Latest Legal Updates in the Healthcare Industry

Examining the legal risks and complexities with respect to healthcare fraud and abuse laws

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Agenda

- Role of Private Equity in Healthcare
- Private Equity & The False Claims Act
- Fraud and Abuse Considerations
- Private Equity & Antitrust
- False Claims Act Insurance for Private Equity
- Digital Health Overview
- AI Implications

Private Equity in the Healthcare Space - Opportunities

- Capital Infusion
- Operational Development
- Technological Advancement
- Consolidation and Integration
- Restructuring
- Efficiency and Cost Management
- Innovation and Research
- Enhanced Patient Care

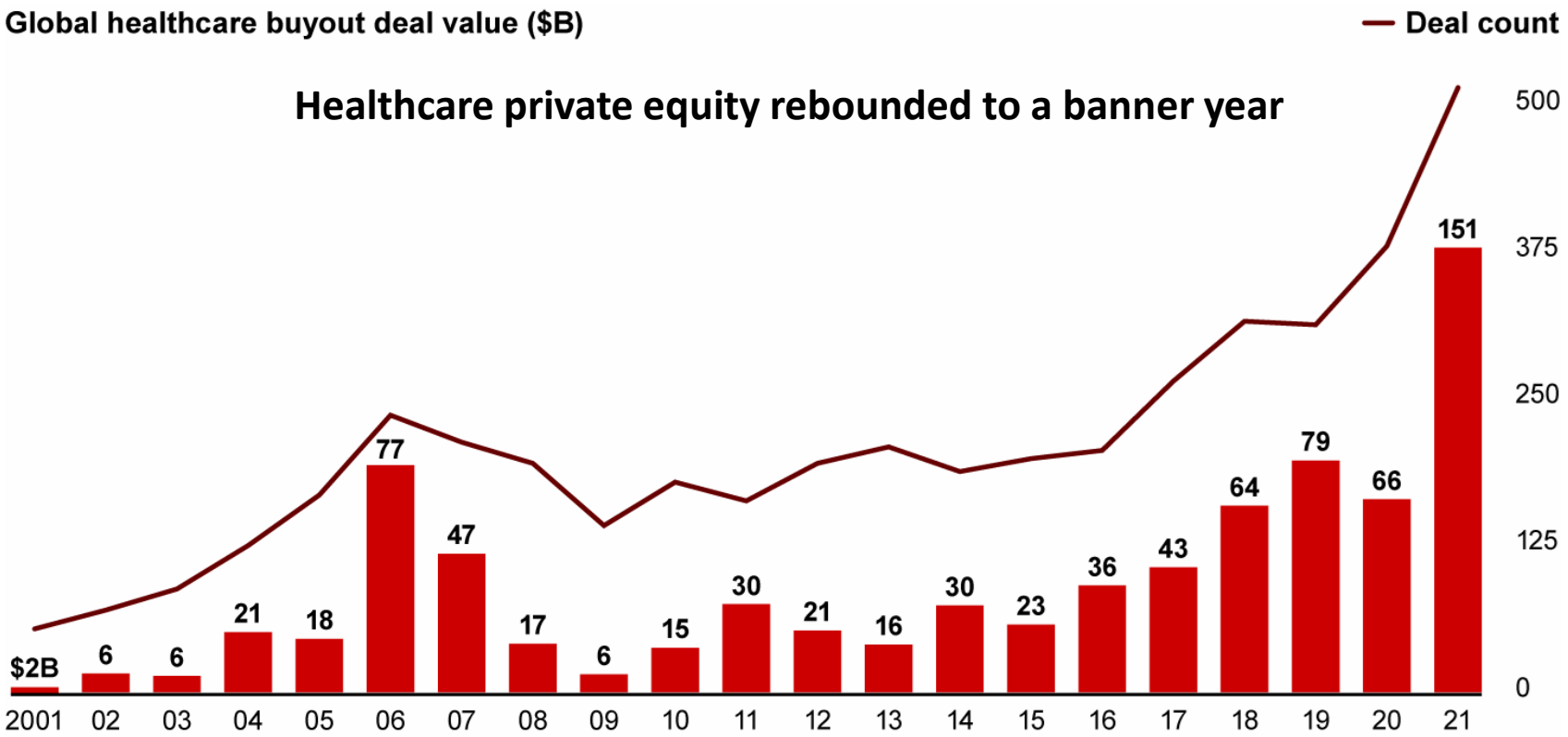
Private Equity in the Healthcare Space - Challenges

- Balancing Profit Motive with Quality Care
- Regulatory Compliance
  - Fraud and Abuse Laws
- Service Disparities
- Transparency, Ethics, and Conflict of Interests
- Patient Privacy and Data Security
- Licensing and Accreditation
- Additional Due Diligence and Compliance Planning

Private Equity and the FCA

- The federal government is the single largest payor in the healthcare system:
  - Medicare, Medicaid, TRICARE, Federal Employee Health Benefits Program.
- The Department of Justice has stated that ***private equity firms and their investors*** may be held liable not only for the actions of the portfolio companies in which they invest, but for the private equity firms' own action or inaction.
- The False Claims Act (FCA) plays a significant role in deterring fraud and abuse in various industries, including healthcare, where private equity (PE) investments often take place.

