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Healthcare Fraud & Corruption
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Here to Stay: Telehealth & New Jersey's Regulatory Framework.

I. Introduction

According to the Centers for Disease Control and Prevention, 1 in 5 children, either currently or at some point during their life, have had a seriously debilitating mental illness.¹ The average delay between the onset of symptoms and intervention is 8-10 years.² This delay in recognizing and treating mental illness amongst children and adolescents results in increases in school drop outs, juvenile incarceration, and suicide.³ Something must be done to improve access to quality mental healthcare in the United States.

In January 2019, the New Jersey Department of Health (NJ DOH) received \$2.3 million, over the course of five years, from the federal Health Resources and Services Administration (HRSA), and the Nicholson Foundation, to “enhance primary, behavioral, and mental healthcare for children and adolescents through telehealth consultation and new education programs.”⁴ The NJ DOH intends to alleviate some of the logistical issues that consumers face when seeking healthcare through telehealth.⁵ For families juggling work, school, extra-curricular activities and a home life, making time to see a doctor can often be difficult. Telehealth services can address this issue by putting the doctor at your fingertips.

¹ Learn About Mental Health - Mental Health - CDC, Centers for Disease Control and Prevention, <https://www.cdc.gov/mentalhealth/learn/index.htm> (last visited May 11, 2019).

² Mental Health Facts – Children & Teens- National Alliance on Mental Illness, <https://www.nami.org/NAMI/media/NAMI-Media/Infographics/Children-MH-Facts-NAMI.pdf>

³ id.

⁴ News, Department of Health | News | New Jersey Department of Health Awarded \$2.3 Million to Enhance Pediatric Mental Health Care through Telehealth (2019), <https://www.nj.gov/health/news/2019/approved/20190110a.shtml>.

⁵ id.

Expanding access to healthcare through telehealth is not without its pitfalls. With new and innovative technology comes an enhanced risk of fraud and misuse. Since federal healthcare fraud laws have limitations, particularly when it comes to regulating telehealth services, it is imperative that New Jersey have appropriate consumer protections in place. This paper will start by interpreting existing Telehealth and Telemedicine statutes and move on to discuss fraud concerns, the limitations of federal statutes, existing New Jersey statutes and any gaps in the existing regulatory framework that New Jersey should address before promoting further expansion of healthcare services through telehealth.

II. What are Telehealth and Telemedicine?

The terms telehealth and telemedicine are often used interchangeably because both terms refer to the use of technology to provide healthcare at a distance. Telehealth refers to a broad scope of activities which can include both clinical and non-clinical services.⁶ Telemedicine is used more narrowly to refer specifically to clinical services.⁷ Since telehealth is defined more broadly, the federal Medicare statute uses the term telehealth exclusively. Some state statutes, like New Jersey's, utilize both terms in an effort to eliminate any ambiguity within the law.

Under the Medicare Statute, the practice of telehealth allows a physician or practitioner who is licensed to practice under state law, and is located at a distant site, to bill and receive payment for services delivered to a patient, located at an originating site, via an interactive telecommunications system.⁸ Put simply, telehealth services utilize telephone, video and internet technologies to increase access to healthcare providers. This is often done through video

⁶ What's the difference between telemedicine and telehealth?, AAFP Home (2018), <https://www.aafp.org/media-center/kits/telemedicine-and-telehealth.html>.

⁷ id.

⁸ Telehealth Services, 42 CFR § 410.78 (2011).

conferencing, remote patient monitoring, and store and forward technology.⁹ This technology can be used to enhance the quality of care provided to patients while simultaneously reducing costs, provided that insurance is willing to cover the services.

Mobile applications are one way that telehealth services are helping to expand access to healthcare. Known as mHealth, these applications can keep track of health measurements, set medication and appointment reminders, and share information with clinicians.¹⁰ Users have a variety of mHealth tools at their disposal, including asthma and diabetes management tools.¹¹ A study by Wyoming Medicaid showed that women who used the mHealth application “Due Date Plus”, an application for tracking pregnancy milestones, showed increased compliance with prenatal care instructions and decreased occurrences of infants born underweight.¹²

For patients living in rural areas or without a reliable means of transportation, physicians may utilize video conferencing technology to provide appointments. This technology has also been utilized in the treatment of military personnel and inmates. In February 2017, New Jersey Department of Health awarded a \$290,000 grant to Virtua Health for the purpose of assisting veterans in need of access to primary and behavioral healthcare but face mobility challenges.¹³ The NJ DOH anticipates that the expansion of services to veterans will help remove a stigma against seeking treatment and allow providers to better care for conditions such as depression, post-traumatic stress disorder, and even brain injury.¹⁴ The South Carolina Department of Corrections and the Medical University of South Carolina have teamed up to provide healthcare

⁹ What is Telehealth? – NEJM Catalyst, NEJM Catalyst (2019), <https://catalyst.nejm.org/what-is-telehealth/>.

¹⁰ id.

¹¹ id.

¹² id.

¹³ News | Christie Administration Awards Virtua \$290,000 to Serve Veterans Via Telehealth (2017), <https://www.state.nj.us/health/news/2017/20170127a.shtml>.

