2024 HEALTH LAW YEAR IN REVIEW

Foster Garvey

Introduction: Foster Garvey PC is pleased to provide a health law update for 2024. This update highlights enforcement activities and trends nationally and within Washington State, cases that reflect emerging enforcement activities or illustrate certain non-compliance, and new or amended health care laws and regulations. It is neither exhaustive nor does it address recent or forthcoming changes in federal or state policy. This publication is solely for educational purposes and should not be construed as legal advice. Please reach out to the Foster Garvey health care attorneys with questions or specific concerns.

Table of Contents

I. **Fraud and Abuse Updates:** Nationally and regionally there has been an uptick in fraud and abuse enforcement activity. Agencies that enforce fraud and abuse laws, including the U.S. Department of Health and Human Services ("HHS"), Office of Inspector General ("OIG") and U.S. Department of Justice ("DOJ"), continue to focus their efforts on suspect financial arrangements between providers and entities involving referrals or orders of items or services and other high-risk transactions such as those involving durable medical equipment. This section provides a high-level overview of the OIG and DOJ's enforcement efforts in 2024 and provides examples of a few enforcement cases involving the federal Anti-Kickback Statute ("AKS"), the physician self-referral law (i.e., "Stark" law), and the False Claims Act ("FCA").

1. HHS-OIG Recovered Billions from Enforcement: The U.S. Department of Health and Human Services ("HHS"), through the Office of Inspector General ("OIG"), is expected to recover $7.13 billion from entities and individuals receiving funds from HHS programs in 2024. The recoveries involve enforcement actions and audits. In addition to monetary recoveries, the OIG actions included 1,548 civil and criminal cases and exclusion of 3,234 individuals and entities from participating in Federal health care programs (e.g., Medicare, Medicaid, TRICARE). The OIG attributed these outcomes, in part, to using "sophisticated data analytics and modern techniques" to identify and detect fraud, waste and abuse. The OIG continues to prioritize it efforts based on programs that are at highest risk for illegal schemes (e.g., durable medical equipment") that seek Federal health care program ("FHCP") funds.

   The OIG also highlighted a new strategic plan for Safeguarding the Integrity of HHS Grants and Contracts (Oct. 2024), which is aimed at closing vulnerability gaps in HHS awards.

2. U.S. DOJ Recovers $2.9 Billion in Settlements in 2024: The U.S. Department of Justice ("DOJ") recovered $2.9 billion in False Claim Act ("FCA") recoveries in 2024. Out of this total amount, $1.67 billion in recoveries is directly from the health care sector including hospitals and other medical facilities and physicians. The DOJ highlighted its success through vigorous enforcement and the increased role of whistleblowers. As to the latter, the DOJ reported a record-breaking year of whistleblower actions totaling 979. $2.4 billion of total recoveries related to whistleblower awards. The DOJ also emphasized its commitment to incentivizing and rewarding self-disclosures, cooperation, and remedying non-compliance with effective remedial measures. The DOJ reported providing credits to defendants who

cooperated including more favorable settlement terms/conditions and reduced fines.

3. U.S. Attorney's Office, E.D. of WA Reports "Exponential Growth" In Health Care Fraud Prosecutions: In November of 2024, the U.S. Attorney Office for the Eastern District of Washington ("USAO EDWA") announced its continued and increased number of health care fraud prosecutions in the last few years. The cases prosecuted included several physicians who allegedly engaged in a kickback scheme related to DME. Also highlighted in the report is part III of a case involving a neurosurgeon who allegedly performed medically unnecessary spinal procedures. Part I involved a $22.7 million settlement in 2022 and the requirement for a corporate integrity agreement. Part II involved a settlement in 2023 where the physician was required to pay $1.1 million dollars and agreed to be excluded from participating in FHCP. The USAO EDWA also expressed criticism of the physician compensation arrangement.

