.

In this situation demonstrates, the providers would face numerous criminal drug charges such as conspiracy to dispense a controlled substance outside the usual course of professional practice without legitimate medical purpose.[24] They would also face charges for unlawfully dispensing controlled substances, unlawfully dispensing of controlled substances and committing health care fraud.[25]

According to the relevant statute, "it shall be unlawful for any person to *knowingly* or *intentionally* … to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense a controlled substance…"[26] The *knowing* and *intentionality* factors of various distribution laws implemented throughout the country give the courts the credence to place extra emphasis on the provider's credentials and expertise. Under their assumption, the level of expertise afforded to these providers automatically grants them a heightened standard of care requiring that they know the effects that their prescription practices pose on their populations.[27] In general, the

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[23] *Drug Scheduling*, U.S. DEP'T OF DRUG ENF'T ADMIN., https://www.dea.gov/drug-information/drug-scheduling.
[24] 21 U.S.C. § 841(b).
[25] *Id.*
[26] 21 U.S.C. § 841(b).
[27] United States v. Duldulao, 87, F.4th 1239, 1253 (11th Cir. 2023) ("The district court instructed the jury that the government was required to prove that: two or more persons in some way intended to try to accomplish a shared and unlawful plan as charged in the second superseding indictment; and that the defendant knew the unlawful purpose of the plan and

court have the discretion to consider a healthcare provider's brief lapse in judgment as they would with many other criminal drug offenders. For this reason, providers have an affirmative duty to report drug violations at their place of employment. The current requirement put in place by the DEA is laid out in the below excerpt from 21 C.F.R. § 1301.91.

> § 1301.91 Employee responsibility to report drug diversion:
> § 1301.81 Employee responsibility to report drug diversion. It is, therefore, the position of DEA that an employee who has knowledge of drug diversion from his employer by a fellow employee has an obligation to report such information to a responsible security official of the employer.[28]

While this requirement does provide a decent overview for what a provider should do when they know that they are with an employer, there is little guidance on what actual suspicious activities look like.[29] As noted earlier, courts tend to rely on the assumption that the provider should already know how to identify these fraudulent operations simply based on their expertise, likely as a motive to keep the standard high and laws against drug operations strict.[30] Considering the previous hypothetical scenario discussed above, it would be in Betty's best interest to understand how to identify these drug operations, however, proper federal-level guidelines do not currently exist and should put in place that help guide providers through navigating their duty. With these clarifications in place, expansions to reporting criteria

willfully joined in it; and that the object of the unlawful plan was to distribute and dispense, and cause the distribution and dispensing of [controlled substances] for no legitimate medical purpose of professional practice.").

[28] 21 CFR § 1301.91.

[29] *See* United States v. Lang, 717 Fed. Appx. 523, 543 (2017) (Court upheld decision from *United States v. Sadler*, 750 F.3d 585, 593 (6th Cir. 2014) in which there was sufficient evidence to support the defendant's drug-conspiracy convictions and distribution at a pain clinic despite the reasoning that ""a climate of activity that reeks something foul," the evidence is sufficient when it, so to speak, identifies of the odor." *See United States v. Morrison*, 220 F. App'x 389, 393 (6th Cir. 2007) and United States v. Wieschenberg, 604 F.2d 326, 332 (5th Cir. 1979) (emphasis added).

[30] 21 CFR § 1301.91.

should also be added that would broaden the definition of what constitutes as suspcious drug activity.

A proposed supplemental guideline would read as follows:

> Proposed Guidelines for Duty to Report Requirement:
> Pursuant to § 1301.81, a health care provider is engaging in suspicious activity while prescribing schedule-II, III, IV, and V medications when they show fraudulent, offensive, or otherwise dangerous activity that puts the patient populations at risk.

These proposed guidelines will make the threshold level of conduct that providers are required to report more subjective. This would increase the number of cases opened based on a provider's judgment and feelings. Additionally, it keeps the patient in mind which instinctively raises the standard of care for providers in communities overwhelmed by the opioid epidemic. One risk, however, is that encouraging providers to freely report all suspicious activity could potentially be physically laborious and financially burdensome for the DEA when dealing with dead-end investigations. However, the overall benefit of keeping the population in mind would encourage these providers to report even the most apparent of cases.

In this hypothetical, Betty would understand that this health clinic is located in an area where opioid use is high. Although she sees that the patient has been prescribed with a high amount of Oxycodone before, she decides that the minor injury did not constitute as a legitimate medical purpose for an opioid prescription. Under these new proposed regulations, she would also see that he is only eighteen and she would refuse to sign the prescription. She would then leave the facility, and reports to Dr. Smith immediately.

III. SOLUTION 2: STRENGTHENING COMPLIANCE & EDUCATION PROGRAMS

Strengthening internal compliance programs within health facilities would help these facilities to strengthen drug prescription regulations, which would

make it more difficult for providers to play a role in pill mill operations. Although most of these pill mill operations typically stem from physicians outsourcing their operating to lower-end health professionals, supervising physicians can also face the problem of being taken advantage of by their preceptors—or licensed providers that oversee health and medical students in their clinical practice—for the financial incentives.[31] As a result, this dynamic only heightens the level of responsibility that the OIG is given to oversee these practices and protect patients and providers. Like other crimes, fraud and abuse violations within the healthcare system can begin with minor wrongdoings that grow into big mistakes with heavy criminal liabilities. The current system utilizes criminal and disciplinary action to keep providers from violating these laws, but it greatly underestimates the manipulative nature and duress that takes place to keep providers from reporting or jumping ship.

Consider again the hypothetical, but this time, Betty signs the large prescription with the intent to report immediately after work that day. Then, Dr. Smith proceeds to become aggressive and threatens to "ruin her" if she goes forward with reporting. Betty decides not to report but refuses to see any more of Dr. Smith's patients. There are no internal compliance systems in place at this facility. Betty eventually quits indefinitely and never reports the incident out of fear of reprisal.

The lack of internal oversight and education programs at facilities in low-income communities keep problematic reporting structures alive. These providers are not only abusing their health sensitive populations,[32] but they are also taking advantage of the livelihoods of fellow providers for their own

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[31] *See e.g.*, *Press Release: Pill Mill Physician Sentenced to 13 Years for Conspiracy to Distribute Narcotics*, U.S. ATT'Y OFF. NORTH. TEX., (May 13, 2019), https://www.justice.gov/usao-ndtx/pr/pill-mill-physician-sentenced-13-years-conspiracy-distribute-narcotics.

[32] *See* U.S. DEPT. OF HEALTH & HUM. SERVS., *supra* note at 17.

gain. As a result, systems for further guidance and training systems on how providers can navigate through these situations should be put in place that are population specific. Population-specific education and training programs would keep providers properly stay informed about the best patient care and internal management approaches.[33] These programs would include public awareness campaigns to educate patients about the risks of prescription drug abuse, proper medication use, and the importance of safely storing and disposing of medications as well as mandatory training programs specializing on the health outcomes of their patient populations.

Tailoring medical practices towards drug diversion would create a proper preliminary step to deter medical providers from over-prescribing controlled substances. Likewise, an initial focus on alternative pain management options will also be beneficial for healthcare providers looking to access alternative pain therapies that utilize non-opioid medications. Drawbacks to this provision are to be expected, including patient dissatisfaction—even from patients who are or are not abusing narcotics—and an increased number of doctor visits to adjust their medications accordingly. Similarly, for population-specific incentives, drug diversion efforts should be offered on a case-by-case basis.

