Enforcement and Compliance Risks Associated with the Opioid Crisis

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- Robert Trusiak represents hospital and physician clients on regulatory, statutory, and enforcement issues. He separately provides complete health care consulting services for physician providers, hospitals, research labs, skilled nursing facilities, pharmaceutical companies, and durable medical equipment entities and counsels clients on a number of state and federal health care regulatory matters, including HIPAA, HITECH, Shield Act, health care reform, fraud and abuse, Stark Law and health care compliance issues.

- Previously, Robert served as Chief Compliance Officer, Senior Associate General Counsel and Privacy Officer at Kaleida Health where he successfully managed the internal Compliance team, litigation teams of outside counsel, litigated administrative and contractual actions, ensured regulatory and statutory compliance, and resolved matters involving accrediting and enforcement entities as well as individual matters.

- Robert also served as Assistant United States Attorney until his retirement in 2012 as Chief of the Affirmative Civil Enforcement Unit. Robert prosecuted civil and criminal cases on behalf of the United States of America involving health care fraud, Department of Defense fraud, HUD fraud, grant fraud, VA fraud, ERISA violations, Tax fraud, Securities fraud, Customs violations, USDA violations, and all forms of procurement fraud.

- Robert was also an Adjunct Professor, University at Buffalo, SUNY, teaching in 2015 and 2016 a graduate level course entitled Health Care Fraud and Abuse.

DISCUSSION TOPICS

- Scope of the crisis.
- Who is responsible for compliance?
- Where does it end?
- Government responses to the opioid crisis
- Next Steps for tomorrow morning.

The I-STOP program and DEA efforts provide sufficient oversight controls and obviate the need for rigorous opioid oversight by compliance officers.

The Board at my provider organization in the past 24 months has received at least one report on our organization efforts to address opioid risk.

In my compliance role, I have spent the following time monitoring opioid prescribing trends at my provider organization in the last 12 months:

SCOPE OF THE OPIOID CRISIS

- Every day, more than 130 people in the United States die after overdosing on opioids.
- The opioid crisis has cost the United States more than $504 billion, according to a 2017 report by the White House Council of Economic Advisers.
- The misuse of and addiction to opioids—including prescription pain relievers, heroin, and synthetic opioids such as fentanyl—is a serious national crisis that affects public health as well as social and economic welfare.
- The Centers for Disease Control and Prevention estimates the total "economic burden" of prescription opioid misuse alone in the United States is $78.5 billion a year, including the costs of healthcare, lost productivity, addiction treatment, and criminal justice involvement.

Source: National Institute on Drug Abuse

SCOPE OF THE OPIOD CRISIS

- Roughly 21 to 29 percent of patients prescribed opioids for chronic pain misuse them.
- Between 8 and 12 percent develop an opioid use disorder.
- An estimated 4 to 6 percent who misuse prescription opioids transition to heroin.
- About 80 percent of people who use heroin first misused prescription opioids.
- This issue has become a public health crisis with devastating consequences including increases in opioid misuse and related overdoses, as well as the rising incidence of neonatal abstinence syndrome due to opioid use and misuse during pregnancy.
- The increase in injection drug use has also contributed to the spread of infectious diseases including HIV and hepatitis C.

Source: National Institute on Drug Abuse

SCOPE OF THE CRISIS

- In 2017, more than 47,000 Americans died as a result of an opioid overdose, including prescription opioids, heroin, and illicitly manufactured fentanyl.
- That same year, an estimated 1.7 million people in the United States suffered from substance use disorders related to prescription opioid pain relievers, and 652,000 suffered from a heroin use disorder (not mutually exclusive).

Source: National Institute on Drug Abuse

WHO IS RESPONSIBLE FOR COMPLIANCE?

- Between 2006 to 2012, 76 billion opioid pills were distributed in the United States.
- Stated otherwise, that amount is more than TWO HUNDRED (200) pills for every man, woman and child.*
- Who was responsible for compliance during the time opioid sales were climbing dramatically?

* Buffalo News, 10/12/19, "How the feds failed us on opioids"

WHO IS RESPONSIBLE FOR COMPLIANCE?

- DEA?
  - DEA filed a number of civil actions against drug distributors for failing to report suspicious opiate orders.
    - DEA collected $500 million in fines.*
      - Sufficient response?
- Drug Manufacturers?
- Drug Distributors?
- Joint Commission?