¹⁴ id.

to inmates using video scopes and high resolution cameras.¹⁵ This practice reduces prisoner transportation costs and increases safety by keeping the inmates in and the providers out of correctional facilities.¹⁶

Telehealth also includes Remote Patient Monitoring which involves reporting, collection, transmission, and evaluation of patient health data through devices such as wearables, mobile devices, smartphone applications, and internet enabled computers.¹⁷ In partnership with Stanford University, Apple is testing whether its Apple Watch can be used to detect irregular heart patterns, and AliveCor's KardiaBand allows Apple Watch wearers to perform electrocardiograms in 30 seconds that can easily be transmitted to physicians.¹⁸ With such technology becoming more pervasive throughout society, telehealth services are becoming a part of our daily lives and routines.

It can be hard to imagine government programs, like Medicare and Medicaid covering the cost of Apple Watches for each beneficiary. In order to understand the scope of what Medicare is willing to cover, it is important to look at some of the terms defined within statute. Distant site means the site at which the physician or practitioner delivering the service is located at the time the service is provided via a telecommunications system.¹⁹ These means that a physician could potentially provide care to a patient anywhere in the United States, provided that the physician has met all of the licensing requirements of the state that houses the originating site. Medicare's definition and regulation of originating sites makes understanding the scope of activity covered by Medicare complicated. Originating site means the location of an eligible Medicare beneficiary at

¹⁵ id.

¹⁶ id.

¹⁷ What is Telehealth? – NEJM Catalyst, NEJM Catalyst (2019), <https://catalyst.nejm.org/what-is-telehealth/>.

¹⁸ id.

¹⁹ Telehealth Services, 42 CFR 410.78(a)2 (2011).

the time the service being furnished via a telecommunications system occurs.²⁰ 42 CFR 410.78(b)

4 places further limitations on what constitutes an originating site:

Except as provided in paragraph (b)(4)(iv) of this section, originating sites must be located in a health professional shortage area (as defined under section 332(a)(1)(A) of the Public Health Service Act (42 U.S.C. 254e(a)(1)(A)) that is within a rural census tract of an MSA as determined by the Health Resources and Services Administration as of December 31st of the preceding calendar year.²¹

Less common requirements include being located in a county that is not included in a Metropolitan Statistical Area as defined in section 1886(d)(2)(D) of the Act as of December 31st of the preceding year, or participating in a Federal telemedicine demonstration project that has been approved prior to December 31, 2000, regardless of its geographic location.²²

This section of the statute can be a lot to digest. The important takeaways are that the location must be in a rural designated, healthcare professional shortage area or participating in a federal demonstration project. These site limitations severely limit the number of healthcare providers in New Jersey that qualify to bill Medicare for telehealth services rendered. In fact, only two healthcare providers, and one correctional facility, meet both the rural designation and Health Care Provider Shortage area requirements for billing Medicare.²³ This means that it is up to State-run insurance, such as Medicaid, and private insurers to cover the costs of telehealth services for a majority of New Jersey.

²⁰ id.

²¹ id.

²² Telehealth Services, 42 CFR 410.78(b)4 (2011).

²³ HPSA Find, <https://data.hrsa.gov/tools/shortage-area/hpsa-find> (last visited Apr 2019).

On July 21, 2017, the New Jersey Legislature passed the Telemedicine and Telehealth Act.²⁴ This statute derives much of its language and requirements from the federal Medicare statute. Telehealth and Telemedicine providers are required to:

*be validly licensed, certified, or registered, pursuant to Title 45 of the Revised Statutes, to provide such services in the State of New Jersey; (2) remain subject to regulation by the appropriate New Jersey State licensing board or other New Jersey State professional regulatory entity; (3) act in compliance with existing requirements regarding the maintenance of liability insurance; and (4) remain subject to New Jersey jurisdiction if either the patient or the provider is located in New Jersey at the time services are provided.*²⁵

While the New Jersey Act adopts many of the same definitions as Medicare, it does not set the same geographic limitations on an originating site. It expands access to telehealth services by defining an originating site as “a site at which a patient is located at the time that health care services are provided to the patient by means of telemedicine or telehealth.”²⁶ The statute contains no additional provisions which would limit the geographic scope of coverage for telehealth services.

New Jersey further expanded access to telehealth services by requiring that health insurers view health services rendered via telehealth as equivalent to services provided in-person.

*A carrier that offers a health benefits plan in this State shall provide coverage and payment for health care services delivered to a covered person through telemedicine or telehealth, on the same basis as, and at a provider reimbursement rate that does not exceed the provider reimbursement rate that is applicable, when the services are delivered through in-person contact and consultation in New Jersey.*²⁷

²⁴ N.J. STAT. ANN. § 45:1-61

²⁵ *Id.* § 45:1-62

²⁶ *Id.* § 45:1-61

²⁷ N.J. STAT. ANN. § 26:2S-29(a)

A similar provision of the statute applies the same requirement to all state run insurance programs. This guarantees that all state regulated providers must cover telehealth services to the same extent that they would in-person care. This resolves one of the major problems facing many states with regards to telehealth, the willingness of insurers to cover the costs of services.

Another key issue facing telehealth is the proper establishment of a doctor-patient relationship. In order to protect patients during the rapid expansion of telehealth services, New Jersey set down requirements for establishing such a relationship. When first initiating contact between a telehealth service provider and a patient, it is important to ensure that a proper doctor-patient relationship has been established. With the exception of prescribing Schedule II controlled dangerous substances, an in-person visit is not required in order to establish a proper doctor-patient relationship in New Jersey²⁸. A telehealth provider must, at a minimum, identify the patient using the patient's name, date of birth, phone number, and address.²⁹ A provider must also divulge their own credentials and, prior to initiating contact, review the patient's medical records and determine if the provider may be able to provide the same standard of care through telemedicine that they would during an in-person visit.³⁰

In order to facilitate, and properly regulate, this expansion of telehealth services in New Jersey, State licensing boards are required to promulgate rules. These rules are to:

include best practices for the professional engagement in telemedicine and telehealth; ensure that the services patients receive using telemedicine or telehealth are appropriate, medically necessary, and meet current quality of care standards; include measures to prevent fraud and abuse in connection with the use of telemedicine and telehealth, including requirements concerning the filing of claims and maintaining appropriate records of services provided; and provide substantially similar metrics for evaluating quality of care and

²⁸ N.J. STAT. ANN. § 45:1-63

²⁹ id.