Looking back at the previous scenario, but applying these new compliance incentives, Betty would, again, consider the SDOH of the patient's health populations and divert the patient away from the controlled substances before leaving the facility and reporting it to the DEA accordingly. She would have utilized skills she had gained from proper training and development accordingly.

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[33] Mohammad Shahzad, et al., *A population-based approach to integrated healthcare delivery: a scoping review of clinical care and public health collaboration*, 19 BMC PUB. HEALTH 708, (2019), https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-019-7002-z.

IV. SOLUTION 3: UTILIZING TECH TO MONITOR AND REGULATE PRESCRIPTIONS

Over the years, computerized technology has proven to play a vital role in the health care industry. Innovations in technology should be leveraged to combat the opioid epidemic. Similarly, federal-level population-specific Prescription Drug Monitoring Programs (PDMPs) should be implemented alongside taskforces that would work to eliminate the epidemic. PMDPs are state-level interventions created to "improve clinical practice and protect patients at risk." [34] A PDMP is an "electronic database that tracks controlled substance prescription in a state. PDMPs can provide health authorities timely information about prescribing and patient behaviors that contribute to the epidemic and facilitate nimble and targeted response."[35] PDMPs can help identify patients who may be doctor shopping or obtaining prescriptions from multiple providers.[36] As a result, its providers should be required to consult PDMPs before prescribing controlled substances.

When discussing technology in health care, the conversation of telemedicine is inevitable. Respectively, regulations in telemedicine that develop clearer guidelines governing the use of telemedicine for prescribing healthcare services should be put in place.[37] The remote nature of telemedicine can often make spotting signs of addiction difficult for providers. Education programs that specifically instruct on signs of addiction in a remote setting could help guide providers respectively. Additionally, regulating telemedicine to develop clearer guidelines for governing the use of telemedicine for prescribing healthcare services should be put in place.

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[34] *PDMPs: What States Need to Know*, CTRS. FOR DISEASE CONTROL & PREVENTION, https://www.cdc.gov/drugoverdose/pdmp/index.html (last visited May 19, 2021).
[35] *Id.*
[36] *Id.*
[37] Trent Emerick, et al., *Telemedicine for Chronic Pain in the COVID-19 Era and Beyond*, 9 PAIN MED. 1743, (Sept. 21, 2020), https://academic.oup.com/painmedicine/article/21/9/1743/5903978.

Telemedicine could also utilize a similar system to the PMDP as discussed earlier by implementing a telemedicine oversight platform.[38] This incentive could also encourage audits within online EHR systems.

In addition to, enhanced screening and referral for substance use disorders, the OIG should implement screening protocols in healthcare settings to identify patients at risk of substance use disorders and provide appropriate referrals for treatment and support services. Further, community-based prevention, collaborative coordinated care, and intervention programs will help support population-specific initiatives aimed at preventing prescription drug abuse. These programs could also provide addiction treatment and recovery support and address underlying determinants of substance abuse.

V. CONCLUSION

As it stands, the provider's expertise and specialization in the field implies that they understand the nuance behind the ongoing issue of opioid abuse, pill mills, and know how to avoid exacerbating the problems. However, while health providers hold a level of understanding higher than the average person, they are still human beings who can be suspectable to insidious practices out of fear, greed, or desperation. Likewise, while courts are handling disciplinary penalties for fraudulent and abuse prescription practices, the OIG should also provide some oversight for healthcare providers to avoiding and mitigate unlawful and inadequate health practices. As a result, not only will this protect healthcare workers, but it will also ensure that patients will receive adequate care across all demographics.

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[38] *Id.*

The Gap in Fraud and Abuse Law: Advocating for Health Equity in Women's Reproductive Testing and Procedures

Katherine O'Malley

I. SHEDDING LIGHT ON HEALTHCARE FRAUD IN WOMEN'S REPRODUCTIVE HEALTH

One may think that fraud and abuse laws in healthcare protect patients from fraudulent practices such as overtreatment or unnecessary procedures. Unfortunately, the protection is afforded to the government rather than directly to the patient.[1] There are two primary fraud and abuse laws healthcare providers must follow: the Anti-Kickback Statute (AKS) and the False Claims Act (FCA).[2] Each law is precisely engineered to protect the government's allocation of money, such that violations are only triggered when providers defraud the government and abuse federally funded programs like Medicare.[3]

The goal of this analysis is to shed light on healthcare fraud in women's reproductive healthcare as well as to present one potential solution to help protect the patient. First, this article will discuss the existing laws, their enforcement, and a specific fraudulent scheme. Next, this article will discuss how this government-centric approach fails to protect the patients themselves from fraud and abuse within the healthcare system, which leaves a gap in protection specifically for more vulnerable patients–women. Finally, this article will propose an amendment to the Anti-Kickback Statute to protect

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[1] *I. Physician Relationships With Payers*, U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. OF INSPECTOR GEN., https://oig.hhs.gov/compliance/physician-education/i-physician-relationships-with-payers/ (last visited Feb. 13, 2024) ("When the Federal Government covers items or services rendered to Medicare and Medicaid beneficiaries, the Federal fraud and abuse laws apply").

[2] Christina M. Kuta, *Health care fraud and abuse laws: Why "Intent" may be key,* MED. ECON. (Sept. 19, 2023), https://www.medicaleconomics.com/view/health-care-fraud-and-abuse-laws-why-intent-may-be-key.

[3] *See generally Fraud & Abuse Law*, U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. OF INSPECTOR GEN., https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/ (last visited Feb. 11, 2024) (summarizing federal fraud and abuse laws such as the Anti-Kickback Statute and the False Claims Act); U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. OF INSPECTOR GEN.*, supra* note 1.

the patient on specific issues relating to fraudulent unnecessary testing and procedures conducted in women's health care.

II. BACKGROUND ON EXISTING LAW AND ENFORCEMENT

A common healthcare fraud scheme is the payment of "kickbacks" in exchange for referrals, which can lead to inappropriate medical care because it corrupts a provider's medical decision-making.[4]

> [T]he Anti-Kickback Statute…prohibits knowingly and willfully paying (or offering to pay) or receiving (or soliciting) any remuneration (including any kickback, bribe, or rebate)-directly or indirectly, overtly or covertly, in cash or in kind-in exchange for prescribing, purchasing, or recommending any service, treatment, or item for which payment will be made by Medicare, Medicaid, or any other federally-funded health care program.[5]

This remuneration can include anything of value, not only monetary value.[6] It is essential to note that this criminal statute requires knowingly or willfully offering or soliciting anything of value to induce referrals or the generation of business paid for by *federal healthcare programs*.[7] This means the AKS is only violated if the Federal government is implicated. However, "[t]he statute does not require proof of a loss to any federal health care program[.]"[8] To evaluate such mental states, courts apply the "one purpose"

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[4] Nicole F. Stowell et al., *Investigating Healthcare Fraud: Its Scope, Applicable Laws, and Regulations*, 11 WM & MARY L. REV. 479, 485 (2020).