* Buffalo News, supra.

WHO IS RESPONSIBLE FOR COMPLIANCE?

Joint Commission?

- In December 2001, the Joint Commission and the National Pharmaceutical Council (founded in 1953 and supported by the nation's major research-based biopharmaceutical companies) combined to issue a 101-page monograph entitled "Pain: Current understanding of assessment, management, and treatments."
- Excerpts:*
  - Page 4: Pain is defined as "whatever the experiencing person says it is, existing whenever s/he says it does. This definition emphasizes that pain is a subjective experience with no objective measures. **It also stresses that the patient, not clinician, is the authority on the pain and that his or her self-report is the most reliable indicator of pain.**
  - Page 16: For example, some clinicians incorrectly assume that exposure to an addictive drug usually results in addiction. Table 6: **Common misconceptions about pain: Use of opioids in patients with pain will cause them to become addicted. Page 17: In general, patients in pain do not become addicted to opioids. Although the actual risk of addiction is unknown, it is thought to be quite low.**
  - Page 38: Long-acting and sustained-release opioids are useful for patients with continuous pain, as they lessen the severity of end-of-dose pain and often allow the patient to sleep through the night. Page 67: Table 38. Administer opioids primarily via oral or transdermal routes, using long-acting medications when possible.

* The Opioid Epidemic: What Was the Joint Commission's Role? May 16, 2016 | Articles, Doctor's Voice, Skeptical Scalpel

WHERE DOES IT END?

- The following slides detail the absolute crush of state and federal government responses to the opioid crisis.
- Where do the private (mass tort and class action litigation), state and federal responses end to the opioid crisis?
- This is not a clinical question concerning the end to the human aspects of the opioid crisis.
- This is a legal and compliance question.
- How will this crisis legally evolve in terms of the blame game?
- Who will be cast as the perpetrators of wrongdoing after the legal efforts against pharma end?
- What should you be doing now to insulate your organization against potential prospective hazards?

Government Responses: Opioid Coordinator

- In February 2018 Attorney General Jeff Sessions appointed former federal prosecutor Mary Daly to the Justice Department's newly created post of opioid coordinator.
- Sessions also directed each U.S. Attorney to designate an "opioid coordinator" in his/her region who will:
    1. facilitate the intake of opioid and fentanyl cases;
    2. convene law enforcement task forces to identify opioid cases for federal prosecution; and
    3. provide legal advice and training on opioid prosecutions.

Government Response: New Federal Task Forces

- In 2018, DOJ created the Prescription Interdiction & Litigation Task Force (PIL).
  - Includes officials from across DOJ who use civil and criminal tools to redress opioid abuse, with a focus on manufacturers and distributors.
- A new Medicare Strike Force was created on August 12, 2018 addressing opioid abuse in specific metropolitan areas.

Government Response: New Data Analytics

An OIG representative at the 2018 HCCA Compliance Institute provided the following example of the agency's use of data in identifying at risk opioid patients and potentially abusive providers.

- 44 million Part D beneficiaries in 2016
- 14.4 million received opioids.
- 90,000 were at high risk of opioid abuse.
- 70,000 received extreme amounts of opioids
  - More than 240 morphine equivalent milligrams per day for more than 12 mos.
- 678 received more than 1,000 morphine equivalent milligrams per day, each day, for more than one year.
- One beneficiary, out of 44 million, received 134 prescriptions for opioids in a 12 month period.

Government Response: Prosecution

- In 2014, Dignity Health agreed to pay $1.55 million to resolve allegations that its compliance procedures and controls failed to prevent diversion of over 20,000 oxycodone tablets.
- In 2015, Massachusetts General Hospital agreed to pay $2.3 million to resolve allegations that lax controls enabled its employees to divert approximately 16,000 oxycodone pills from automated dispensing machines.
- In 2016, Appalachian Regional Healthcare, Inc. agreed to pay $150,000 to resolve allegations that its pharmacy filled improper prescriptions written by an ER physician.