³⁰ id.

*patient outcomes in connection with services provided using telemedicine and telehealth as currently apply to services provided in person.*³¹

Before any of this can be done, state licensing boards are waiting on findings from the Telehealth and Telemedicine Review Commission. The Commission was established by the Telehealth and Telemedicine act for the purposes of making recommendations on executive, legislative, regulatory, and administrative actions necessary to promote and improve quality and access to telehealth and telemedicine.³² It is to present a report of its recommendations to the Governor, Department of Health, and State licensing boards two years after its first meeting.³³ Since the seventh commissioner was appointed in February 2018, the commission has until February 2020 to present its findings.³⁴ It is not likely that any State licensing boards will take regulatory action prior to receiving the recommendations of the review commission. With the Review Commission's findings outstanding, and access to health care via telemedicine growing progressively, it is important to analyze the telehealth service industry in New Jersey, its exposure to fraud and abuse, the regulatory framework designed to protect consumers, and any solutions that may be required to enhance consumer protection.

III. Fraud and Abuse Considerations

As access to telehealth services expand, so does the risk of fraud schemes utilizing telehealth. Most recently, the FBI and HHS-OIG, in connection with the Medicare Fraud Strike Force (MFSF), investigated a \$1.7 billion fraud scheme involving durable medical equipment (DME) and telehealth service companies.³⁵ The MFSF brings together members of the Office of

³¹ Id. § 45:1-62(i)1a.

³² Id. § 45:1-65(a).

³³ Id. § 45:1-65(f).

³⁴ id.

³⁵ One of the Largest Health Care Fraud Schemes Results in Charges Against 24 Individuals Responsible for Over \$1.2 Billion in Losses, THE UNITED STATES DEPARTMENT OF JUSTICE (2019),

the Inspector General, Department of Justice, United States Attorneys, FBI, and local law enforcement.³⁶ The Newark/Philadelphia division, which played a role in prosecuting investigating this case, was formed as recently as August 2018.³⁷

The case involved 24 defendants, including five telemedicine companies, dozens of DME companies, and three licensed medical professionals.³⁸ Participants in the scheme contacted hundreds of elderly and/or disabled Medicare beneficiaries from calls centers in the Philippines and Latin America.³⁹ Callers would up-sell beneficiaries in order to get them to accept free to low cost DME braces that were not medically necessary.⁴⁰ In some cases, beneficiaries would be sent, and Medicare would be billed for, multiple braces.⁴¹ When the time came for consumers caught in this scheme to actually require braces, Medicare would often deny coverage due to previous, unnecessary billing for the same DME brace.⁴²

MFSF Attorneys have brought charges, in New Jersey, against participants for illegal health care kickbacks, international money laundering, conspiracy to commit health care fraud, and health care fraud.⁴³ Specifically, John DeCoroso, M.D. of Toms River, New Jersey was charged for writing medically unnecessary prescriptions, often without ever speaking to patients, while working for two telemedicine companies.⁴⁴

<https://www.justice.gov/opa/pr/federal-indictments-and-law-enforcement-actions-one-largest-health-care-fraud-schemes> (last visited Apr 2019).

³⁶ Medicare Fraud Strike Force, HHS (2017), <https://oig.hhs.gov/fraud/strike-force/> (last visited Apr 2019).

³⁷ id.

³⁸ One of the Largest Health Care Fraud Schemes Results in Charges Against 24 Individuals Responsible for Over \$1.2 Billion in Losses, THE UNITED STATES DEPARTMENT OF JUSTICE (2019),

³⁹ id.

⁴⁰ id.

⁴¹ id.

⁴² id.

⁴³ id.

⁴⁴ id.

In November 2018, Dr. Bernard Ogon, of Burlington, New Jersey, was arrested for his role in a telemedicine scheme that resulted in Dr. Ogon unnecessarily prescribing expensive, compounded medications to patients.⁴⁵ According to the government, telemedicine companies would provide Dr. Ogon with pre-filled out prescriptions and Dr. Ogon would sign off on these prescriptions without ever establishing a proper doctor-patient relationship.⁴⁶ In some cases, Dr. Ogon would even sign for prescriptions for patients located in states where he was not licensed to practice.⁴⁷ The participating telemedicine companies would pay Ogon on a per-prescription basis.⁴⁸ Dr. Ogon was charged with one count of conspiracy to commit healthcare fraud.⁴⁹

On February 5, 2018, Monty Ray Grow, a former NFL player, was convicted of conspiracy to commit health care fraud by a federal jury for his involvement in a telemedicine scheme designed to defraud Tricare health care of nearly \$20 million.⁵⁰ Tricare is a government program for active and retired members of the United States Military and their families. Grow would induce Tricare beneficiaries to order expensive, medically unnecessary, compound pharmaceuticals by paying them directly or indirectly for their prescriptions.⁵¹ He would also pay telemedicine companies whose doctors wrote these prescriptions, knowing that these doctors never examined patients.⁵² The prescription prices would be inflated using artificially engineered ingredients designed to maximize profits.⁵³ Once Tricare covered the cost of the prescription, Grow would

⁴⁵ Burlington, New Jersey, Doctor Arrested for Role in \$20 Million Telemedicine Compounded Medication Scheme, THE UNITED STATES DEPARTMENT OF JUSTICE (2018), <https://www.justice.gov/usao-nj/pr/burlington-new-jersey-doctor-arrested-role-20-million-telemedicine-compounded-medication> (last visited Apr 2019)

⁴⁶ id.