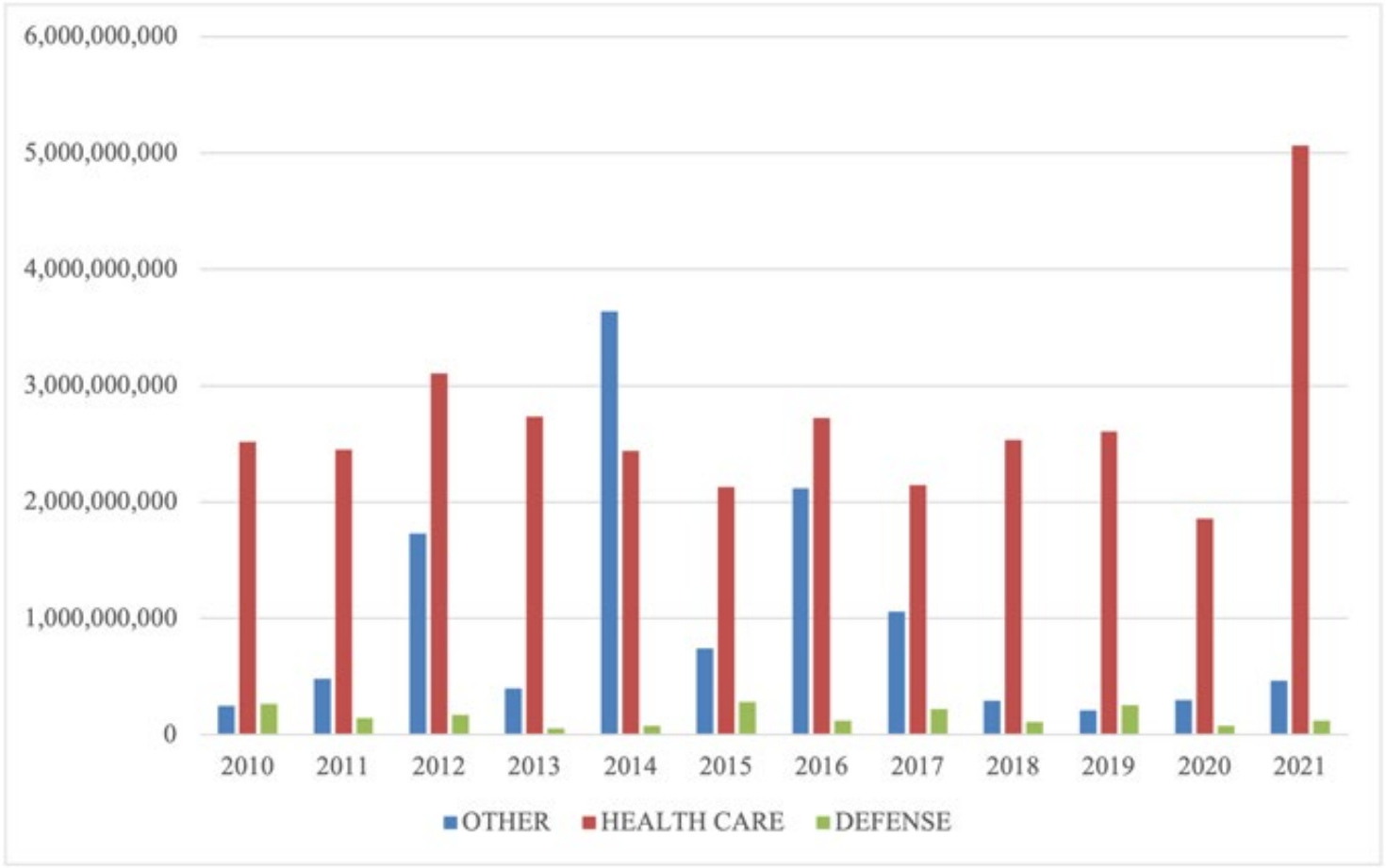
Private Equity Is A Major Force in Healthcare



Notes: Dollar numbers are rounded; excludes spin-offs, add-ons, loan-to-own transactions, and acquisitions of bankrupt assets; numbers based on announcement data; includes announced deals that are completed or pending, with data subject to change; deal value doesn't account for deals with undisclosed values; total buyout deal values updated based on Dealogic 2021 sponsor classifications
Sources: Dealogic; AVCJ; Bain analysis

Source: Bain & Co. "Healthcare Private Equity Market 2021: The Year in Review"

Most FCA Cases and $ Recoveries ($5B out of $5.6B in 2021) Involve Healthcare



: DOJ "Fraud Statistics – Overview" (Feb. 1, 2022)