[5] *See* 42 U.S.C. § 1320a-7b(b); Matthew Larson et al., *Health Care Fraud*, 58 AM. CRIM. L. REV. 1073, 1081 (2021); Kuta, *supra* note 2; U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. OF INSPECTOR GEN., *supra* note 3.

[6] *Anti-kickback Statute and Physician Self-Referral Laws (Stark Laws),* AM. SOC'Y OF ANESTHESIOLOGISTS, https://www.asahq.org/quality-and-practice-management/managing-your-practice/timely-topics-in-payment-and-practice-management/anti-kickback-statute-and-physician-self-referral-laws-stark-laws ("Examples of prohibited kickbacks include receiving financial incentives for referrals, free or very low rent for office space, or excessive compensation for medical directorships. Other kickbacks include waving copayments, either routinely or on a selective case-by-case basis.")

[7] U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. OF INSPECTOR GEN., *supra* note 3; 42 U.S.C. § 1320a-7b(b).

[8] Larson et al., *supra* note 5 at 1086.

test, where "if one purpose of an arrangement is to give or receive remuneration in exchange for referrals, then the AKS is implicated even if the services or items at issue otherwise were medically necessary and appropriately provided."[9] The statute attempts to protect the overall costs of health care because such fraudulent practices would drive up costs to federally funded programs like Medicare.[10]

If physicians violate the AKS, the same violation can implicate the False Claims Act.[11] The FCA prohibits providers from knowingly giving false information to the government when seeking payment from the government through a federally funded program.[12] "Knowingly" has been interpreted by the courts to mean that the physician either knew the information was false, deliberately ignored whether it was true or false, or recklessly disregarded whether it was true or false.[13] Penalties for an FCA violation may include large fines, bans from government healthcare programs, or imprisonment.[14] The Department of Justice, the Department of Health & Human Services Office of Inspector General (OIG), and the Centers for Medicare & Medicaid Services (CMS) enforce these laws.[15]

III. GROUNDING LEGAL RECOMMENDATIONS IN THE CONTEXT OF REPRODUCTIVE HEALTH EQUITY FOR WOMEN

Before addressing the legal issues relating to women's reproductive health services, it is essential to address the reality of the experiences of women

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[9] Kuta, *supra* note 2; *see also* Larson et al., *supra* note 5 at 1083 ("The 'knowing and willful' requirement is satisfied by showing that the defendant was aware his conduct was unlawful and that he acted voluntarily and purposely; specific knowledge of the statute is not required.").
[10] Larson et al., *supra* note 5 at 1082.
[11] *Id.* at 1131; *see also* 31 U.S.C. § 3729.
[12] U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. OF INSPECTOR GEN., *supra* note 3; Larson et al., *supra* note 5 at 1126-1130.
[13] U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. OF INSPECTOR GEN., *supra* note 3.
[14] *Id.*; *Laws Against Health Care Fraud Fact Sheet,* CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/files/document/overviewfwalawsagainstfactsheet072616pdf.
[15] U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. OF INSPECTOR GEN., *supra* note 3.

trying to maintain their health in an unbalanced societal structure. Women face many barriers to effective medical healthcare when navigating their health concerns.[16] Concurrently, there is overwhelming evidence of a lack of effectiveness in responding to women's complaints of pain regarding their reproductive organs.[17] Women of color, especially Black women, are forty percent less likely to receive medication to ease acute pain.[18] Inequality also occurs outside the context of reproductive health, such as with cardiovascular pain.[19] When compared with men, women are less likely to be admitted to the hospital, less likely to be given electrocardiography testing, and experience longer wait times when presenting to an emergency room with the same chest pains.[20] This fact is even more troubling because "cardiovascular mortality among young women has been… rising in recent years."[21]

Moving onto the legal space, "the law of reproductive issues has implicitly centered on observing and controlling the pregnant woman . . . using evidence that is available from the outside."[22] However, since women's pain is internal, it is, therefore, subject to dismissal.[23] It is important to frame legal questions of reproductive rights within this context of dismissal in order to

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[16] Kristen Schorpp Rapp et al., *State-Level Sexism and Gender Disparities in Heath Care Access and Quality in the United States,* 63 J. OF HEALTH & SOC. BEHAV. 2, 8 (2022).
[17] ANUSHAY HOSSAIN, THE PAIN GAP: HOW SEXISM IN HEALTHCARE & RACISM KILL WOMEN 37-52 (Simon Element, 2021) ("In researching this book, I spoke with almost one hundred women with various medical issues. All of them had had their pain dismissed by medical professionals").
[18] *Id.* at 23-35 ("As with most things in healthcare, if the situation is bad for women, it's even worse for women of color, especially Black women. Studies find that compared to white patients, Black patients are 40 percent less likely to receive medication to ease acute pain and Hispanic patients are 25 percent less likely").
[19] Darcy Banco et al., *Sex and Race Differences in the Evaluation and Treatment of Young Adults Presenting to the Emergency Department With Chest Pain*, J. OF THE AM. HEART ASSOC. 1, 7 (2022).
[20] *Id.*
[21] *Id.*
[22] Catharine A. MacKinnon, *Reflections on Sex Equality Under Law,* 100 YALE L. J. 1281, 1310 (Mar. 1991).
[23] *Id.*

understand that women are a more vulnerable population, not only to mistreatment, but to fraud and abuse as well. Protecting women's reproductive health must be a priority in both our legal and healthcare systems, and we must ground this discussion in both the legal and social context of sex inequality.[24]

In addition to pain dismissal, there is another simultaneous issue: overtesting.[25] Although it may be a difficult pill to swallow, women are victims of overtesting, specifically when it comes to their reproductive healthcare.[26] One study states that "[o]vertesting includes unnecessary medical tests in both asymptomatic and symptomatic people, where testing does not improve clinical decision making (clinical utility), or health outcomes (clinical effectiveness)."[27] Moreover, overtesting can lead to false negative results, misdiagnoses and overdiagnosis, "where people are labeled as having a 'disease' for a condition that would not have caused them harm

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[24] *Id.* at 1309 ("Grounding a sex equality approach to reproductive control requires situating pregnancy in the legal and social context of sex inequality and capturing the unique relationship between the pregnant woman and her fetus.").

[25] Jason D. Wright et al., *Overuse of Cervical Cancer Screening Tests Among Women With Average Risk in the United States From 2013 to 2014*, JAMA NETWORK OPEN, 1, 7 (Apr. 29, 2021), https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2779304?resultClick=3 ("The findings of this cohort study suggest that among commercially insured women with average risk who underwent cervical cancer screening in 2013 to 2014, cervical cancer screening tests were frequently overused.").

[26] Tara Haelle, *Putting Tests to the Test: Many Medical Procedures Prove Unnecessary—and Risky*, SCI. AM. (Mar. 5, 2013), https://www.scientificamerican.com/article/medical-procedures-prove-unnecessary/ ("The routine use of 130 different medical screenings, tests and treatments are often unnecessary and should be scaled back, according to 25 medical specialty organizations. … unnecessary interventions that waste money and can actually do more harm than good"); Rani Marx, *Overscreening for Women's Cancer: Time for Change*, 42 MED. DECISION MAKING 1041, 1041-43, https://journals.sagepub.com/doi/full/10.1177/0272989X221123547 [hereinafter *Overscreening Women's Cancer*]; Rani Marx, *Overzealous Women's Health Screening? My Story*, 36 J. OF GEN. INTERNAL MED. 2825, 2825-26 (2020), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8390733/ [hereinafter *Women's Health Screening]*; Jennifer L. Moss et al., *Geographic Variation in Overscreening for Colorectal, Cervical, and Breast Cancer Among Older Adults*, JAMA OPEN NETWORK, 1, 8 (May 17, 2021), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8127072/.