Government Response: National Takedown

- In June 2018, Attorney General Jeff Sessions and Department of Health and Human Services (HHS) Secretary Alex M. Azar III, announced the largest ever health care fraud enforcement action involving 601 charged defendants across 58 federal districts, including 165 doctors, nurses and other licensed medical professionals, for their alleged participation in health care fraud schemes involving more than $2 billion in false billings.
- Of those charged, 162 defendants, including 76 doctors, were charged for their roles in prescribing and distributing opioids and other dangerous narcotics.
- In addition, HHS announced that from July 2017 to June 2018, it has excluded 2,700 individuals from participation in Medicare, Medicaid, and all other Federal health care programs, which includes 587 providers excluded for conduct related to opioid diversion and abuse.

Government Response: Federal Legislative Action

- The Drug Quality Security Act (DQSA) was enacted by Congress on November 27, 2013 and will be fully operational by 2023.
- Title II of DQSA, the Drug Supply Chain Security Act (DSCSA) outlines steps to build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States.
- DSCSA directs the Food and Drug Administration (FDA) to establish national licensure standards for wholesale distributors and third-party logistics providers and requires these entities to report licensure and other information to the FDA annually.
- Pharmacies must only accept prescription drugs that are accompanied by three pieces of product tracing documentation – transaction information, transaction history, and transaction statement. This documentation must be stored in paper or electronic format for six years.

Source: DSCSA-fda.gov

Government Response: Federal Legislative Action

- The President on Oct. 24, 2018 signed into law the Substance Abuse Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT).
- A comprehensive law that requires efforts across federal agencies to mitigate the opioid epidemic.
  - The SUPPORT Act provides for greater access to treatment, alternative pain management, and payment mechanisms to make recovery more accessible.
  - The SUPPORT Act also contains increased fraud and abuse tools .
  - The Act created the Eliminating kickbacks in Recovery Act which makes it illegal for providers to solicit, receive, induce or offer to pay remuneration in return for referring patients to a recovery home, clinical treatment facility, or lab.
    - Penalty: $200,00 in fines and up to 10 years in prison.

Government Response: New CMS Rules on Frequently Abused Drugs

- Part D Sponsors in 2019 started managing frequently abused drugs (FAD) as part of their drug management programs.
- Beneficiaries are deemed at risk if they are identified by clinical guidelines to be at risk for misusing or abusing FADs.
- Part D Sponsors need to conduct case management, obtain prescriber buy in that the limitation is appropriate, and provide specific beneficiary notices about the limitation.
- Some beneficiaries are exempt from these requirements due to the nature of their care needs; *e.g.*, hospice.

Government Response: New York State Legislative Action

- Effective 8/27/2013, the I-STOP program requires prescribers to consult the Prescription Monitoring Program Registry when writing prescriptions for Schedule II, III and IV controlled substances.
- To cut down on prescription pad thefts, NYS required mandatory electronic prescribing as of 3/27/2016 with limited exceptions.
- Effective 3/1/2018, a Written Treatment Plan for Opioid Prescribing is required if a practitioner prescribes opioids for pain that has lasted for more than 3 months or past the time of normal healing.
- In 2019 the Drug Protection Act was approved. Article 20-D of NYS Tax Law established an excise tax on the sale of certain opioids. An annual report is to be filed with the NYS DOH detailing all opioids sold into or within NYS. The first report is due 7/20/2020 for drugs sold from 7/1/2019 through 12/31/2019.

Source: NYS BNE website

GOVERNMENT RESPONSE: ENFORCEMENT EFFORTS

- Purdue Pharma LP is just one of the opioid companies being sued by more than 2,000 cities and counties for "grossly" misrepresenting "the risks of long-term use of those drugs for persons with chronic pain," according to court documents. ... Purdue Pharma has earned more than $35 billion from the sale of OxyContin.
- Purdue filed for Chapter 11 protection along with more than a dozen affiliates on Sept. 15, 2019. Shortly before filing, the company reached a tentative settlement with states in which roughly 2,000 suits would be dropped in exchange for the Sacklers giving up their stake in the company, selling off their ownership in other pharmaceutical companies and turning at least $3 billion of the proceeds over to the estate.
- Twenty-four states, the District of Columbia and hundreds of cities, counties, Native American tribes and other governmental entities refused the deal, and the company asked for a nationwide stay of all of the suits against it and the Sacklers.