A New Era of Private Equity Enforcement Risk

- The recent influx of private equity capital in healthcare coincides with a precarious time for the Medicare program, as the Medicare Part A trust fund will become insolvent by 2028 according to the most recent 2022 Medicare Trustees Report
- At the same time, PE is driving consolidation in the health care marketplace, with horizontal, vertical and cross-market integration allegedly driving up health care costs
- ***Significantly, these enforcement risks are moving from the portfolio company to the private equity firms themselves***
- Recent cases against private equity firms underscore the fact that being reactive is no longer a viable option – PE firms must be proactive and prepare now, before the subpoena arrives

Antitrust Takeaways for PE Firms

- Expect antitrust scrutiny when acquiring multiple companies in same industry
- Roll Ups likely to face antitrust scrutiny
- PE firms and portfolio companies should develop compliance and assessment tools to detect and prevent potential interlocking directorates
- PE firms with portfolio companies that are competitors or potential competitors should be mindful of information flow to avoid accusation of facilitating or participating in collusive anticompetitive agreements

What Is The Civil False Claims Act?

- Civil War era statute also known as Lincoln's law
- Primary purpose is to combat fraud against the government, particularly in the context of government programs and contracts.
- Authorizes whistleblowers (relators) to bring actions on behalf of the United States.
  - Known as "qui tam" suits
  - Receive 15%-25% of the recovery *plus* their attorneys' fees and costs
  - 652 *whistleblower* suits were filed in 2022
- Damages
  - 3x amount paid to or lost by government
  - Fines/Civil penalties range from $13,508 to $27,018 *per claim*
  - Whistleblowers attorneys' fees

Basic Elements of the False Claims Act

- The False Claims Act is implicated when any person:
    1. Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval to the government (or a government contractor); or
    2. Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim.
        a. The terms "knowing" and "knowingly" mean that a person, with respect to information:
            - has ***actual knowledge*** of the information;
            - acts in ***deliberate ignorance*** of the truth or falsity of the information; or
            - acts in ***reckless disregard*** of the truth or falsity of the information.
        b. In a recent decision, the U.S. Supreme Court held that whether a person has "knowingly" submitted a false claim depends on his or her subjective belief at the time the claim is submitted – not on what an objectively reasonable person may have known or believed.
        c. The FCA does not require proof of a specific intent to defraud.
    3. The false information must be ***material*** to the government's decision to pay.

False Claims Act Activity

- Oral arguments were heard by the U.S. Supreme Court on April 19th
  - *U.S. v. SuperValu Inc.* and *U.S. v Safeway, Inc.*
- The issue in both cases: whether a defendant's contemporaneous subjective interpretation of an ambiguous regulation is relevant to whether it *knowingly* violated the Federal False Claims Act.
  - It was alleged that the retail pharmacies had knowingly submitted false reports of their Usual and Customary drug prices to the government for reimbursement under Medicare Part D and Medicaid, because the reports allegedly did not account for discounted drug prices offered through certain prescription drug price-matching and membership clubs.
  - A lower court determined that (i) the legal standards at issue were ambiguous and (ii) because the pharmacies' conduct was objectively reasonable in light of that ambiguity, there was no need to examine evidence of their actual knowledge at the time of claim submission.

False Claims Act Activity

- The Supreme Court's ruling (on June 1, 2023) was narrow and avoided many of the arguments raised.
  - The Court held that defendants could be held liable under the FCA if they had a subjective belief that the claims they submitted were false (regardless of whether they interpreted the regulatory requirement correctly or not).
  - The Court also further described the meaning of "reckless disregard" to include, but not be limited to, those circumstances where providers are
    - "conscious of a substantial and unjustifiable risk that their claims are false, but submit the claims anyway."

False Claims Act Activity – Going Forward

It has been long recommended in the context of a health care provider's Compliance Program that:

Documentation of *correspondence with or any directives from government agencies* that interpret a rule that impacts claim submission or standards of participation in a Federal health care program be maintained.

During oral argument, the justices suggested that companies also contemporaneously document advice of counsel, even if waiving attorney-client privilege later on becomes necessary.

It's now advisable to document subjective beliefs showing good faith efforts to do the right thing.