[27] Justin H. Lam et al., *Why clinicians overtest: development of a thematic framework*, 20 NAT'L LIBR. OF MED.: NAT'L CTR. FOR BIOTECHNOLOGY INFO. 2 (2020).

if it were left undetected and untreated."[28] Often, the provider has a financial interest through ownership of these tests and services.[29] This creates the perfect storm for fraud and abuse of women's reproductive healthcare services.

IV. AN EGREGIOUS VIOLATION OF FRAUD AND ABUSE LAWS

In March of 2023, a grand jury indicted Dr. Mona Ghosh, a women's healthcare physician in Chicago, Illinois, on thirteen counts of healthcare fraud.[30] Dr. Ghosh owned and operated Progressive Women's Healthcare, S.C., where Dr. Ghosh allegedly performed unnecessary tests and procedures.[31] These procedures included endometrial ablations and laboratory tests.[32] Endometrial ablation is an invasive surgery where the doctor "destroys the lining of the uterus" and is either performed in a doctor's office or surgery room.[33] The FBI estimates that Dr. Ghosh fraudulently obtained approximately $796,000 in payments from multiple federally funded health care benefit programs, TRICARE and Medicaid.[34]

The Acting U.S. Attorney Pasqual stated, "[t]argeting government and private healthcare programs relied on by the public to maintain their well-being is a serious crime…."[35] Moreover, Special Agent Wheeler said, "[w]hen healthcare providers illegally manipulate our healthcare system, it

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[28] *Id.*
[29] *Id.* at 4; Marx, *Women's Health Screening, supra* note 26 at 2825, 2826 ("And there is the financial incentive to do more, a major driver of our insurance system.").
[30] Press Release, *Physician Indicted on Thirteen Counts of Healthcare Fraud*, U.S. ATT'Y'S OFF., N. DIST. OF ILL. (Mar. 14, 2023) https://www.justice.gov/usao-ndil/pr/physician-indicted-thirteen-counts-healthcare-fraud.
[31] *Id.*
[32] *Women's health care doctor accused of defrauding insurance companies, Medicaid*, CBS CHI., (Mar. 14, 2023, 2:43 PM), https://www.cbsnews.com/chicago/news/womens-health-care-doctor-accused-defrauding/.
[33] *Endometrial ablation: Overview*, MAYO CLINIC, https://www.mayoclinic.org/tests-procedures/endometrial-ablation/about/pac-20393932 (last visited Feb. 14, 2024).
[34] *Seeking Information in Dr. Mona Ghosh Investigation*, FED. BUREAU OF INVESTIGATIONS, https://forms.fbi.gov/monaghoshinvestigation (last visited Feb. 14, 2024).
[35] U.S. ATT'Y'S OFF., N. DIST. OF ILL., *supra* note 30.

diminishes the trust Americans have in vital programs."[36] These statements sound as though the government is looking out for the patient's well-being. However, this grand jury indictment would not have happened had this doctor fraudulently charged only private insurance or out-of-pocket patients, thus leaving it in the hands of individuals to bring a suit. If Dr. Ghosh had not implicated federal benefits programs, it is likely that the government would not have extended their resources to inform themselves of Dr. Ghosh's scheme through investigations.

The purpose and rationale behind Fraud and Abuse laws are clear. The U.S. Department of Health and Human Services states, "[t]he presence of some dishonest health care providers who exploit the health care system for illegal personal gain has created the need for laws that combat fraud and abuse and ensure appropriate quality medical care."[37] So then, why are these fraud and abuse laws only triggered when federally funded programs are defrauded? Here lies the gap in protection. If these laws are to help ensure appropriate quality medical care, then the law should protect against fraud occurring in women's health care, regardless of the source of payment. The fraud and abuse law umbrella should protect women from unnecessary testing and procedures, irrespective of how such services were paid for, as this is not the only case of such egregious fraud.[38]

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[36] *Id.*

[37] *Introduction*, U.S. DEP'T OF HEALTH & HUM. SERVS. OFF. OF INSPECTOR GEN., https://oig.hhs.gov/compliance/physician-education/introduction/ (last visited Feb. 11, 2024).

[38] *See* James M. Schwayder, *Health care fraud exposed: The penalties of deception can be much worse than medical negligence,* 66 CONTEMP. OB/GYN J. 30, 30-32 (July 2021) ("Between 2010 and 2019, private and government payors experienced $21 million in losses for unnecessary surgeries and procedures. The FBI concluded that the physician knowingly and willfully executed a scheme to defraud Medicaid and Medicare.")

V. PROPOSAL OF A NEW AMENDMENT TO THE AKS: ABUSE OF WOMEN'S HEALTH AND REPRODUCTIVE RIGHTS AMENDMENT (AWHRRA)

The existing AKS that governs specific acts of fraud and abuse in our healthcare system should include private fraud transactions in the reproductive healthcare space. This paper proposes the Abuse of Women's Health and Reproductive Rights Amendment (AWHRRA). This amendment aims to extend enforcement of the AKS to capture more bad actors, regardless of the payment source, in specific and egregious instances where providers defraud patients seeking reproductive healthcare services. The current laws, such as AKS and FCA,[39] leave a gap in protection because they are only implicated if the provider defrauds a federally funded program. Thus, this proposed amendment intends to close this gap by including providers who have focused on defrauding solely private insurance and out-of-pocket patients.

This proposed amendment is similar to an existing statute called the Eliminating Kickbacks in Recovery Act of 2018 (EKRA)[40], which extended protection to both federal and private payor relationships in the substance abuse industry. EKRA extended this protection by broadening the statute's language to "healthcare benefit programs" and expanded the definition to include private payors.[41] The AWHRRA intends to do the same for the reproductive healthcare industry.