4. Federal Anti-Kickback Statute (AKS) Updates:

   i. Hospital Bonus Payments to Hospitalists and Emergency Physicians Subject of an AKS Settlement. Oroville Hospital, a 153-bed acute care hospital, entered into a $10.25 million dollar settlement for allegedly paying hospitalists and emergency department physicians who contracted with the hospital based on the value or volume of their inpatient admissions. The financial arrangement with these physicians allegedly involved a bonus structure. The settlement also resolves allegations that Oroville Hospital failed to enter into a financial arrangement with these same hospitalists in compliance with the physician self-referral law (commonly known as the "Stark" law) for inpatient and outpatient referrals of designated health services.

   ii. $15 Million Settlement for Gift Card Program. The federal government asserted that MMM Holdings ("MMM") submitted or caused to be submitted claims for payment to the Medicare Program relating to a gift card incentive scheme in violation of the AKS. Specifically, MMM distributed gift cards to administrative assistants of providers to induce the referral, recommendation, or arrangement for enrollment of thousands of Medicare beneficiaries in an MMM Medicare Advantage plan. The settlement took into consideration MMM's cooperative efforts and remedial measures and controls.

iii. Hospital Settlement for Paying Physicians Business Expenses. The settlement involves Norton Clark Hospital paying remuneration in the form of below fair market value ("FMV") business expense reimbursement for a building jointly owned between the hospital and a physician practice, who referred patients to the hospital.

iv. Offering Free Inventory Management Services to Physicians is the Subject of an AKS Settlement. Besse Medical entered into a $1.67 million settlement with the government for allegedly providing a free inventory management system to certain medical providers to induce them to purchase certain expensive drugs from Besse Medical.

5. Federal Physician Self-Referral Law (Stark) Updates:

i. Above FMV Compensation to Employed Physicians Ends with a Hospital Settling for $345 Million. Community Health Network ("CHN") settled with the government for allegedly violating the Stark law by paying salaries of employed physicians including specialty practice physicians significantly higher (sometimes as much as double) what they were receiving in their own private practices. CHN hired a FMV consultant to analyze their compensation structure and CHN allegedly provided false compensation numbers and repeatedly ignored the consultant's warnings that paying above FMV would be inconsistent with the law. CHN also allegedly violated the Stark law by paying these physicians performance bonuses based on making a certain number of referrals to CHN.

ii. Public Hospital Authority Settles for Above FMV Compensation Paid to Employed Physicians. The government alleged that certain defendants including Chattanooga-Hamilton County Hospital Authority ("Public Hospital") failed to comply with a Stark law exception by paying employed physicians well above FMV. The government alleged that Public Hospital received tainted referrals of designated health services from these physicians and knowingly submitted these improper claims to Medicare in violation of the law.

6. Federal False Claims Act ("FCA") Updates:

i. Health Care Consulting Firm Settles for Marketing Strategies in Violation of the Law. McKinsey & Company ("McKinsey") entered into a $323 million settlement under the FCA in one of the first known civil and

criminal enforcement actions for sales and marketing advice. Specifically, the consulting services involved sales and marketing advice of opioid drugs that were subject to being reimbursed by FHCPs. In addition to criminal and civil liability as part of the settlement, McKinsey is required to adopt an effective compliance program that includes implementing certain procedures for oversight involving "high-risk client engagements."

ii. Physicians' Settle for Overbilling Medicare and Failing to Return Overpayment. Sixteen (16) separate physician cardiology groups allegedly billed Medicare for certain drugs used for diagnosing certain medical conditions and failed to return the overpayments as required by law. The government highlighted that Medicare contractors publish guidance on how to accurately report their acquisition costs to Medicare, but the physician practices knowingly failed to comply with these requirements, which caused the submission of inflated costs to Medicare.

iii. Skilled Nursing Facility Settles for $21.3 Million for Inappropriate Therapy Services. Grand Health Care System ("GHCS") owns and operates twelve (12) skilled nursing facilities ("SNFs") where it allegedly violated the FCA by knowingly submitting claims to FHCPs based on providing more therapy services than was medically reasonable and necessary, or submitting claims that inaccurately reported the time spent providing services. As part of the settlement, GHCS admitted that management implemented expected "quotas," which included lengths of stays. GHCS also admitted to limiting the number beneficiaries that could be discharged at one time which resulted in some Medicare beneficiaries "staying on therapy longer than was reasonable and medically necessary."

iv. Federal Contractor Settles FCA for Failing to Secure Medicare Beneficiary Data. ASREC Federal Data Solutions ("AFDS") entered into a $306,722 settlement for failing to appropriately secure Medicare beneficiaries personally identifiable information ("Data") as required pursuant to its contract with the Center for Medicare and Medicaid Services ("CMS"). Allegedly AFDS and its subcontractor failed to encrypt the Data on its subcontractor's servers as contractually required and this failure allowed a threat actor to access the Data causing a breach. Failing to use proper encryption was an alleged misrepresentation of its cybersecurity program and/or a breach of its contract with CMS.