⁴⁷ id.

⁴⁸ id.

⁴⁹ id.

⁵⁰ Tampa Resident Convicted for Involvement with Tricare Health Care Fraud Scheme, THE UNITED STATES DEPARTMENT OF JUSTICE (2018), <https://www.justice.gov/usao-sdfl/pr/tampa-resident-convicted-involvement-tricare-health-care-fraud-scheme> (last visited Apr 2019).

⁵¹ id.

⁵² id.

⁵³ id.

split the profits with the participating pharmacy.⁵⁴ Marty Grow was convicted on 18 counts of conspiracy to commit health care fraud, conspiracy to pay and receive health care kickbacks, unlawful receipt of kickbacks, and money laundering.⁵⁵ He is currently serving a term of over 20 years in federal prison.⁵⁶

Telemedicine fraud schemes do not always target government benefits exclusively. On October 12, 2018, the Federal District Court for the Eastern District of Tennessee unsealed a 32 count indictment that charged four individuals and seven companies in a \$1 billion fraud scheme.⁵⁷ This included the unsealing of two plea agreements in which HealthRight, LLC, a telemedicine company, and Scott Roix pleaded guilty to felony conspiracy and conspiracy to commit wire fraud for their involvement in the telemedicine scheme.⁵⁸ The scheme involved fraudulently soliciting insurance information from private insurance beneficiaries for the purposes of prescribing pain creams, and other similar products, at an inflated price.⁵⁹ The indicted defendants all face charges of conspiracy to commit health care fraud, mail fraud, and introducing misbranded drugs into interstate commerce.⁶⁰

These various schemes show that fraud and abuse within the telehealth industry is not a one-off occurrence. It is important to ensure the proper regulatory framework is in place to deter fraud and misuse before expanding the availability of telehealth services in New Jersey. “New

⁵⁴ id.

⁵⁵ id.

⁵⁶ Buster Thompson, MONTY RAY GROW, INVERNESS NATIVE AND FOOTBALL STANDOUT, SENTENCED TO MORE THAN 20 YEARS FOR HEALTH CARE SCHEME CHRONICLE ONLINE (2018), https://www.chronicleonline.com/news/crime_and_courts/monty-ray-grow-inverness-native-and-football-standout-sentenced-to/article_36d6be9c-41bc-11e8-a1e9-ff949315b0f6.html (last visited Apr 2019).

⁵⁷ Four Men and Seven Companies Indicted for Billion-Dollar Telemedicine Fraud Conspiracy, Telemedicine Company and CEO Plead Guilty in Two Fraud Schemes, THE UNITED STATES DEPARTMENT OF JUSTICE (2018), <https://www.justice.gov/usao-edtn/pr/four-men-and-seven-companies-indicted-billion-dollar-telemedicine-fraud-conspiracy> (last visited Apr 2019).

⁵⁸ id.

⁵⁹ id.

⁶⁰ id.

Jersey is home to some of the best healthcare facilities and most successful pharmaceutical companies in the country,” said U.S. Attorney Craig Carpenito. “Unfortunately, that also means that we offer substantial targets for those who would try to defraud the health care system...”⁶¹

The United States is seeing a rapid increase in enforcement activity, relating to telehealth service providers, over a short period of time. In order to facilitate successful prosecution within the healthcare industry, it is important to ensure that the proper regulatory tools are in place. While federal statutes exist to prevent fraud against federally funded insurance programs, New Jersey must make sure that its own regulations provide sufficient fraud protections. The most common tools for regulating telehealth service companies are the False Claims Act, Anti-Kickback Statute, Stark Law, and, tying them all together, parallel proceedings. Each tools should be analyzed when determining the effectiveness of New Jersey’s regulatory scheme.

a. False Claims

The most glaring issue presented by the telemedicine schemes described above is violation of the False Claims Act (FCA). The FCA is a general statute that imposes civil penalties on any person who “knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval.”⁶² Unfortunately for participants in these schemes, the consequences for filing a false claim with a federal healthcare program do not stop at civil penalties. The Social Security Act, which houses the Medicare and Medicaid statutes, imposes criminal liability on “whoever knowingly and willfully makes or causes to be made any false statement or representation of a

⁶¹ Assistant Attorney General Benczkowski Announces Newark/Philadelphia Medicare Fraud Strike Force to Focus on Health Care Fraud and Illegal Opioid Prescriptions, The United States Department of Justice (2018), <https://www.justice.gov/opa/pr/assistant-attorney-general-benczkowski-announces-newarkphiladelphia-medicare-fraud-strike> (last visited Apr 2019).

⁶² False Claims Act, 31 USC § 3729(a)1.

material fact in any application for any benefit or payment under a Federal health care program...”⁶³

The first instance of the False Claims Act action against a telehealth provider was brought in 2016.⁶⁴ The Federal government entered in to a \$36,000 settlement with Dr. Anton Fry and CPC Associates of Danbury, Connecticut.⁶⁵ In this matter, the government alleged that Dr. Fry and CPC Associates submitted improper claims to Medicare for psychiatric services provided over the phone.⁶⁶ The patients that Dr. Fry was providing services for did not reside within a rural, health professional shortage area making them ineligible for telehealth service coverage under Medicare.⁶⁷ Any attempt by Dr. Fry to bill Medicare for these services would be considered violations of the False Claims Act.