Government Response: Enforcement Efforts

Johnson & Johnson

- In a landmark ruling, an Oklahoma judge ordered J&J on August 27, 2019 to pay $572 million for contributing to the state's opioid crisis.
- The Judge stated "The opioid crisis is an imminent danger and menace to Oklahomans. My judgment includes findings of fact and conclusions of law that the state met its burden that the defendants Janssen and Johnson & Johnson's misleading marketing and promotion of opioids created a nuisance as defined by 50 O.S. Section 1, including a finding that those actions compromised the health and safety of thousands of Oklahomans. Specifically, defendants caused an opioid crisis that is evidenced by increased rates of addiction, overdose deaths and neonatal abstinence syndrome in Oklahoma. This is a temporary public nuisance that can be abated. And the proper remedy for public nuisance is equitable abatement. As I just stated, the opioid crisis has ravaged the state of Oklahoma. It must be abated immediately. For this reason, I am entering an abatement plan that consists of costs totaling $572,102,028 to immediately remediate the nuisance."
- On appeal.

GOVERNMENT RESPONSE: ENFORCEMENT EFFORTS

Opioid Multi District Litigation Bellwether Trial

- Scheduled to begin Mon., Oct. 21, 2019.
- Mark the first time that a jury — which was officially assembled on Thursday, October 18, 2019 — has been asked to hold drug companies responsible for the opioid crisis.
- Overdoses involving prescription and illicit opioids have claimed more than 400,000 lives since 1999, representing what plaintiffs in multidistrict opioid litigation have called "the worst man-made epidemic in modern medical history."
- As currently envisioned, the bellwether trial would pit the northern Ohio counties of Cuyahoga and Summit against drugmaker Teva Pharmaceuticals and five companies accused of unlawful painkiller distribution: AmerisourceBergen Corp., Cardinal Health Inc., McKesson Corp., Walgreen Co. and Henry Schein Inc. The counties have requested as much as $9 billion, much of it for addiction treatment and prevention, if the trial goes all the way to a verdict.

Source: Law360, 10/17/19, https://www.law360.com/health/articles/1209863/what-to-watch-as-opioid-mdl-nears-moment-of-truth?nl_pk=d500baca-eda4-41c0-acc2-23589e7a118d&utm_source=newsletter&utm_medium=email&utm_campaign=health.

GOVERNMENT RESPONSE: ENFORCEMENT EFFORTS

- **Opioid Multi District Litigation Bellwether Trial**
  - J&J's brief denounced "unscrupulous doctors" for writing improper painkiller prescriptions, pointed to "foreign criminal cartels that flooded the country with heroin and fentanyl" and argued that the federal government failed to take "adequate steps to combat prescription drug diversion."
  - In a separate brief, Teva Pharmaceuticals argued that Cuyahoga and Summit should look in the mirror if they're searching for causes of the opioid crisis, arguing that the counties' continuing coverage of opioids for chronic pain is a factor.
  - In another trial brief, drug distribution giant McKesson Corp. — which in 2017 paid a record $150 million penalty for alleged violations of the Controlled Substances Act — vowed to seek a jury verdict that would "allocate fault for plaintiffs' injuries among multiple alleged causes." McKesson specifically pointed fingers at criminals "who diverted opioids to illicit use," the "plaintiffs themselves" and "the opioid manufacturers who allegedly caused doctors to write medically unnecessary opioid prescriptions."

Source: Law360, 10/17/19, https://www.law360.com/health/articles/1209863/what-to-watch-as-opioid-mdl-nears-moment-of-truth?nl_pk=d500baca-eda4-41c0-acc2-23589e7a118d&utm_source=newsletter&utm_medium=email&utm_campaign=health.

GOVERNMENT RESPONSE: ENFORCEMENT EFFORTS

- **Opioid Multi District Litigation Bellwether Trial—Theory of Liability**
  - The most consequential legal claim advanced by Cuyahoga and Summit is that pharmaceutical companies created a "public nuisance" in the form of the opioid crisis. Most of the roughly $9 billion sought by plaintiffs hinges on the nuisance theory's success. The nuisance theory is deeply controversial in the product liability bar; many defense lawyers note that nuisance cases have historically been limited to blighted or disreputable properties, such as polluted waterways or brothels. But Oklahoma's first-in-the-nation opioid trial — which took place this year outside the MDL and only targeted Johnson & Johnson — saw the nuisance theory wielded successfully to win a nine-figure bench judgment against J&J.
  - Ohio's common law definition of a public nuisance prohibits an "unreasonable interference with a right common to the general public." The counties' other legal claims generally allege a corrupt racketeering conspiracy intended to maintain illegitimate opioid sales. According to the counties, the companies have all fulfilled opioid orders despite red flags, and some of them "jointly".
  - As one example of opioid sales in the areas, plaintiffs attorneys say that almost 400 million opioid pills were shipped into Cuyahoga County from 2006 to 2014, the equivalent of roughly 35 pills every year for every resident.
  - **What is to prevent the same nuisance theory applied against a hospital?**
    - NY defn of public nuisance: A public nuisance is that which obstructs the public in the exercise of rights common to all. See *New York Trap Rock Corp. v. Town of Clarkstown*, 299 N.Y. 77, 85 N.E.2d 873 (N.Y. 1949).