II. Privacy and Security Updates. The health care industry has been a high value target of threat actors for many years, but this year saw one of the biggest data breaches ever recorded along with industry-wide disruption caused by security incidents. Due to the rapidly increasing threat posed by threat actors including cybercriminals, federal and state legislatures and/or government agencies are proposing or adopting new laws to mitigate this threat to health care providers and those providing services or supplies in this industry. This year also saw some important privacy and security regulatory changes affecting reproductive health care records and substance use disorder records. This section will provide a high-level overview of some privacy and security legal updates that may impact many health care providers.

1. HIPAA Updates

i. The Year of Big Data Breaches: The U.S. Department of Health & Human Services ("HHS"), Office for Civil Rights ("OCR") reports that since 2018 there has been a 264% increase in large breaches involving ransomware alone. The biggest cyberattack of the year, which affected a substantial portion of the U.S. health care industry, was Change Healthcare. As of July 19, 2024, Change Healthcare reported the breach affected one hundred ninety million individuals. Within the government and health care industry, there is concern that the health care sector is not prepared to meet the cybersecurity challenges and risks the industry is facing, and additional action must be taken by federal and state governments.

ii. HHS Proposes measures to Strengthen Cybersecurity in Health Care. As a result of the cybersecurity threats to the U.S. healthcare system, HHS-OCR proposed a rule to amend HIPAA requiring Covered Entities and Business Associates to strengthen their cybersecurity posture with certain additional controls and actions. For example, the proposed rule would require modernization of cybersecurity programs with new advances in technology, and adoption of certain cybersecurity best practices, methodologies and procedures.

iii. Reproductive Health Care HIPAA Final Rule. HHS-OCR issued a Final Rule to strengthen HIPAA protections around disclosures of protected health information ("PHI") involving legal reproductive health care services. Among other things, regulated entities must obtain an attestation from a requestor when they receive a request for PHI potentially related to

reproductive health care. The rule became effective June 25, 2024, with a compliance date of December 23, 2024, except for the Notice of Privacy Practices which has a different compliance deadline of February 16, 2026.

iv. Substance Use Disorder Records (Part 2) Final Rule: The Final Rule aims to make certain 42 CFR Part 2 ("Part 2") regulatory requirements consistent with HIPAA. Part 2 regulatory amendments address patient consent requirements, permitted and restricted use of Part 2 records, segregation of Part 2 records, penalties for violations, and breach notification.

2. Washington:

i. WA AGO Data Breach Report 2024: 2024 saw the highest number of data breaches in Washington State history according to the attorney general. Specifically, there have been over 11.6 million data breach notices sent to Washington residents. This is five million more breach notices than the previous all-time high in 2021. Two "mega breaches," which included one health care organization, contributed to the significant increase in data breaches. The attorney general proposed amending Washington's breach notification rule to "protect Washingtonians' data and minimize risks."

III. Other Legal and Compliance Updates – Federal and Washington State. One of the most challenging issues with working in the health care industry is keeping abreast of the numerous statutory and regulatory updates and enforcement actions. This section does not attempt to address the numerous new laws, amendments to laws, and important enforcement actions affecting health care providers and organizations. However, the goal is to provide an overview of various legal and compliance updates that are expected to impact certain segments of the health care industry. Please note that this update is provider-specific and may not apply to many health care providers.

1. Patient Dumping Law and Access to Reproductive Health Care Services Updates.

i. Federal EMTALA Enforcement Cases

1. Emergency Physician Settles for Failing to Accept an Appropriate Transfer. An emergency physician entered into a $65,000 settlement with the OIG for allegedly violating EMTALA by

refusing to accept a patient transfer. Specifically, the physician refused to accept an "appropriate" patient transfer from another facility when the hospital had the capabilities and capacity to treat the patient. The requesting facility lacked the capabilities and capacity to treat the patient at the time the transfer was requested.