The AWHRRA proposes to amend the AKS, which prohibits giving or receiving any "remuneration" in exchange for referrals or other business-generated parties.[42] The following is a proposed **amendment** to the AKS

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[39] 42 U.S.C. § 1320a-7b(b); 31 U.S.C. § 3729.
[40] 18 U.S.C. § 220; Larson et al., *supra* note 5 at 1124.
[41] Larson et al., *supra* note 5 at 1123-24 ("The fact that EKRA covers both federal and private payors flows from EKRA's broad definition of 'health care benefit program.' See 18 U.S.C. §220(e)").
[42] Criminal Penalties for Acts Involving Federal Health Care Programs (Anti-Kickback Statute), 42 U.S.C. § 1320a-7b(b).

called the AWHRRA: **"**(b) Illegal remunerations (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind…"[43] **and (C) in circumstances where a provider knowingly and willfully provides or furnishes egregiously unnecessary reproductive medical procedures or tests, such that the provider consistently disregards current medical standard of care and the provider has a significant financial interest in providing multitudes of egregiously unnecessary testings or procedures, including but not limited to services covered by a health care benefit program***,* the provider "shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both."[44]

This amendment has four parts: (1) mental state, (2) presence of a significant financial interest in administering such tests or procedures, (3) disregard for the standard of care, and (4) remuneration of any kind regardless of the source of payment. Each part functions to protect the patient from fraudulent behavior in the reproductive healthcare space while simultaneously encouraging the best current practices. The fourth prong of this amendment is key to encapsulating fraud regardless of the source of payment. Similar to EKRA, health care benefit programs should be interpreted to encapsulate private payors.[45]

Defining egregiously unnecessary tests and procedures to prove a violation of AWHRRA is complex because, as discussed previously, there are already obstacles to women's healthcare that must not be exacerbated.[46] In order to not exacerbate this problem, the proposed egregious standard should be high and in accordance with the current standard of care. One

[43] *Id.*
[44] *Id.*
[45] 18 U.S.C. § 220.
[46] *See generally* Hossain, *supra* note 17 at 23-35.

instance of an unnecessary test is not enough to satisfy the proposed egregious standard. Egregiously unnecessary procedures should include circumstances where the provider maintains an obvious fraudulent scheme by consistently providing medically unnecessary and inappropriate procedures or tests in order to benefit financially. For example, if in a consistent pattern, ". . . the [provider] inaccurately plays up the benefit of the procedure [or test to] deceive the patient into believing that it is necessary, or inappropriately minimizes the potential risks…"[47] then the provider could be held liable under the AWHRRA. This includes when there are so many occurrences of this deception that there is an obvious scheme to profit rather than provide the proper care. To reiterate, this egregious standard should be a high bar to meet to allow for provider autonomy in providing the best care for the patient and should only be enforced in the most egregious of circumstances like the Ghosh case.

Moreover, it is important to explicitly state in the amendment that the provider disregarded the current standard of care because we want to avoid capturing instances where providers follow any current guidelines that recommend overscreening and, in turn, could improperly face significant liability. The AWHRRA incentivizes providers to stay up to date on the best standard of care to further the goal of protecting the patient. It is important to note that this amendment is by no means advocating for less testing and screening in women's healthcare.

One critique of this amendment is that we do not want to encourage defensive medicine. "Defensive medicine occurs when a provider renders medical service to protect themselves from potential damages."[48] This

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[47] Ean Tam, *Methods to Reduce Medical Over-testing of Patients*, INTERSECT: THE STAN. J. OF SCI., TECH., & SOC'Y, 1, 6 (Apr. 3, 2022), https://ojs.stanford.edu/ojs/index.php/intersect/article/view/2132.
[48] *Id.*

includes potential liability for malpractice claims.[49] As described in one study, "overtesting is a manifestation of defensive medicine." Therefore, the AWHRRA precisely combats defensive medicine and fraudulent practices where providers financially benefit from misusing tests or procedures for financial gain. This amendment is necessary because defensive medicine is a major contributor to healthcare costs,[50] and AWHRRA creates an incentive to lessen unnecessary testing. This incentive would potentially lower the costs for patients and the government in this specific specialty of women's reproductive healthcare. This amendment does not supplant medical malpractice claims but rather compliments the fight against abusive and fraudulent medicine. Others may argue that medical malpractice claims would cover such wrongs against the patient, but this should be in conjunction with medical malpractice suits, and due to its fraudulent behavior and medical wrongdoing, the liability should be two-fold.

This amendment is intended only to capture the most apparent fraud cases where a provider attempts or succeeds at defrauding the patient. In order to limit the scope of the AWHRRA to further a patient-centric approach to protection and only capture fraudulent, harmful behavior, the statutory language should include language that indicates psychological, physical, or financial harm to the patient. As discussed, the language of FCA and AKS only indicates violation if the government is implicated through Federal health care programs. In contrast, AWHRRA extends protection regardless of the source of payment to show the importance of protecting the patient and to promote more affordable healthcare. This is especially important in women's healthcare because women are more likely than men to skip or

[49] *Id.*
[50] *Id.* at 11 ("President Barack Obama would again reference defensive medicine as a major contributor to healthcare costs.").

postpone accessing health care because of the cost.[51] If the fraud and abuse laws remain unchanged, then providers like Dr. Mona Ghosh can escape these laws if they only target out-of-pocket or private insurance payors.

This amendment aligns with the goal of enhancing women's reproductive healthcare. Moreover, the goal of this amendment is not to add more obstacles for women, especially given the already existing mistreatment within basic reproductive health care. Enforcement agencies must acknowledge these barriers before implementing a change with such strength because women simply require a greater need for health care services.[52] Criminalizing egregious fraudulent testing behavior would de-incentivize the fraudulent overtesting of female patients in an effort to give power back to the female patient. This empowerment is needed in the healthcare space where "[w]omen have been accorded neither individuality nor power."[53] Although scholar Catharine Mackinnon would probably argue that criminalizing providers would potentially deprive women, and only women, of the care they need, this amendment is highly narrowed in its approach as we do not want to criminalize routine testing procedures. Rather, this amendment aims to help move medicine to a more efficient and well-rounded healthcare system where providers can confidently provide the most up-to-date practices.

A similar amendment could be made to the FCA. "[T]o prove that a claim is false, fictitious, or fraudulent, the government must show that a medical procedure or the provision of equipment did not occur, or was not medically necessary."[54] As discussed, the FCA is only implicated if the false statement

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[51] Lunna Lopes et al., *Americans' Challenges s with Health Care Costs*, KAISER FAM. FOUND., (Mar. 1, 2024), https://www.kff.org/health-costs/issue-brief/americans-challenges-with-health-care-costs/.
[52] Rapp et al., *supra* note 16.
[53] MacKinnon, *supra* note 22 at 1311.
[54] Larson et al., *supra* note 5 at 1128.

is made to the government for payment by a federally funded healthcare program. Therefore, an amendment to the FCA targeted only towards the reproductive healthcare industry should be made similar to the proposed AWHRRA amendment to incorporate private payers.

VI. CONCLUSION

The proposed amendment, AWHRRA, requires a careful balance of protecting women receiving medical services for their reproductive health and reprimanding wrongdoers. This amendment is aligned with the current fraud and abuse laws, which claim that their purpose is to protect the patient. Therefore, this change only furthers that goal by extending protection beyond federally funded forms of payment to include private insurance and out-of-pocket payments in specific instances of fraud in reproductive healthcare. Not only should this proposed change be made, but it should shed light on the current experiences of women receiving medical care for their reproductive health.