Activity Earlier This Week…

- *United States ex rel. Aldridge v. Corporate Management, Inc.* (Aug. 21, 2023)
- Fifth Circuit ruled that a jury properly found that the operators of a Mississippi hospital violated the False Claims Act by overbilling Medicare.
- Decision mostly involved procedural issues and stated that the $33 million trebled recovery must be reduced “by over half” for the government’s delay in the case.
- Qui Tam suit
- Emphasis on Individual Liability
  - Yates Memo (2015)

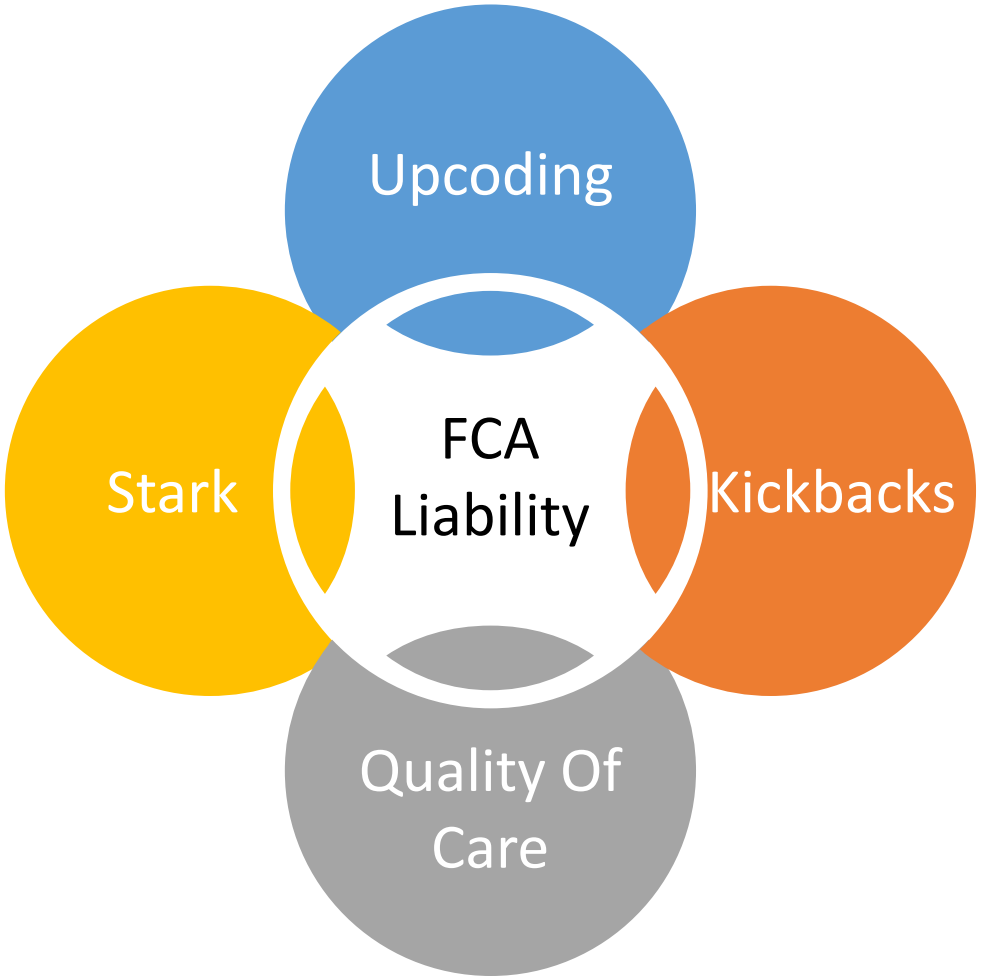
FCA as a Fraud and Abuse Deterrent

- Whistleblower Incentives
- Liability for Ignoring Fraud
- Corporate Integrity Agreements (CIAs)
- Encouraging Due Diligence and Risk Assessments
- Financial Consequences and Damages

The False Claims Act: Potential Damages

- Potential damages/penalties under the False Claims Act include:
  - Treble damages (i.e., three times the damages which the government sustains because of the act).
  - Whistleblower attorneys' fees/costs and other expenses.
  - Civil monetary penalties of not less than $5,500 and not more than $11,000 *per claim* (for conduct occurring between September 30, 1999 and November 2, 2016).
    - Subject to annual inflationary adjustments based on the Consumer Price Index.
    - For violations assessed after January 30, 2023, the minimum FCA penalty has been increased to a minimum of $13,508 per claim, and a maximum of $27,018 per claim.
  - Exclusion from Federal Health Care Programs.

Common FCA Liability Theories



Three Pillars Of Defense

Diligence Tools

Saving a Deal Under Investigation

Defending the Investment Post-Closing

Risk Mitigation

- **Thorough Due Diligence**
  - Evaluate the target company's compliance history, billing practices, relationships with government healthcare programs, and any ongoing investigations.
- **Effective Compliance Programs**
  - Ensure policies, protocols, and procedures address FCA risks and encourage ethical behavior
- **Monitoring and Auditing**
  - Establish regular check-ins and processes to detect and address potential violations promptly
  - Implement detection strategies
  - Create and encourage internal reporting mechanisms
- **Whistleblower Awareness and Employee Education**
- **Transparency and Collaboration**

Maintaining Compliance At All Stages

Risk Allocation in Contracts:

- When structuring deals, consider contractual provisions that allocate the risk of potential FCA liabilities between the private equity firm and the portfolio company.

Post-Acquisition Integration:

- Maintain oversight of portfolio companies to ensure that compliance practices are upheld.
- Address any compliance concerns that arise during the post-acquisition period.