In order to protect those with private insurance from these types of telemedicine schemes, New Jersey has its own False Claims Act equivalent; The New Jersey Insurance Fraud Prevention Act.⁶⁸ The act is violated when a person or practitioner “presents or causes to be presented any written or oral statement as part of, or in support of or opposition to, a claim for payment or other benefit pursuant to an insurance policy or the "Unsatisfied Claim and Judgment Fund Law".⁶⁹ The person or practitioner must do so “knowing that the statement contains any false or misleading information concerning any fact or thing material to the claim.”⁷⁰ The act also grants the Commissioner of the New Jersey Department of Banking and Insurance authority to bring civil

⁶³ Medicare & Medicaid, 42 USC § 1320a-7b(a)

⁶⁴ Amy Lerman, Telehealth Growth = Expansion of Fraud & Abuse Enforcement, AHLA Connections, March 2019.

⁶⁵ id.

⁶⁶ id.

⁶⁷ id.

⁶⁸ N.J. STAT. ANN. § 17:33A-2.

⁶⁹ id.

⁷⁰ id.

action and levy civil administrative penalties against any person that has violated any provision of the act.⁷¹

State Prosecutors may also bring criminal charges for Health care claims fraud under the New Jersey Criminal Code.⁷² The criminal statute defines Health care claims fraud as:

*making, or causing to be made, a false, fictitious, fraudulent, or misleading statement of material fact in, or omitting a material fact from, or causing a material fact to be omitted from, any record, bill, claim or other document, in writing, electronically or in any other form, that a person attempts to submit, submits, causes to be submitted, or attempts to cause to be submitted for payment or reimbursement for health care service.*⁷³

Practitioners that knowingly commit health care claims fraud are guilty of a second degree crime and subject to 5-10 years imprisonment and a fine of up to five times the pecuniary benefit obtained.⁷⁴

b. Anti-kickback Statutes

The second major violation apparent in each of the described telemedicine schemes is of the Federal Anti-Kickback statute (AKS). The AKS originates from the same section of the Social Security Act that allows criminal sanctions for false claims.⁷⁵ It prohibits transactions intended to induce remunerations, such as kickbacks, bribes or rebates, of any kind.⁷⁶ Whoever knowingly solicits, receives, or pays any remuneration in return for referrals or the purchase, lease, order, of goods and services that may, in part, be billed to a Federal health care program is guilty of a felony upon conviction.⁷⁷ In the case of Dr. Ogon, when he allegedly began receiving per-

⁷¹ id.

⁷² N.J. STAT. ANN. § 2C:21-4.2.

⁷³ id.

⁷⁴ id.

⁷⁵ Criminal Penalties for acts involving Federal health care programs, 42 USC § 1320a-7b(b).

⁷⁶ id.

⁷⁷ id.

prescription payments from telemedicine companies, he was in violation of the anti-kickback statute.

It is important, when analyzing the AKS, to understand how and when the Department of Health and Human Services-Office of the Inspector General will enforce the statute. AKS violations are not always as obvious or egregious as those Dr. Ogon or Monty Grow and often require a case-by-case analysis. The Office of the Inspector General (OIG) issued its first advisory opinion relating to kickbacks and telehealth in November 1998⁷⁸. The opinion concerned the leasing of certain telehealth services equipment from an ophthalmologist to an optometrist for the purposes of providing free telehealth consultations⁷⁹. The OIG first analyzed whether or not the rent paid pursuant to a lease agreement violated the AKS and determined that the payments squarely fell within the statute's equipment leasing safe harbor⁸⁰. The second issue that the OIG analyzed was whether or not, by providing free telehealth consultations, the ophthalmologist would be enabling the optometrist to expand her business⁸¹. It was determined that, since the optometrist would not be advertising or charging a fee for these consultations, the overall value of the consultations to the optometrist was minimal⁸². The greatest benefit would be to the consumer. Although there was potential that this arrangement could result in unlawful remuneration, the facts of the situation lead the OIG to determine that the parties would not be subject to any administrative sanctions⁸³.

⁷⁸ Fraud and Abuse Issues in Telehealth, American Health Lawyers Association, September 2015, https://www.healthlawyers.org/Events/Programs/Materials/Documents/FC15/o_kung_romney.pdf

⁷⁹ ADVISORY OPINION NO. 98-18, https://oig.hhs.gov/fraud/docs/advisoryopinions/1998/ao98_18.htm (last visited Apr 2019).

⁸⁰ id.

⁸¹ id.

⁸² id.

⁸³ id.