Reforming Stark Law to Address Physician Burnout in Value-Based Care Models

Yasmine Shaaban

I. STARK LAW'S TRANSITION TO A VALUE-BASED CAREE MODEL

Amidst the evolving landscape of healthcare regulations, the Physician Self-Referral Law, known as the "Stark Law", stands as a pivotal point of discussion, particularly with the recent amendment published by the Centers for Medicare and Medicaid Services (CMS) on December 2nd, 2020.[1] Stark Law forbids physicians from referring patients to receive "designated health services" payable by Medicare or Medicaid from entities with whom the physician or a physician's immediate family member has a financial relationship with, unless an exception is met.[2] Before the December 2020 amendment, Stark Law was primarily based on the fee-for-service healthcare model, in which providers were reimbursed based on the volume of services they provided, regardless of the outcomes or quality of care delivered.[3]

In recent years, there has been a shift from fee-for-service models to value-based care models in which payment is based on quality measures and health outcomes.[4] Value-based care is healthcare focused on quality of care, provider performance, and patient experience.[5] Physicians and other providers in this model work together to manage a patient's overall health, while still considering their personal health goals.[6] The amount providers earn for their services correlates with their patient outcomes, such as quality,

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[1] 42 C.F.R §411 (2020).
[2] U.S. DEP'T HEALTH & HUM. SERV., FRAUD & ABUSE LAWS, https://oig.hhs.gov/compliance/physician-education/fraud-abuse-laws/.
[3] Leona Rajaee, *Fee for Service vs Value Based Care: The Differences, Explained,* ELATION HEALTH (June 7, 2023), https://www.elationhealth.com/resources/blogs/fee-for-service-vs-value-based-care-the-differences-explained.
[4] Arvin Garg et al., *Addressing the Social Determinants of Health: Challenges and Opportunities in a Value-Based Model*, 143 PEDIATRICS PERSP. 1 (2019).
[5] *Value-Based Care*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/priorities/innovation/key-concepts/value-based-care (last visited Feb. 20, 2024).
[6] *Id.*

equity, and cost of care.[7] This model aims to hold providers more accountable for improving patient outcomes while providing them greater flexibility to deliver optimal care at the right time.[8]

The 2020 Final Rule, "Modernizing and Clarifying the Physician Self-Referral Regulations"[9], created new exceptions for value-based arrangements designed to provide more flexibility and clarity for healthcare providers engaging in value-based care initiatives.[10] These initiatives prioritize patient outcomes and satisfaction over the volume of services provided, aiming to improve healthcare quality without controlling costs.[11] One of the most significant updates to the Stark Law that the 2020 Final Rule included was the addition of new exceptions "for value-based arrangements that satisfy specified requirements based on the characteristics of the arrangement and the level of financial risk assumed by the parties."[12] The exceptions were based on three levels of risk:[13]

> 1. **Value-based arrangements with full financial risk**: The value-based enterprise must assume full financial risk for "all patient care items and services covered by a payor for each patient in the target patient population."[14] This encompasses "capitation payments", which are fixed payments per patient over a specific timeframe, and, global budget payments from the payor covering all healthcare services and items for the entire patient population under consideration.[15]

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[7] Corinne Lewis et al., *Value-Based Care: What It Is, and Why It's Needed,* THE COMMONWEALTH FUND (Feb. 7, 2023), https://www.commonwealthfund.org/publications/explainer/2023/feb/value-based-care-what-it-is-why-its-needed.
[8] *Id.*
[9] Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations, 85 Fed. Reg. 77492 (Dec. 2, 2020).
[10] *Id.* at 77493.
[11] Lewis, *supra* note 7.
[12] *Id.*
[13] Chad Eckhardt et al., *New Value-Based Enterprise Opportunities in Healthcare,* FROST BROWN TODD (Sept. 12, 2022), https://frostbrowntodd.com/new-value-based-enterprise-opportunities-in-healthcare/.
[14] *Id.*
[15] *Id.*

2. **Value-based arrangements with meaningful downside financial risk:** This exception mandates that the physician must bear "significant financial risk" regarding the remuneration they receive.[16] This obliges the physician to assume the responsibility of repaying or forgoing "10% or more of the remuneration the physician receives under the value-based enterprise for failing to achieve the related purpose or activity."[17]
3. **Any value-based arrangement, without regard to the level of risk, provided specified requirements are met:** This last exception does not require the value-based enterprise or the physician to assume any financial liability.[18] As a result, this exception requires written agreements detailing the value-based activities planned and how they will contribute to the objectives of the enterprise.[19] Further, the writing needs to identify the targeted patient population, nature of the remuneration, methods used to determine the remuneration, and if applicable, the outcome measures against which the recipient of the remuneration is assessed.[20]

II. CHALLENGES WITH STARK LAW IN THE CONTEXT OF VALUE-BASED CARE: PHYSICIAN BURNOUT

Unfortunately, there are challenges to value-based care posed by Stark Law that may contribute to physician burnout.[21] Burnout is a long-term stress reaction that includes emotional exhaustion, depersonalization, and feelings of decreased personal achievement.[22] A 2018 study showed a significant correlation between burnout and patient safety across various facets of

[16] *Id.*
[17] *Id.*
[18] *Id.*
[19] Eckhardt et al., *supra* note 13.
[20] *Id.*
[21] Tom Friedman, *Value-based care will add fire to physician burnout,* MED. ECON.'S (April 24, 2018), https://www.medicaleconomics.com/view/value-based-care-will-add-fire-physician-burnout.
[22] *What is physician burnout?,* AM. MED. ASS'N. (2023), https://www.ama-assn.org/practice-management/physician-health/what-physician-burnout.

healthcare delivery.[23] The presence of burnout was linked to the work process, individual characteristics, and collaborative efforts within healthcare teams.[24] Specific hospital departments and wards with elevated burnout levels experienced a significant decline in teamwork dynamics, safety protocols, and overall job satisfaction.[25] Moreover, heightened levels of burnout were associated with adverse consequences for patients, including patient dissatisfaction and increased vocalization of this dissatisfaction from patients and families.[26] Emotional fatigue and depersonalization exacerbated this, leading healthcare professionals to become distant and indifferent to patient needs, thereby compromising care quality.[27]

Most challenges faced by physicians in the transition to a value-based care model are "often associated with system inefficiencies, administrative burdens, increased regulation, and technology requirements."[28] A 2019 survey asked over 1,000 healthcare leaders to identify barriers posed by the value-based care landscape.[29] One significant barrier identified was the difficulty in collecting and reporting patient information.[30] The respondents reasoned that "if patient data is inaccessible to providers, it is essentially useless in terms of care coordination and preventive medicine."[31] They also identified one of the biggest barriers to the adoption of value-based

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[23] Cíntia de Lima Garcia et al., *Influence of Burnout on Patient Safety: Systematic Review and Meta-Analysis,* 55 MEDICINA (KAUNAS), 553, 556 (2019).
[24] *Id.* at 562.
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] AM. MED. ASS'N., *Measuring and addressing physician burnout* (2023), https://www.ama-assn.org/practice-management/physician-health/measuring-and-addressing-physician-burnout.
[29] *The Future of Value Based Care: 2019 Survey Results,* DEFINITIVE HEALTHCARE., https://www.definitivehc.com/blog/value-based-care-2019-survey-results (last visited Apr. 5, 2024).
[30] *Id.*
[31] *Id.*

payments, regarding practice sustainability, was the everchanging revenue stream and the difficulty in understanding the complexity of financial risk involved in these programs.[32] Another major barrier was a lack of resources, including staffing shortages.[33]

III. Analysis and Proposed Reforms of Stark Law Provisions

A thorough analysis of each problematic provision of the Stark Law will help convey that further reform is indeed necessary to lessen the risk of physician burnout when transitioning to value-based care.

a. Collaborations and Care Coordination

The strict regulations provided by Stark Law may impede efforts for collaborations and partnerships between physicians and non-physician entities, hindering shared financial agreements that may prove essential for improving patient outcomes and reducing costs.[34] Specifically, section (a)(1) of the act prohibits referrals if a physician has a financial relationship with an entity, thereby constraining a provider's ability to refer patients to specific providers or facilities based on their performance in value-based care initiatives.[35] The definition of "financial relationship" in the provision, including "ownership or investment interests" and "compensation arrangements" outlined in section (a)(2), can restrict arrangements that would incentivize coordination and quality improvement in these types of care

[32] *Id.*
[33] *Id.*
[34] Kim Stanger, *Common Stark Concerns for Hospitals,* Holland & Hart (2019).
[35] *supra* note 1.

models.[36] As a result, physicians may feel frustrated by their inability to collaborate effectively, potentially leading to burnout.