Other Legal Considerations

1. **Anti-Kickback Statute (AKS)**: The AKS prohibits offering, paying, soliciting, or receiving anything of value in exchange for patient referrals or the generation of business reimbursed by federal healthcare programs. Violations of the AKS can result in substantial fines, criminal charges, and exclusion from participation in federal healthcare programs.

2. **Stark Law (Physician Self-Referral Law)**: The Stark Law prohibits physicians from referring patients for designated health services to entities with which they have a financial relationship, unless an exception applies. Similarly, entities are prohibited from billing for services resulting from prohibited referrals. The Stark Law aims to prevent self-referral arrangements that could lead to overutilization and unnecessary procedures.

3. **State-Specific Laws**: In addition to federal laws, healthcare companies must also comply with state-specific fraud and abuse laws, which can vary widely.

The Anti-Kickback Statute

- Big expensive dinners, paid-for vacations, golf outings, sham speaker fees:

  These are becoming relics of the past as bad actors become more sophisticated.

- One of the latest kickback schemes targets non-medical staff. For example:
  - Pending FCA case against pharma companies allege kickbacks were paid *to physician office staff* to circumvent prior authorizations.

The Anti-Kickback Statute

Also, we are seeing reports lately of allegations that:

Pharma companies funneled illegal kickbacks to patients through a charitable organization;	A home health care provider assumed the cost of post-discharge care for uninsured hospital patients (subsidizing the hospital's charity care budget in exchange for referrals of home care patients).

Takeaway: if a payment or a service *of any kind* results in patient referrals (and is not covered under an applicable safe harbor) there is a potential kickback situation, with potential for FCA liability.

Focus on Mental Health: New Stark and AKS Provisions

- As part of the Consolidated Appropriations Act of 2023 (enacted December 29, 2022 – Public Law 117-328), Congress created new exceptions to the Stark Law and the Anti-Kickback Statute for certain "**wellness programs**."
  - The new exception allows specified entities to provide a "bona fide mental health or behavioral health improvement or maintenance program" to physicians (under the Stark Law) and to physicians and other clinicians (under the AKS).
    - The program must consist of counseling, mental health services, a suicide prevention program, or a substance use disorder prevention and treatment program; and
    - Must be made available for the primary purpose of preventing suicide, improving mental health and resiliency, or providing training in appropriate strategies to promote the mental health and resiliency of the physician (under the Stark Law) or the physician and other clinician (under the AKS).

New Stark/AKS Provisions Related to Mental Health

- The Physician Wellness Program must be set out in a written policy, that is approved in advance of its operation by the governing body of the entity providing the program (and updated in advance to any substantial changes to the program's operation). The policy must include:
  - a description of the content and duration of the program;
  - a description of the evidence-based support for the design of the program;
  - the estimated cost of the program;
  - the personnel conducting the program (including their qualifications); and
  - the method by which the entity will evaluate the use and success of the program.

The **entity** providing the program must have a formal medical staff and be:

- a hospital
- an ambulatory surgical center
- a community health center
- a rural emergency hospital
- a rural health clinic*
- a skilled nursing facility or
- a similar entity, as determined by the D.H.H.S. Secretary

Rural health clinic is not included in the list of entities under the AKS.

New Stark/AKS Provisions Related to Mental Health

- The program must be offered to all physicians (under the Stark Law) or physicians and clinicians (under the AKS) who practice in the geographic area served by the entity (including those who hold bona fide appointments to the medical staff or otherwise have clinical privileges at the entity) on the same terms and conditions and without regard to the volume or value of referrals or other business generated by the physician for the entity;
- The provision of the program, and its value, may not be contingent upon the number or value of referrals made by a physician to the entity or the amount or value of other business generated by a physician for the entity.
- The program must also be evidence-based and conducted by a qualified health professional.

Battling Telehealth Fraud: One of DOJ's Priorities

- Since 2019, the DOJ's Health Care Fraud Unit has charged 163 defendants in connection with telemedicine schemes, including 40 medical professionals, involving more than $475 billion billed, and $1.65 billion paid by Federal health care programs.

Focus on Telehealth

- OIG: *Targeted Oversight of Telehealth Necessary*
  - Telehealth increased dramatically during the first year of the pandemic. More than 28 million Medicare beneficiaries—about 2 in 5—used telehealth services that first year. In total, beneficiaries used 88 times more telehealth services during the first year of the pandemic than they did in the prior year.