2. Hospital Fails to Provide Medical Screening Exam for a Patient Who "Arrived" to ED. A hospital settles with the OIG for $49,000 for allegedly failing to perform a required medical screening exam as required by EMTALA. Specifically, the emergency medical services (EMS) crew transporting the patient had previously called the hospital's emergency department ("ED") to inform them of the patient's condition and the hospital stated they did not have a specialist on call who could manage the patient's condition. EMS transported the patient to the hospital's ED and was met by a hospital employee in the hospital's ambulance bay. After a conversation occurred, EMS left the hospital without the patient receiving a medical screening exam.

ii. WA Emergency Abortion Care Rule: Since the United States Supreme Court struck down *Roe v. Wade*, there has been significant litigation regarding states limiting reproductive health care services including abortion and the application of EMTALA to emergency reproductive health services. Washington's former governor issued Directive 25-01 on January 10, 2025, directing the Washington Department of Health to adopt an emergency rule requiring hospitals that provide emergency services "to offer and provide treatment, including abortion where warranted, to a pregnant person with an emergency medical condition according to the standard of care or to make a legally authorized transfer." The directive also prohibits hospitals from withholding care or prioritizing the continuation of a pregnancy.

2. Charity Care and Financial Assistance to Patients

i. Washington:

1. AGO Secures Largest Charity Care Settlement in History. Providence Health & Services ('"Providence") was sued by the AGO for allegedly failing to properly notify hospital patients about

the availability of charity care and determine whether patients are eligible for certain discounts or free care based on their income level. The AGO asserted that Providence sent eligible patients, which included Medicaid beneficiaries, to debt collectors. The settlement included forgiving more than $137 million in medical debt, refunding $20 million to patients, and implementing controls to screen patients for charity care before attempting to collect payment.

2. Medical Debt Collector Ordered to Pay $827,000 Penalty: In March 2024, the Attorney General's Office won a trial against Optimum Outcomes "for violating the medical debt collections rights of Washington patients more than 82,000 times," which equated to a $10 penalty per violation. Optimum was the debt collector for Providence, who had previously settled with the AGO for allegedly violating Washington's hospital charity care law. The AGO asserted Optimum failed to provide patients with legally required information about their rights when faced with a medical debt.

ii. IRS Examining Tax Exempt Hospitals Community Benefits Compliance. On November 19, 2024, certain senators sent a letter to the Internal Revenue Service ("IRS") asserting that nonprofit hospitals may not be providing required financial assistance to needy patients in compliance with the IRS requirements. The IRS indicated that it "will verify whether tax-exempt hospitals are complying with their statutory obligations under… [IRC] 501(c)(3), including the community benefit standard, and Section 501(r)."

3. Washington's New Uniform Telehealth Law: Effective June 6, 2024, Washington Uniform Telehealth Law took effect. *See* RCW 18.134 et. Seq. The law codifies telehealth services to patients located within Washington State. The law applies to physicians (MDs and DOs), podiatric physicians, advanced registered nurse practitioners and physician assistants.

4. CMS Issues Guidance for Time-share and Leased Space Arrangements in Critical Access Hospitals ("CAHs"). To promote access to care in rural communities, CMS issued guidance to CAHs on leveraging space sharing arrangements (i.e., time share or leased space arrangements) with other health

care entities while complying with Medicare conditions of participation ("CoPs"). CMS emphasized that CAH who participate in these arrangements are expected to demonstrate their independent compliance with the CoP at all times. CAHs are also reminded by CMS to comply with the Stark law when entering into these arrangements with physicians or their immediate family members.

5. Federal No Surprise Act Complaint Data and Enforcement Report. As of June 30, 2024, CMS published data identifying, among other things, the top No Surprise Act complaints against providers, facilities, and air ambulance suppliers. The top three (3) complaints are:

    1. Surprise billing for non-emergency services at an in-network facility;
    2. Surprise billing for emergency services; and
    3. Good faith estimates.

    Through enforcement, CMS required covered individuals to take remedial and corrective action and provided $4,183,383 in monetary relief to consumers or providers.