Source: Law360, 10/17/19, https://www.law360.com/health/articles/1209863/what-to-watch-as-opioid-mdl-nears-moment-of-truth?nl_pk=d500baca-eda4-41c0-acc2-23589e7a118d&utm_source=newsletter&utm_medium=email&utm_campaign=health.

GOVERNMENT RESPONSE: ENFORCEMENT EFFORTS

- **Opioid Multi District Litigation Bellwether Trial**
  - **Four Drug Companies Reach Last-Minute Settlement in Opioid Litigation***
  - Four drug companies have reached a settlement at the last minute to avoid a trial seeking to blame them for fueling the opioid crisis, according to people familiar with the matter.
  - Details of the settlements with McKesson Corp., Cardinal Health Inc., AmerisourceBergen Corp. and Teva Pharmaceutical Industries Ltd. will be announced Monday morning, the people said.

*The Wall Street Journal, 10/21/19, https://www.msn.com/en-us/money/companies/four-drug-companies-reach-last-minute-settlement-in-opioid-litigation/ar-AAJ6ZDR?ocid=spartandhp.

GOVERNMENT RESPONSE: ENFORCEMENT EFFORTS

- **Opioid Multi District Litigation Bellwether Trial**
  - Four attorneys general on Monday, Oct. 21, 2019 unveiled a proposed $48 billion deal with major drug companies — Teva Pharmaceuticals, Johnson & Johnson and the nation's largest drug distributors — to resolve a wave of opioid-crisis lawsuits.
  - The proposed global deal would settle suits accusing Teva, J&J, McKesson Corp., Cardinal Health Inc. and AmerisourceBergen Corp. of fueling an addiction epidemic with reckless painkiller sales.
  - Under the deal, Teva would cough up $23 billion in drug donations and $250 million in cash over 10 years, J&J would pay $4 billion over two or three years, and distributors would pay $18 billion over 18 years, while chipping in another $3 billion in distribution and monitoring services over 10 years.

*Source Law360 at https://www.law360.com/health/articles/1211876/state-ags-reach-48b-proposed-deal-to-end-opioid-cases?nl_pk=d500baca-eda4-41c0-acc2-23589e7a118d&utm_source=newsletter&utm_medium=email&utm_campaign=health.

HOW TO MANAGE THE OPIOID COMPLIANCE CRISIS

- Stay Informed
- Policies
- Monitoring
- Governance
- Know the law

Stay Informed

- Stay informed about what is happening on the regulatory, legislative, enforcement and judicial fronts with regard to opioids.
- Collaborate with internal departments, patient advocacy groups, clinical experts and others to develop strategies to handle risk areas related to opioid fraud and abuse.
- View the podcast entitled OIG's Work Against the Opioid Epidemic at https://oig.hhs.gov/newsroom/podcasts/2017/opioid-stream.html.

What you can do tomorrow: Monitoring

- Coordinate with internal personnel to initiate internal data monitoring that specifically targets opioid fraud and abuse.
- Have an interdisciplinary team to review prescriber analysis and treatment protocols.
- Hospital pharmacists are uniquely qualified to curb opioid diversion. Establish an opioid diversion prevention and detection programs through which pharmacists can ensure the supply of opioids are used appropriately and prevent misuse through diversion.
- Pharmacists can also use data from the NYS Prescription Monitoring Program Registry to track prescribing practices and patient behaviors that can lead to abuse.

What you can do tomorrow: Monitoring

- Review the OIG Report entitled **Toolkit: Using Data Analysis To Calculate Opioid Levels and Identify Patients At Risk of Misuse or Overdose.**
  - OIG Report OEI-02-17-00560.
  - https://oig.hhs.gov/oei/reports/oei-02-17-00560.asp.
  - This toolkit provides detailed steps for using prescription drug claims data to analyze patients' opioid levels and identify certain patients who are at risk of opioid misuse or overdose. It is based on the methodology that OIG has developed in our extensive work on opioids.
  - Mimic the toolkit data metrics for your organization.