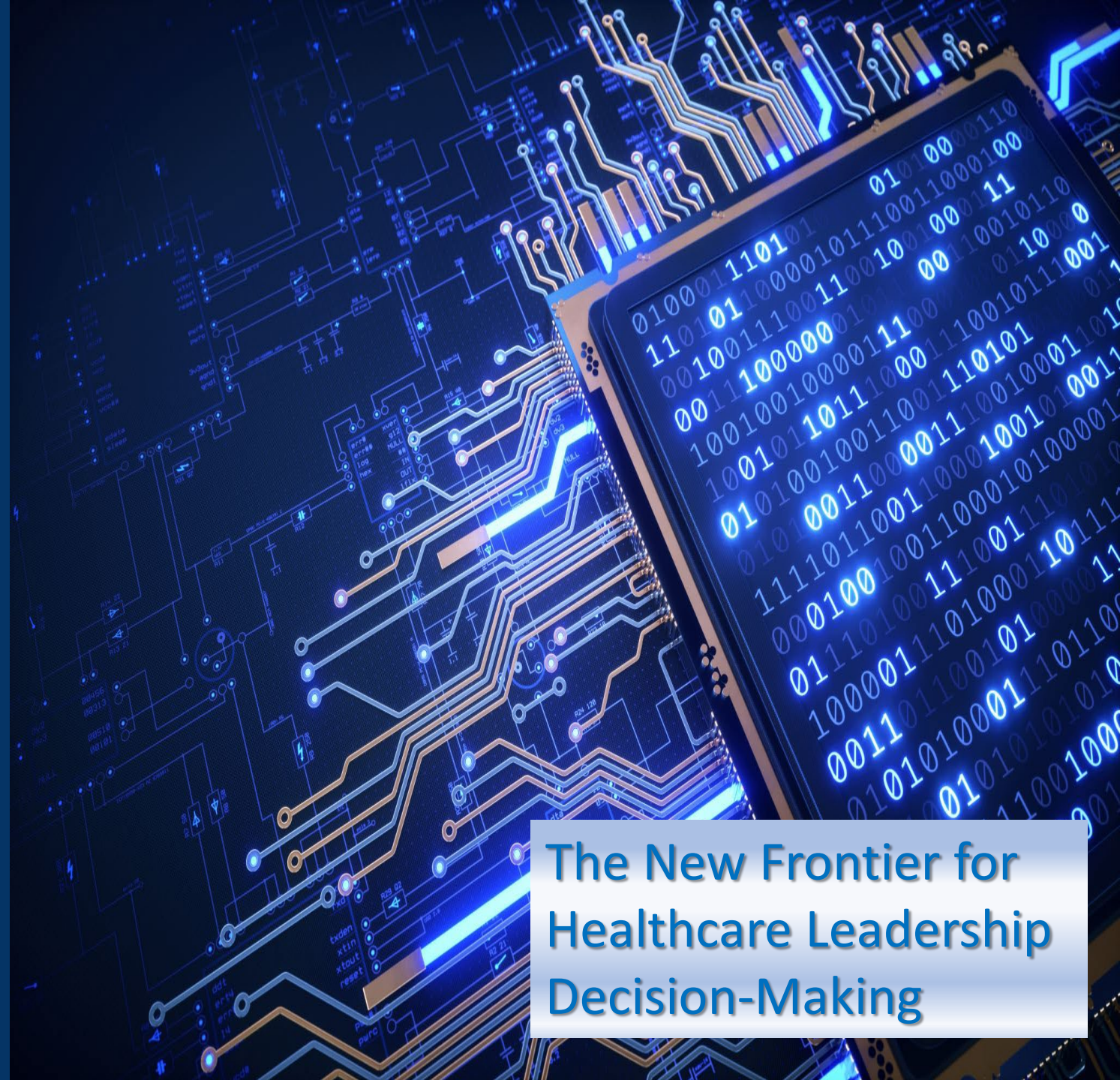
Focus on Telehealth

- *OIG has developed 7 measures that may indicate fraud, waste, or abuse in telehealth services:*
  - Billing **both** a telehealth service and a facility fee for most visits
  - Billing telehealth services at the **highest, most expensive level** every time
  - Billing telehealth services for a **high number of days** in a year
  - Billing **both** Medicare fee-for-service and a Medicare Advantage plan for the same service for a high proportion of services
  - Billing a **high average number of hours** of telehealth services per visit
  - Billing telehealth services for a **high number of beneficiaries**
  - Billing for a **telehealth service and ordering medical equipment** for a high proportion of beneficiaries