The OIG provided a similar analysis in June of 2004 regarding a school based telemedicine system.⁸⁴ This system created a program for low income children that operated at eighteen locations in rural counties.⁸⁵ Many of the children receiving services in the school based clinics were Medicaid or Children's Health Insurance Program eligible.⁸⁶ The proposed telehealth arrangement would allow students to be seen by onsite nurses who would conduct basic screening tests and consult with physicians at a distant site.⁸⁷ The OIG found that by developing, operating, administering, and funding the telemedicine network, the Health System would confer benefits on three potential sources: 1) the school based clinics, 2) the consulting practitioners, 3) the patients.⁸⁸ Because the program provided adequate safeguards and a public benefit by providing safe access to screening services for low income children, the OIG concluded that it would not subject the system to administrative sanctions.⁸⁹

In a 2011 Advisory Opinion, the OIG analyzed whether a telemedicine arrangement that would enable community to hospitals to immediately consult with stroke neurologists at specialized hospitals would violate the AKS.⁹⁰ Hospitals that specialize in the treatment of stroke patients often provide access to consultations to community hospitals 24 hours a day, however, the consultations are limited to telephone calls and often do not provide adequate information for proper treatment.⁹¹ The technology provided would greatly enhance the ability of consulting physicians to properly diagnose and recommend treatment for a stroke⁹². The OIG heavily

⁸⁴ ADVISORY OPINION NO. 04-07, <http://oig.hhs.gov/fraud/docs/advisoryopinions/2004/AdvOpn04-07A.pdf>. (last visited Apr 2019).

⁸⁵ id.

⁸⁶ id.

⁸⁷ id.

⁸⁸ id.

⁸⁹ id.

⁹⁰ ADVISORY OPINION NO. 11-12, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2011/advopn11-12.pdf> (last visited Apr 2019).

⁹¹ id.

⁹² id.

considered the assertion that the arrangement was designed to decrease the number of transfers from community hospitals to the provider hospital, limiting the volume and value of referrals, and would, ultimately, provide a greater quality of care to patients.⁹³ Given these considerations, the OIG determined that, while the arrangement might generate prohibited remuneration, it would not pursue any type of administrative action.

In a most recent, May 2018, Advisory Opinion, The Office of the Inspector General analyzed whether or not a not-for-profit telehealth service provider could furnish a county clinic with information technology equipment and services intended to facilitate telemedicine encounters with the clinic's patients.⁹⁴ The case was very fact sensitive and took in to account safeguards within the arrangement between the provider and the clinic, public health concerns and the fact that the clinic's patients would be the primary beneficiaries of the arrangement.⁹⁵ In the end, the OIG determined that, while the arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business was present, the OIG would not impose administrative sanctions.⁹⁶

In addition to the OIG opinions, several safe harbors exist within the AKS that, if a remuneration arrangement falls squarely inside of, would shield parties from prosecution. These safe harbors include space rental, equipment rental, personal services and management contracts, bona fide employment, and managed care organizations.⁹⁷ The most common safe harbors that are likely to apply in any telehealth service arrangement are equipment rental, electronic prescribing items and services, and electronic recording items and services.

⁹³ id.

⁹⁴ ADVISORY OPINION NO. 18-03, <https://oig.hhs.gov/fraud/docs/advisoryopinions/2018/AdvOpn18-03.pdf> (last visited Apr 2019).

⁹⁵ id.

⁹⁶ id.

⁹⁷Fraud and Abuse Issues in Telehealth, American Health Lawyers Association, September 2015, https://www.healthlawyers.org/Events/Programs/Materials/Documents/FC15/o_kung_romney.pdf.

The equipment rental safe harbor establishes that remuneration does not include any payment made by a lessee of equipment to the lessor of the equipment for the use of the equipment, as long as all of the following standards are met-⁹⁸

- (1) The lease agreement is set out in writing and signed by the parties.
- (2) The lease covers all of the equipment leased between the parties for the term of the lease and specifies the equipment covered by the lease.
- (3) If the lease is intended to provide the lessee with use of the equipment for periodic intervals of time, rather than on a full-time basis for the term of the lease, the lease specifies exactly the schedule of such intervals, their precise length, and the exact rent for such interval.
- (4) The term of the lease is for not less than one year.
- (5) The aggregate rental charge is set in advance, is consistent with fair market value in arms-length transactions and is not determined in a manner that takes into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under Medicare, Medicaid or all other Federal health care programs.
- (6) The aggregate equipment rental does not exceed that which is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.⁹⁹

Many of the HHS-OIG advisory opinions addressed arrangements involving equipment rental for the purposes of providing telehealth services. This is a common type of arrangement throughout the telehealth services industry.

The electronic prescribing items and services safe harbor establishes that remuneration does not include nonmonetary remuneration (consisting of items and services in the form of hardware, software, or information technology and training services) necessary and used solely to receive and transmit electronic prescription information, if all of a listing of eight, complex criteria

⁹⁸ Medicare and State Health Programs, Exceptions, 42 CFR § 1001.952(c) (2011).

⁹⁹ id.

are met.¹⁰⁰ Electronic prescribing is a necessary element of telehealth services for individuals that are located in healthcare shortage areas or have transportation issues. It is also a common component in the telehealth fraud schemes described above. It is important to have well established and understood safe harbor for electronic prescribing in order to facilitate care and treatment for those most in need but also to aid in the prosecution of fraudulent activity.

The electronic health records items and services safe harbor establishes that remuneration does not include nonmonetary remuneration (consisting of items and services in the form of software or information technology and training services) necessary and used predominantly to create, maintain, transmit, or receive electronic health records, if all of a list of 13 conditions are met.¹⁰¹ With the growing use of mHealth related applications and remote patient monitoring, it is important that physicians have access to the technology necessary to store electronic health records.

The safe harbors briefly detailed above constitute a small portion of those available through the AKS. Physicians and telehealth providers should be mindful of these exceptions, and their criteria, when entering in to an arrangement. A violation of the AKS results in liability on both sides.¹⁰²

Since the Federal Anti-Kickback statute only applies when government programs, such as Medicare and Medicaid, are billed for services, varying state statutes are left to protect against potential remuneration abuses against private policy holders. New Jersey does have a State law equivalent to the AKS but its scope is very limited.¹⁰³ The New Jersey Medical Assistance and

¹⁰⁰ A listing of the criteria for necessary for the electronic prescribing items and services safe harbor can be found at 42 CFR 1001.952(x).