Section (a)(1) of the Stark Law should be modified to include provisions allowing referrals by physicians with financial relationships with entities if such referrals are deemed necessary for maintaining the quality of patient care and are aligned with value-based care initiatives. This provision should be added as part 'C' in section (a)(1) and should state:

> "Notwithstanding the provisions of subparagraphs (A) and (B), a physician may make a referral to an entity with which they have a financial relationship with, provided that such referral meets the conditions outlined in section (g), as deemed necessary for maintaining the quality of patient care and alignment with value-based care initiatives."

A phased approach is necessary to roll out this revision effectively. In the short term, regulatory agencies and healthcare organizations will need to conduct thorough assessments of existing collaborations and financial arrangements to identify areas where current Stark Law provisions create obstacles. Simultaneously, education and training programs should be developed to ensure healthcare providers understand the revised regulations and compliance requirements. In the long term, the implementation process will involve updating policies, guidelines, and compliance frameworks to accommodate the proposed amendments.

Critics of this proposed reform may argue that allowing referrals based on financial relationships risks prioritizing financial gain over patient welfare. They contend that such a provision would introduce ambiguity and potential conflicts of interest, undermining the integrity of the healthcare system. However, this amendment would encourage physicians to make referrals based on performance and outcomes of providers, regardless of a financial relationship with them. This approach ensures optimal patient care while

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[36] *Id.*

alleviating the burden of restrictive regulations that contribute to physician burnout.[37]

Additionally, the broad definition of "compensation arrangement" and "remuneration" in section (h)(1)(A) may restrict innovative payment models and value-based arrangements that involve remuneration between physicians and entities.[38] This section should be amended to include exemptions or waivers for financial relationships *essential* for the development and operation of integrated care models, establishing criteria for eligibility, compliance requirements, and safeguards against fraud and abuse.

Allowing healthcare providers to establish necessary financial relationships for effective collaboration in integrated care would facilitate seamless coordination— a critical component of value-based care models.[39] This adjustment would encourage physicians to deliver more comprehensive care without feeling hindered by regulatory constraints, ultimately mitigating the risk of burnout.[40]

To effectively implement this proposed amendment, a strategic and comprehensive approach, involving collaboration among stakeholders — regulatory bodies, healthcare organizations, and legal experts — is necessary. This process involves gathering input from various healthcare professionals and developing education and training programs to inform healthcare

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[37] *CMS Announces Historic Changes to Physician Self-Referral Regulations*, CTRS. FOR MEDICARE & MEDICAID SERVS., https://www.cms.gov/newsroom/press-releases/cms-announces-historic-changes-physician-self-referral-regulations (Nov. 20, 2020).
[38] *supra* note 1.
[39] DEFINITIVE HEALTHCARE, *supra* note 29.
[40] Diana Carrau & Jeffrey Janis, *Physician Burnout: Solutions for Individuals and Organizations,* 9 PRS GLOBAL OPEN 1, 3 (2021).

providers about the proposed exemptions and waivers. Over time, regulations, guidelines, and compliance frameworks will need to be updated to reflect these changes.

While critics may argue that such exemptions risk compromising the law's core purpose of preventing financial conflicts of interest, addressing physician burnout through targeted exemptions for financial relationships in integrated care models outweighs potential costs. Burnout among physicians not only impacts their well-being, but also compromises patient care quality and safety.[41] Providing exemptions could reduce administrative burdens, enhance job satisfactions, and improve teamwork, thereby benefiting patient outcomes and care coordination, ultimately fostering a more resilient healthcare workforce.[42]

b. Incentive Alignment

The updates to Stark Law hamper the development of incentive structures that align the interests of physicians, hospitals, and other entities, in achieving high-quality, cost-effective care, and may lead to a perception of a lack of financial rewards for value-based care efforts. Healthcare providers, usually driven by incentives, may feel demotivated due to the hindrance in developing effective incentive structures, which can lead to burnout. Section (e)(2) imposes requirements for compensation arrangements to be consistent with fair market value, and not based on the volume or value of referrals.[43] These constraints can hinder the ability to design compensation models that incentivize quality and efficiency improvements in value-based care.[44]

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[41] Lauren McTaggart & J. Patrick Walker, *The relationship between resident physician burnout and its' effects on patient care, professionalism, and academic achievement: A review of the literature,* 4 HEALTH SCI. REV. 1, 3 (2022).
[42] *Id.* at 4.
[43] *supra* note 1.
[44] *Id.*

Section (e)(2) should be revised to explicitly permit the development of incentive structures that align with value-based care goals, enabling healthcare entities to motivate physicians effectively and reduce burnout risks. It should be added as the third subsection under "B", as (e)(2)(B)(iii) and state the following:

> "Expressly permits the development of incentive structures that align the interests of physicians, hospitals, and other entities in achieving high-quality, cost-effective care. Such incentive structures may include mechanisms aimed at rewarding physicians for their contribution to value-based care initiatives, with flexibility provided to design incentives that motivate physicians and reduce the risk of burnout associated with perceived lack of financial rewards."

This amendment would encourage the creation of innovative incentive mechanisms aimed at rewarding physicians for their contributions to value-based care initiatives. By providing flexibility in designing incentive structures, healthcare entities can better motivate physicians, thereby reducing the risk of burnout associated with the perceived lack of financial rewards and fostering a culture of collaboration and continuous improvement in patient care delivery.

When this proposed amendment is first implemented, informational sessions and training programs should be conducted to educate healthcare providers, administrators, and legal teams about the updated regulations. Long term objectives will focus on the gradual implementation of revised compensation models and incentive structures across healthcare organizations. Stakeholders will need to collaborate to create and improve creative payment systems that prioritize quality and efficiency improvements within value-based care frameworks.