6. HHS-OIG Special Fraud Alert: Suspect Payments in Marketing Arrangements Related to Medicare Advantage and Providers. This notification is only the fourth Special Fraud Alert ("Alert") issued by the OIG in the last ten years. The Alert expressly warns health care professionals that certain compensation arrangements for marketing Medicare Advantages ("MA") plans could implicate the federal AKS and FCA. The two specific compensation arrangements that are the subject of the Alert are: (1) payments from a Medicare Advantage Organization to health care providers or their staff relating to MA plan marketing and enrollment; and (2) payments from health care providers to third parties (e.g., agents, brokers, etc.) in exchange for referring Medicare enrollees to a particular health care provider. The Alert identifies eight (8) characteristics of an arrangement that may make it suspect. One such example is a health care provider offering or paying "remuneration" (e.g., something of value) to an agent, broker or other third party that "is contingent upon or varies based on the demographics or health status of individuals enrolled or referred for enrollment in an MA plan."

7. HHS Publishes New Compliance Guidance Specific to Nursing Facilities ("NF"). In November of 2024, HHS-OIG issued Nursing Facility Industry Segment-Specific Compliance Program Guidance ("Guidance"). This Guidance along with the HHS-OIG General Compliance Program Guidance

("GCPG") published in 2023 updates the OIG's compliance guidance for NFs. The primary areas addressed in the Guidance includes NF compliance risk areas and ways to mitigate these risks, billing Medicare and Medicaid, and AKS legal risks, and quality care. The OIG makes it clear that it believes that NF quality programs are an essential component of a compliance program and that implementation of such programs should start at the "highest corporate level" of the organization.

8. WA Certificate of Need Law Amendments: Washington's Certificate of Need ("CoN") statute was amended to exempt "hospital at-home services" from the CoN requirements for a hospital's licensed bed count. The amendments became effective June 6, 2024.

9. WA Prior Authorization Modernization Regulation Amendments. On December 27, 2024, the Washington Office of Insurance Commission ("OIC") finalized amendments to certain insurance regulations involving prior authorizations. The amended rule is effective as of January 27, 2025. It revises the time period within which health carriers must respond to certain types of prior authorization requests for health care services and prescription drugs. For example, a carrier must make a determination within one day of receiving all necessary information for an electronic "expedited prior authorization request."

10. Medicare Report and Return Overpayments Rule Amendments. On December 9, 2024, CMS published its final rule for reporting and returning Medicare overpayments. Specifically, the new rule changes the standard for an "identified overpayment" to when a provider has actual knowledge of the existence of the overpayment or acts in deliberate ignorance or in reckless disregard of the truth or falsity of the overpayment. Federal law (Patient Protection and Affordable Care Act) requires Medicare overpayments be returned within 60 days after identifying the overpayment or the date that a corresponding cost report for overpayment is due. However, this final rule allows, where applicable, the suspension of the 60-day report and return deadline for 180 days so a provider can conduct a timely, good faith investigation to determine the existence of related overpayments arising from the "same or similar cause or reason as the initially identified overpayment."

11. Chevron Deference Standard Struck Down. The United States Supreme Court reversed a case known as the "Chevron deference" doctrine, which gave deference to federal agencies with respect to their interpretation of their statutory authority. The Supreme Court ruled that courts are required under the constitution to interpret statutes and may not defer to a federal agency's interpretation of the law. One result of this new ruling may be that individuals

and entities subject to federal regulations will be in a stronger position to challenge agency regulations and other actions (e.g., regulations issued by CMS or HHS-OCR).

12. Federal and State Anti-Competitive Enforcement Activities

    i. Federal Antitrust Enforcement Updates: The DOJ and the Federal Trade Commission were very active with new antitrust initiatives, actions and enforcement. One example is that the DOJ created a new health care task force for tackling "competition problems in health care markets." The task force will broadly review competition in the health care industry including in the areas of payer-provider consolidation, medical billing and health IT services. Other antitrust action includes the FTC adopting a rule banning certain noncompete contracts. Currently, the enforcement of this rule has been stayed pending further litigation.

    ii. WA Antitrust Enforcement Updates. Washington's Attorney General's Office ("AGO") also took antitrust action against consolidation of businesses that provide goods and services to Washington consumers. Specifically, the AGO successfully challenged a proposed merger between Kroger and Albertsons. The AGO asserted that the merger violated Washington's antitrust law because it eliminated a close competitor and decreased customer choice.

IV. **Conclusion:** We hope that these updates assist you in understanding some new developments in health law for the year 2024. Health care is a heavily regulated industry and health law changes rapidly. Our team at Foster Garvey is here to help. For questions regarding this publication, please contact any member of our Health Care team.