¹⁰¹ A listing of the criteria for necessary for the electronic health records items and services safe harbor can be found at 42 CFR 1001.952(y).

¹⁰² Fraud and Abuse Issues in Telehealth, American Health Lawyers Association, September 2015, https://www.healthlawyers.org/Events/Programs/Materials/Documents/FC15/o_kung_romney.pdf.

¹⁰³ N.J. STAT. ANN. § 30:4D-17.

Health Services Act contains a Penalty provision that mirrors the intent of the AKS.¹⁰⁴ It creates civil, and potentially criminal, repercussions for soliciting, offering, or receiving remunerations in connection with item and services that made or reported, in whole or in part, under the act.¹⁰⁵ The scope of the act is limited to persons whose resources are determined to be inadequate to enable them to secure quality medical care on their own.¹⁰⁶ This means that the anti-kickback provisions of this statute only apply to state-funded programs and not private insurance. There are no civil or criminal penalties, under State Law, associated with remunerations for referral of private policy holders.¹⁰⁷

c. Physician Self-Referral

While not apparent in the described cases, no analysis of fraud laws applicable to telehealth service providers would be complete without addressing the Stark Law. The Physician Self-Referral Law (Stark Law) prohibits a provider from billing a federally funded program, such as Medicare or Medicaid, for designated health services when a financial relationship exists between the referring physician (or an immediate family member of the physician) and the service provider.¹⁰⁸ For instance, a physician may not refer a patient to a telehealth service company that is either owned, in whole or in part, by the physician or an immediate family member of the physician. The law does provide for a number of strict exceptions which may be utilized by physicians and providers in order to validate a relationship.¹⁰⁹ Exceptions include, but are not

¹⁰⁴ id.

¹⁰⁵ id.

¹⁰⁶ N.J. STAT. ANN. § 30:4D-2.

¹⁰⁷ In January 2018, the New Jersey Attorney General amended the Administrative Code to set limitations on the dollar amount that a pharmaceutical company is allowed to pay, per meal, during an educational event or promotional activity. An August 2018 notice of proposed rulemaking amended the dollar amount slightly. While technically an anti-remuneration provision, the scope of this rule is so narrow that I will not be analyzing it as part of New Jersey's anti-kickback regulatory scheme.

¹⁰⁸ Prohibition of Certain Referrals, 42 USC § 1395nn.

¹⁰⁹ id.

limited to, rental of office space, equipment rental, and fair market value compensation.¹¹⁰ If a financial relationship fails to meet all of the requirements of a given exception, it is deemed to have violated the Stark Law and both parties are ineligible from billing federal programs.¹¹¹

Many of the services that fall within the Stark Law's definition of designated health services, such as out-patient prescription drugs, may be provided via telehealth. Since the Stark Law only applies when a physician or provider tries to bill a federal program for services, a comparable state law equivalent is necessary in order to prevent these types of fraudulent relationships amongst physicians and telehealth service providers treating privately insured patients.

In 1991, New Jersey enacted the Codey Law as a state law equivalent to the Stark Law.¹¹² Under the Codey Law, "a practitioner shall not refer a patient or direct an employee of the practitioner to refer a patient to a health care service in which the practitioner, or the practitioner's immediate family, or the practitioner in combination with the practitioner's immediate family has a significant beneficial interest..."¹¹³ The law includes some minor exceptions involving grandfathered relationships and ambulatory procedures that are unlikely to apply to most telehealth service relationships.¹¹⁴ The Codey Law ensures that New Jersey has the necessary regulatory framework to address issues of physician self-referral within the telehealth services industry.

d. Parallel Proceedings

Of the tools available to prosecutors for combating fraud within the healthcare industry, parallel proceedings are what tie everything together. Parallel Proceedings is the term for

¹¹⁰ id.

¹¹¹ id.

¹¹² N.J. STAT. ANN. § 45:9-22.5.

¹¹³ id.

¹¹⁴ id.

cooperation between various offices within the US Attorney General's office as well as other federal and state government agencies and departments. The potential for parallel proceedings arises in many of the Department's white collar enforcement priorities, and it is essential that an effective and successful response involve an evaluation of criminal, civil, regulatory, and administrative remedies.¹¹⁵ In some cases, matters may be brought to light during a criminal investigation that require action in a civil case, and vice versa.¹¹⁶ Courts have recognized that "[t]here is nothing improper about the government undertaking simultaneous criminal and civil investigations" provided that we use those proceedings and associated investigative tools for their proper purposes and in appropriate ways."¹¹⁷

By working together, departments and agencies can better protect the interests of the government and the public. Inter-agency cooperation is clearly visible in the investigation of the cases outlined above. It is an essential part of fraud prosecution on the federal and state levels. In order to properly participate in these parallel proceedings, New Jersey needs to make sure that its regulatory framework is equipped to handle all areas of fraud and abuse perpetrated against the widest possible range of the state's healthcare beneficiaries.