Critics of this proposed reform may argue that amending this section to permit such structures risks compromising the law's fundamental principles of preventing financial incentives that could influence patient care decisions. They would likely reason that allowing incentives tied to referrals or specific healthcare services may incentivize overutilization or inappropriate care, potentially compromising patient safety. However, safeguards will be implemented to ensure that any incentive mechanisms comply with ethical and legal standards. These safeguards include rigorous monitoring and oversight to prevent abuse or misconduct, as well as ongoing evaluation to assess the impact on patient outcomes and healthcare costs.

c. Legal Uncertainties

The intricate nature of Stark Law regulations creates legal uncertainties for physicians, leading to a fear of unintentional non-compliance, contributing to heightened stress and anxiety, and potential burnout.[45] Section (b) outlines requirements for exceptions to the referral prohibition, which may deter physician participation in value-based care initiatives due to compliance concerns.[46] Specific exceptions, such as in-office ancillary services outlined in (b)(2), or prepaid plans outlined in (b)(3), have complex criteria that must be met, which could limit the flexibility of arrangements in value-based care models.[47]

A provision should be introduced within section (b) that provides clear and comprehensive guidelines for physicians regarding compliance with Stark Law regulations. This reformation should include accessible resources, such as standardized training programs, online tools, and expert consultation

[45] Michael E. Joseph, *Stark: A stagnant law for an evolving industry,* MCAFEE & TAFT (2016), https://www.mcafeetaft.com/stark-a-stagnant-law-for-an-evolving-industry/.
[46] *supra* note 1.
[47] *Id.*

services aimed at educating physicians on the intricacies of Stark Law and how to ensure compliance in their daily practices. It should be placed after (b)(5), before the next section, and should state:

> "Guidance and Compliance Support for Physicians:
>
> 1. Clear and Comprehensive Guidelines: The Secretary shall establish clear and comprehensive guidelines for physicians to ensure compliance with the regulations set forth in this section.
> 2. Accessible Resources: The Secretary shall develop and provide accessible resources to assist physicians in understanding and adhering to the Stark Law. These resources shall include, but not be limited to, standardized training programs, online tools, and expert consultation services.
> 3. Education and Training Programs: The Secretary shall facilitate the development and dissemination of standardized training programs designed to educate physicians on the intricacies of the Stark Law and provide guidance on how to ensure compliance in their daily practice.
> 4. Online Tools: The Secretary shall establish online tools that enable physicians to easily access relevant information, navigate regulatory requirements, and receive real-time guidance on compliance issues.
> 5. Expert Consultation Services: The Secretary shall establish expert consultation services staffed by knowledgeable professionals who can provide personalized guidance and assistance to physicians seeking clarification on Stark Law compliance matters."

By offering clarity and support in navigating the legal complexities, this reform aims to alleviate the fear of unintentional non-compliance among physicians, ultimately reducing stress and anxiety, and mitigating the risk of burnout. When the revisions are first implemented, a comprehensive communication plan will need to be executed to inform physicians, healthcare entities, and legal professionals about the changes introduced,

including detailed explanations of the newly added provisions, particularly the establishment of guidance and compliance support for physicians. Long term goals will focus on the gradual rollout of accessible resources and support mechanisms to assist physicians in navigating the complexities of Stark Law regulations, such as training programs, online tools, and expert consultation services.

To address potential concerns about the impact of legal uncertainties on physician well-being, proactive measures will be taken to alleviate fears of unintentional non-compliance. By offering clear and comprehensive guidelines, as well as accessible resources and support services, physicians will be better equipped to navigate the intricacies of Stark Law. Ultimately, this will help reduce stress and anxiety levels among healthcare professionals, mitigating the risk of burnout and fostering a more supportive and compliant healthcare environment.

Critics may argue that introducing additional provisions for guidance and compliance support risks inadvertently encouraging a reliance on external resources rather than fostering a deeper understanding of the law's principles. They may explain that such reliance could lead to a superficial approach to compliance and potentially increase the risk of unintentional non-compliance. However, safeguards will be implemented to ensure that these resources complement, rather than replace, physicians' understanding of the fundamental principles of Stark Law. Emphasis will be placed on fostering a deeper comprehension of regulatory requirements while providing practical support to address specific compliance challenges.

d. Health Equity

While value-based care models focus on quality and cost, they may neglect vulnerable groups.[48] Providers might prioritize patients with better outcomes, leaving those with complex needs behind.[49] Financial incentives could discourage treating high-risk or costly patients, deepening disparities.[50] Without targeted efforts, this transition to a value-based care model risks widening the gap in healthcare access and outcomes, especially in marginalized communities. Section (e)(5) places limitations on remuneration for physician recruitment, which may hinder efforts to attract physicians to underserved areas where value-based care initiatives are needed, potentially limiting access to care and the success of value-based care models in those areas.[51]

Section (e)(5) of the Stark Law should be revised to exempt remuneration for physician recruitment in underserved areas from limitations, recognizing the importance of enhancing access to healthcare services in those regions. Underserved areas would be defined by federal, or state agencies based on various criteria, including population demographics and healthcare provider shortages. Remuneration for recruitment purposes would be permissible, provided it directly addresses documented shortages and promotes value-based care initiatives. Eligible forms of remuneration may include signing bonuses, relocation assistance, and support for medical infrastructure

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[48] Hillit Meidar-Alfi, *Health equity: The challenge facing physicians in the move to value-based care,* MED. ECON. (2023), https://www.medicaleconomics.com/view/health-equity-the-challenge-facing-physicians-in-the-move-to-value-based-care.
[49] *Id.*
[50] *Id.*
[51] 42 C.F.R §411 (2020).

development. Entities should be required to maintain records demonstrating recruitment's impact on access to care and value-based care objectives. Exemptions would not extend to arrangements lacking demonstrable contributions to addressing shortages or advancing value-based care.

This revision will be implemented using a strategic approach aiming to strike a balance between the need to address healthcare disparities, particularly in underserved areas, and the promotion of value-based care programs. In the short term, the proposed modifications will be communicated to stakeholders through extensive outreach, with a focus on the importance of improving access to healthcare services for marginalized communities. This will include outreach to federal and state agencies responsible for defining underserved areas based on population demographics and healthcare provider shortages.

Long term goals will center on the gradual implementation of the revised section, focusing on enhancing access to healthcare services in underserved regions through targeted recruitment efforts. Collaborative partnerships between healthcare entities, federal and state agencies, and community organizations will be necessary to identify and address healthcare provider shortages in marginalized communities. This will involve strategic planning to allocate resources effectively and ensure that remuneration for recruitment purposes directly contributes to addressing shortages and promoting value-based care initiatives.

Critics may argue that amending this section to exempt remuneration for physician recruitment in underserved areas risks diluting regulatory oversight and potentially incentivizing recruitment practices that prioritize financial incentives over patient needs. They might reason that exempting certain arrangements from limitations could open the door to abuse or manipulation, potentially exacerbating disparities rather than addressing them. However,

exemptions for remuneration in underserved areas will be carefully structured to align with overarching goals of enhancing access to care and improving healthcare outcomes. Any exemptions granted will be subject to rigorous scrutiny to ensure that they effectively address documented shortages and contribute to advancing value-based care objectives. Additionally, entities seeking exemptions will be required to demonstrate a clear and documented contribution to addressing healthcare provider shortages and advancing value-based care objectives. Robust record-keeping and reporting mechanisms will be established to monitor the impact of recruitment efforts on access to care and healthcare outcomes in underserved communities.

D. CONCLUSION

Through a comprehensive analysis of Stark Law provisions and their impact on physician burnout, it has become evident that targeted legislative reform is essential for facilitating the successful integration of value-based care initiatives. Stark Law reform stands as a mechanism for fostering collaborative healthcare partnerships, incentivizing quality improvement endeavors, and alleviating administrative burdens on providers, thereby laying a foundation for sustainable value-based care implementation. By addressing the root causes of physician burnout, these reforms also hold promise for enhancing health outcomes and narrowing healthcare disparities across diverse populations.