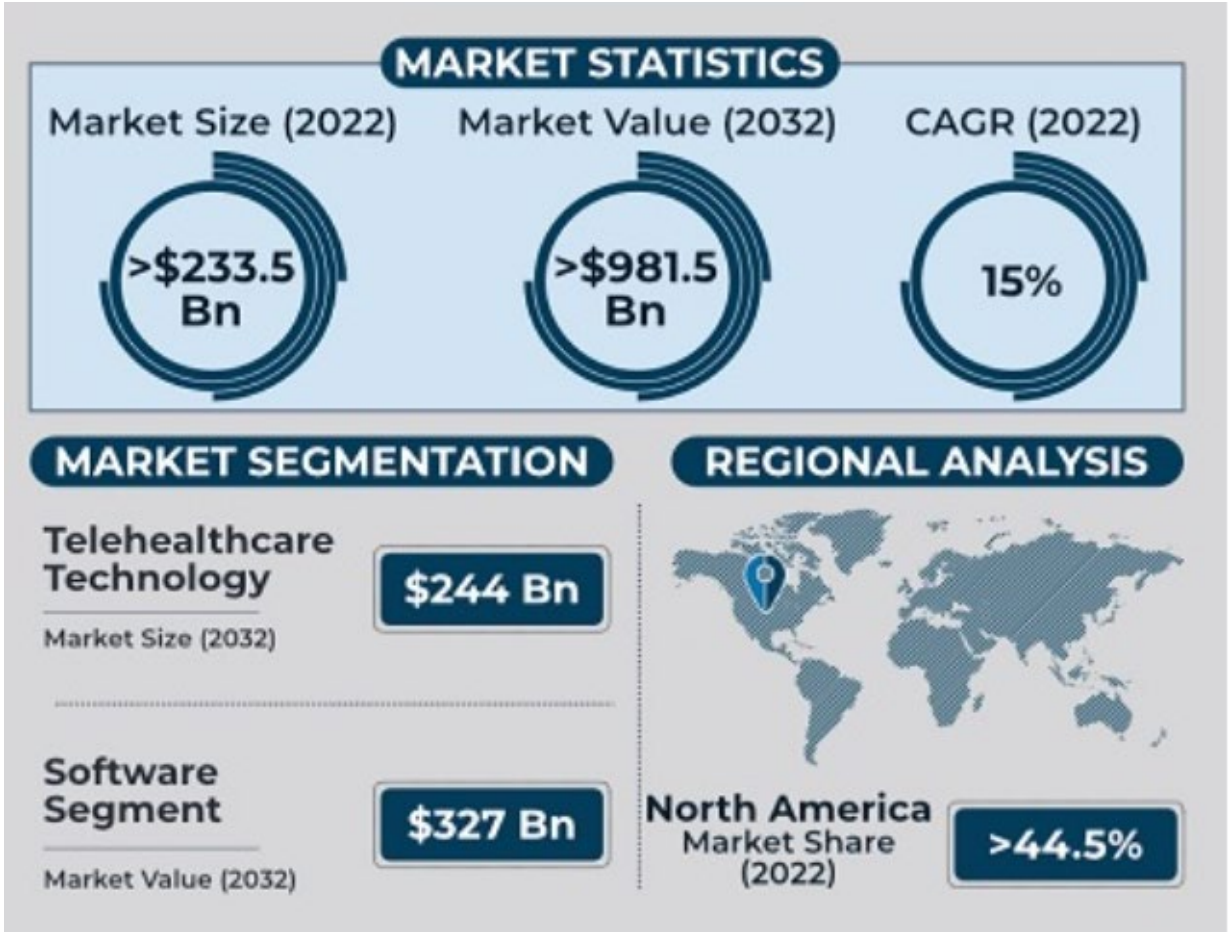
COVID-19 Fraud

- *April 2023*: Justice Department Announces Nationwide Coordinated Law Enforcement Action to Combat COVID-19 Health Care Fraud
  - Criminal charges announced against medical professionals, owners of medical businesses, and others for a variety of COVID-19 fraud schemes with false billings exceeding $490 million.
  - CMS separately announced that it took adverse administrative actions in the last year against 28 medical providers for their alleged involvement in COVID-19 schemes.