Of the major fraud concerns that must be considered when adopting an expansive telehealth and telemedicine law, New Jersey has a state law equivalent for privately insured residents to two of them. The absence of a state law equivalent to the Anti-Kickback Statute leaves a large hole in the regulatory framework that New Jersey has to protect consumers against fraud in the telehealth industry. Adding to New Jersey's regulatory framework will only help facilitate participation in

¹¹⁵ Coordination of Parallel Criminal, Civil, Regulatory, and Administrative Proceedings, THE UNITED STATES DEPARTMENT OF JUSTICE (2018), <https://www.justice.gov/jm/organization-and-functions-manual-27-parallel-proceedings> (last visited May 2019)

¹¹⁶ *id.*

¹¹⁷ *United States v. Stringer*, 535 F.3d 929, 933 (9th Cir. 2008).

parallel proceedings and prosecution of fraud within the telehealth industry. Before accepting and distributing millions of dollars in grants, New Jersey needs to make sure that there is an appropriate regulatory scheme that protects all New Jersey residents from issues of fraud and abuse. Bolstering the protections offered to telehealth service beneficiaries is an essential part of establishing a healthy, well regulated industry.

IV. Proposed Solution:

As the Telehealth and Telemedicine Review Commission puts together its recommendations for regulating the telehealth industry, it should focus on the absence of an AKS equivalent for privately insured individuals. It should utilize its statutory authority to recommend and develop a designated Anti-Kickback provision within the Telehealth and Telemedicine law.

The Federal government recently passed the SUPPORT for Patient and Communities Act (Support Act) which, among other things, produced a similar solution to what I am proposing with regards to patient referrals to recovery homes.¹¹⁸ Title VIII, Subtitle J of the Support Act established the Eliminating Kickbacks in Recovery Act (EKRA).¹¹⁹ This act imposes criminal sanctions and fines on whoever, with respect to services covered by a health benefit program, solicits, receives, or offers remuneration in return for referring a patient or patronage to a recovery home.¹²⁰ EKRA is the first instance of a federal anti-kickback provision applying broadly to both federal and commercial health benefit providers. By using the term health benefit program, instead

¹¹⁸ The Support Act made a number of other changes, specific to telehealth services, which the review commission should take in to consideration when making their recommendations. The act removed geographic restrictions on telehealth services, related to substance abuse diagnosis and treatment that may be covered by Medicare and tasked the Center for Medicare and Medicaid Services (CMS) with providing states with guidance on how reimbursement for furnishing services and treatment for substance abuse disorders under Medicaid using telehealth services This guidance is due to States no later than one year after the enactment of the Support Act. Such guidance could play a major role in shaping any recommendations made by the Review Commission.

¹¹⁹ Illegal Remunerations for referrals to recovery homes, clinical treatment facilities, and laboratories, 18 U.S.C. § 220.

¹²⁰ id.

of the traditional federal health benefit program, EKRA has expanded its applicability broadly. EKRA also has far fewer safe harbors than the AKS, making it a much more complicated law for effected industries to work around.¹²¹

EKRA's broad scope with regards to health benefit programs is limited to recovery homes, clinical treatment facilities, and laboratories.¹²² In this way, EKRA is kept from coming in direct conflict with the AKS. The safe harbors of the AKS continue to apply to a vast majority to health care and telehealth service arrangements. EKRA's expansive authority to include private payers is ultimately checked by the fact that the applicable parties within the health care industry comprise only a small portion of the industry, related directly to opioid treatment.

EKRA serves as a guideline for anti-kickback legislation at the state level. It regulates kickbacks within a specific industry without completely overlapping, or conflicting with, the AKS. The Telehealth and Telemedicine Review Commission can use EKRA, along with the AKS and HHS-OIG guidance on telehealth service agreements, to formulate solution for New Jersey that provides adequate protection for areas of the healthcare industry not covered by federal programs and statutes.

V. Conclusion:

New Jersey needs expanded access to quality health care and telehealth could be the solution. By expanding its use through added funding and increased coverage availability, telehealth could become a convenient source of health care for New Jersey's busy families. The Telehealth and Telemedicine statute puts New Jersey on the right track by removing geographic limitation inherent in the Medicare statute and allowing provider-patient relationships via

¹²¹ id.

¹²² id.

technological means. If New Jersey continues to play its cards right, the day may come when we never have to sit for hours in waiting room again.

Access and availability does not come without a cost. Expansion of telehealth services also means expansion of fraud and misuse schemes through telemedicine. In that regard, New Jersey falls a little short. While state law provides protection against false claims and Stark Law/Codey Law violations, there is a gap in New Jersey's armor when it comes to illegal remuneration. New Jersey's anti-kickback provision falls short by not covering the majority of health care consumers within the state. Without adequate regulation, the promise of telehealth becomes a promise of fraud and corruption.

The Telehealth and Telemedicine Review Commission has the opportunity to make the changes necessary to promote stable growth within the New Jersey telehealth services industry. When developing its recommendations, it should look to the Eliminating Kickbacks in Recovery Act as a framework for constructing a designated anti-kickback statute. The Commission should carefully track the activity of the Medicare Fraud Strike Force to stay informed on the types of fraud that is occurring within the telehealth services industry. It should keep in mind how the HHS-OIG has analyzed and treated certain telehealth service arrangements and look to the AKS for potential safe harbors. The limited provisions of the Medical Assistance and Health Services Act are simply too narrow and must be expanded.

Whether it is for treatment of mental health issues, asthma, diabetes, or opioid addiction, telehealth and telemedicine services are expanding and here to stay. New Jersey can provide a great service to its citizens by embracing, and properly regulating, this portion of the health care industry. By ensuring that the proper protections are in place, we can facilitate stable growth that expands access to quality health care for all of New Jersey's residents.