What you can do tomorrow: Policies

Update and monitor policies pertaining to physical, administrative and technical medication safeguards, inventory management and risk identification.

What you can do tomorrow: Governance

- Inform your governing boards, or board compliance committee, of an overview and updates on new opioid regulations and changes in the law.
- The board needs to appreciate how the opioid epidemic affects the organization as well as expectations from government agencies.

Know the Law

- The "Principles of Federal Prosecution of Business Organizations" in the Justice Manual describe specific factors that prosecutors should consider in conducting an investigation of a corporation, determining whether to bring charges, and negotiating plea or other agreements.
- These factors include "the adequacy and effectiveness of the corporation's compliance program at the time of the offense, as well as at the time of a charging decision" and the corporation's remedial efforts "to implement an adequate and effective corporate compliance program or to improve an existing one."

Evaluating a Corporate Compliance Program Regarding Opioid Abuse

- In the April 2019 U.S. Department of Justice guidance document on *Evaluation of Corporate Compliance Programs*, three "fundamental questions" a prosecutor should ask are identified:
  1. "Is the corporation's compliance program well designed?"
  2. "Is the program being applied earnestly and in good faith?" In other words, is the program being implemented effectively?
  3. "Does the corporation's compliance program work" in practice?
- A health system can take several steps to establish or enhance its compliance program to mitigate opioid diversion.

Program Enhancement Addressing Opioid Abuse

- Conduct comprehensive background checks and investigations of workforce member candidates, including employees, interns, students, contractors, consultants, and volunteers.
- Investigate and report any individual with substantiated wrongful conduct to state and local law enforcement.
- Conduct pre-employment drug testing for specific opioids in addition to common street drugs.

Program Enhancement (cont.)

- Regularly audit opioid dispensing mechanisms and storage facilities and immediately address the audit findings.
  - Determine why dosage/unit counts are off and how the controlled substances went missing.
  - Test vials/ampules of liquid opioids to see whether they have been surreptitiously replaced with saline or water.
- Consider the placement of opioid dispensers/machines. Diverters easily take advantage of machines placed in isolated rooms, out of public view, or near bathrooms where the diverter can quickly hide after stealing the medication.
- Consider installing security cameras near the dispensers.

Program Enhancement (cont.)

- Train all workforce members about diversion and prevention and instill a zero-tolerance culture against diversion.

Responsible Corporate Officer (RCO) Doctrine

- The government has stated its clear intention to prevent the illegal diversion of highly addictive drugs from healthcare institutions. Diversion is the removal of prescription drugs from intended recipients to others, typically for illicit purposes.
- The government may decide to hold officers, managing employees, and even general counsel of health systems accountable for illegal diversion of opioids under the RCO doctrine.
- Under the RCO, management can be held criminally liable for their subordinates' violations of the federal Food, Drug, and Cosmetic Act (FDCA).

The Evolution of the Opioid Crisis: Where, When and How Does It End?

- Crystal balls are at a premium in the risk management business.
- None of us know the end point of the opioid crisis.
- We all need to address the opioid risks consistent with our resources.
- The fact we cannot do everything does not mean we should do nothing.
- If the federal government can identify one Medicare beneficiary, out of 44 million, involved in opioid abuse, then your data analytics must also be sufficiently robust to gain insight into treatment protocols and prescriber analysis.

Shield Act

- The Stop Hacks and Improve Electronic Data Security, or SHIELD Act, is a cybersecurity and data breach law that is scheduled to go into effect on Oct. 23, 2019 and applies to "any person or business that owns ... computerized data which includes private information," as defined in the act, regardless of corporate structure, revenues or location. My organization is ready for the Shield Act.

My organization is ready for the Shield Act.

True

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Shield Act

- The SHIELD Act requires "any person or business that owns or licenses computerized data which includes private information of a resident of New York" to "develop, implement and maintain reasonable safeguards to protect the security, confidentiality and integrity of the private information." The act imposes detailed requirements about the administrative, technical and physical safeguards covered entities must adopt, in meeting data security requirements.

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Questions?

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