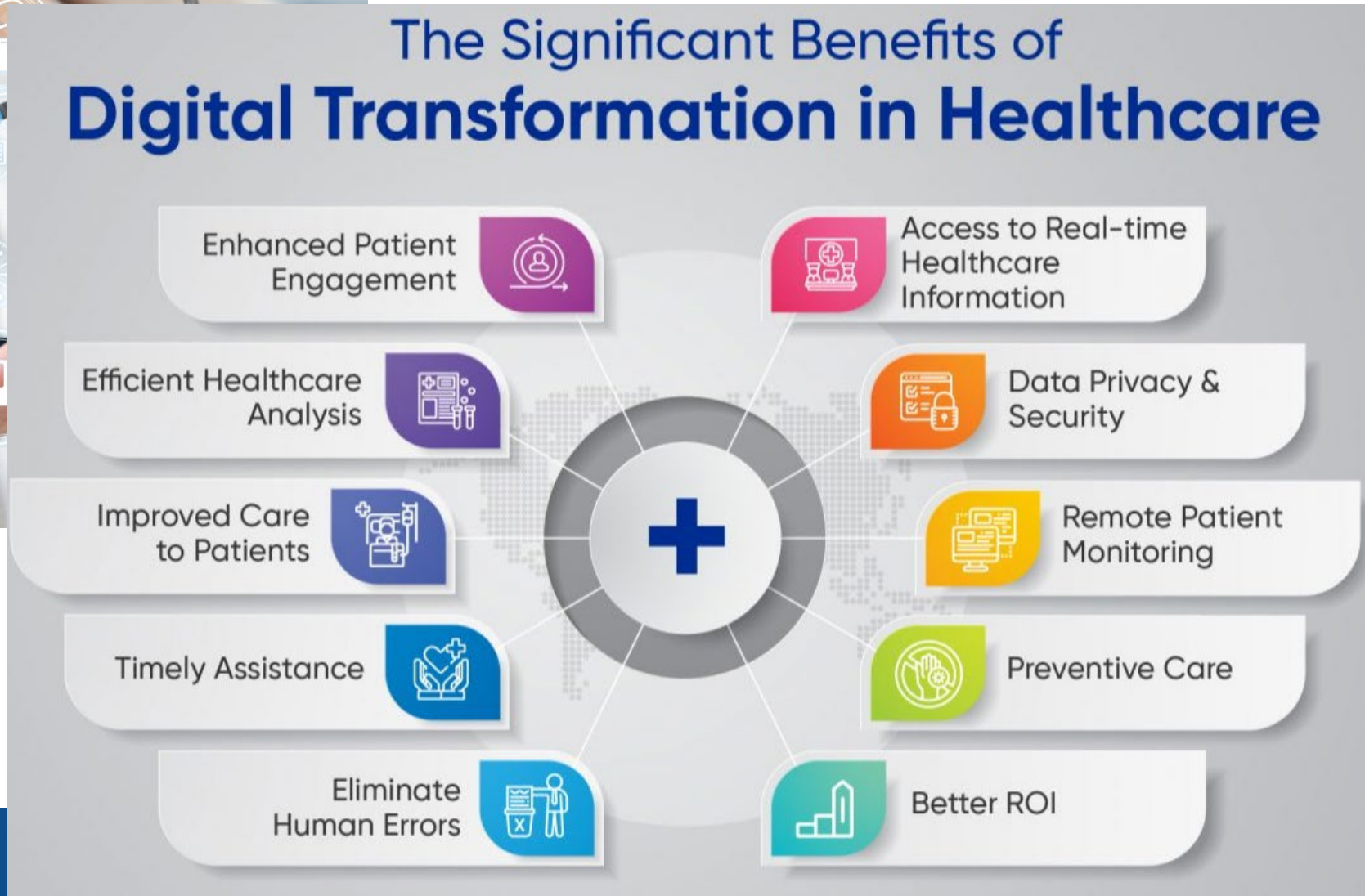
Digital Health, Artificial Intelligence and Machine Learning



Digital Health Overview and Opportunity



What is Digital Health?



Our cross-functional approach means that we partner with companies to advise on the entire life cycle of digital health issues across key disciplines:

Healthcare Regulatory

- Federal and state licensure
- Credentialing
- Telemedicine
- Corporate practice of medicine
- Fraud and abuse
- Medicare, Medicaid and reimbursement
- Value based care and care coordination
- Prescribing, supervision and other state law practice matters

FDA

- Product review and classification
- Product clearance and approval strategies
- Clinical Decision Support (CDS) software
- Clinical trials
- AI / ML considerations

Privacy and Cybersecurity

- HIPAA
- 42 CFR Part 2
- State laws (including health privacy laws and general laws such as CCPA/CPRA, CDPA and CPA)
- International laws, such as GDPR
- Data breach response and preparedness
- Data breach litigation
- Regulatory inquiries

Health Technology

- EHR and interopability concerns
- Certified health IT
- Data sharing
- Information blocking rules

Intellectual Property

- Patentability, freedom to operate
- Licensing
- Technology agreements
- Other IP protections (Trademark, trade secret)

Corporate Structure and Strategy

- Structure
- Fundraising
- Operational considerations
- Exit strategies and transactions
- Commercial contracting and partnerships

AI Expertise Across All Disciplines

AI/ML in Healthcare

- The integration of artificial intelligence (AI) in healthcare has the potential to transform medical diagnosis, treatment, research, and patient care. However, it also raises a range of important legal and ethical considerations that need to be carefully addressed.

Risks:

- Data Privacy and Security
- Informed Consent
- Regulatory Approval
- Bias and Fairness
- Licensure and Scope of Practice
- Continuing Education and Training
- Clinical Validation
- Ethical Use and Transparency

AI is Here – Proceed with Caution

Health care providers are beginning to use cutting edge technology to lessen the clinical documentation burden.

- New applications similar to ChatGPT will enable users to access libraries of documents for a variety of purposes: progress notes, procedure and imaging reports, nursing documentation, certificates of medical necessity, etc.

If the documentation generated is used to support billing, care must be taken to ensure that the documentation is accurate and tailored to the specific patient encounter.

- Similar concerns were raised with the big move from paper to electronic health records.
- Federal and State False Claims Act actions possible if the documentation is false, if the AI produces billing claims for patients that don't exist or for services that were not provided.

Questions?

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