Fox Rothschild LLP
ATTORNEYS AT LAW

HIPAA Audit Preparedness

Elizabeth G. Litten, Esq.

May 12, 2017
HCCA New York Regional Conference
New York, NY

Overview

- HIPAA Audits
- HHS/OCR Settlement Agreements
- OCR's Focus for 2017

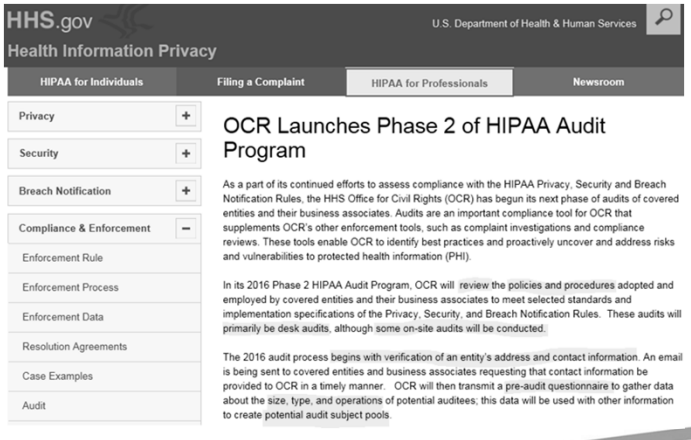
Fox Rothschild LLP
ATTORNEYS AT LAW

HIPAA Audit Program

Fox Rothschild LLP
ATTORNEYS AT LAW

HIPAA Audits

www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/phase2announcement/index.html



Fox Rothschild LLP
ATTORNEYS AT LAW

2016 Phase 2 HIPAA Audit Program Continues

Goal: audit 200-250 Covered Entities (CEs) and Business Associates (BAs)

- Emails verifying contact information received in spring of 2016
- Subset received "Audit Pre-Screening Questionnaire" in spring/summer of 2016 (20 questions)
- 167 CEs selected via randomized selection algorithm for desk audits (BA selection was to have occurred in fall 2016)
- Subset of CEs selected for 2017 on-site audits

Fox Rothschild LLP
ATTORNEYS AT LAW

Phase 2 HIPAA Audit Program, cont.

- Desk Audit HIPAA Controls: 7 Areas of Focus
  - NPP content and practices – 45 CFR 164.520(a)(1) and (b)(1)
  - NPP electronic notice requirements – 164.520(c)(3)
  - Patients' right to access PHI – 164.524
  - Timeliness of breach notification – 164.404(b)
  - Content of breach notification – 164.404(c)(1)
  - Security Risk Analysis – 164.308(a)(1)(ii)(A)
  - Security Risk Management – 164.308(a)(1)(ii)(B)

Fox Rothschild LLP
ATTORNEYS AT LAW

Phase 2 HIPAA Audit Program, cont.

- OCR Q/A Insights:
  - Desk audit may be Privacy-focused or Security-focused
  - Required submission of Privacy Policies and Procedures
  - Required submission of Security Risk Assessments (current, previous year, 6 years ago)
  - Lack of cooperation with desk audit could trigger on-site audit
  - If CE has multiple locations and audit letter is received by administrative office, all locations are subject to the audit
  - Privacy audit will confirm NPP is consistent with access P&Ps

Fox Rothschild LLP
ATTORNEYS AT LAW

Who Is Being Audited?

- Covered Entities
- Business Associates
- Individuals and Organizations
- Large and Small
- Entities “All Sizes and Functions”

Fox Rothschild LLP
ATTORNEYS AT LAW

How Does OCR Pick?

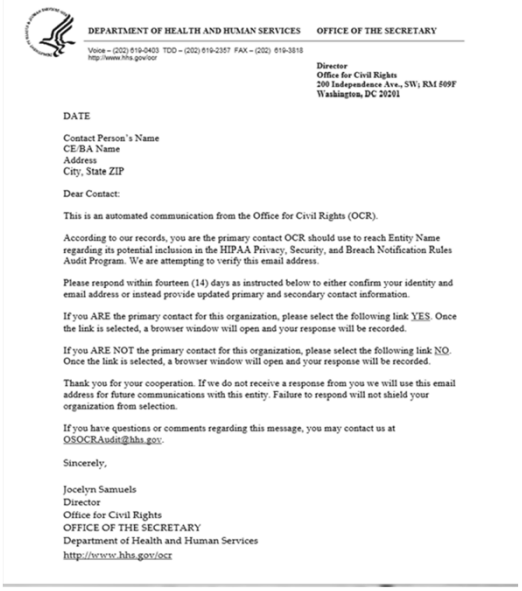
- Want a ***broad spectrum*** of candidates. Entities of ***all sizes and functions***.
- OCR has an algorithm with ***sampling criteria***:
  - Size
  - Type
  - Operations
  - Affiliations/relationship with other health care organizations
  - Public/private
  - Geography
- Did not select entities that had current open complaint investigation or undergoing a compliance review by OCR.

Fox Rothschild LLP
ATTORNEYS AT LAW

The Process

- Contact Info **Verification Letter** *(or email)*
- **Pre-Screening Questionnaire** sent to gather additional data about size, type and operations
- **Identification of Business Associates** (*spreadsheet*)
- OCR selected entities for HIPAA Audit through **random sampling;** selected auditees were **notified by email** of their participation

Fox Rothschild LLP
ATTORNEYS AT LAW



DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF THE SECRETARY

Voice – (202) 619-0403 TDD – (202) 619-2357 FAX – (202) 619-3818
http://www.hhs.gov/ocr

Director
Office for Civil Rights
200 Independence Ave., SW, RM 509F
Washington, DC 20201

DATE

Contact Person's Name
CE/BA Name
Address
City, State ZIP

Dear Contact:

This is an automated communication from the Office for Civil Rights (OCR).

According to our records, you are the primary contact OCR should use to reach Entity Name regarding its potential inclusion in the HIPAA Privacy, Security, and Breach Notification Rules Audit Program. We are attempting to verify this email address.

Please respond within fourteen (14) days as instructed below to either confirm your identity and email address or instead provide updated primary and secondary contact information.

If you ARE the primary contact for this organization, please select the following link YES. Once the link is selected, a browser window will open and your response will be recorded.

If you ARE NOT the primary contact for this organization, please select the following link NO. Once the link is selected, a browser window will open and your response will be recorded.

Thank you for your cooperation. If we do not receive a response from you we will use this email address for future communications with this entity. Failure to respond will not shield your organization from selection.

If you have questions or comments regarding this message, you may contact us at OSOCRAudit@hhs.gov.

Sincerely,

Jocelyn Samuels
Director
Office for Civil Rights
OFFICE OF THE SECRETARY
Department of Health and Human Services
http://www.hhs.gov/ocr

"Communications from OCR will be sent via email and may be incorrectly classified as spam. If your entity's spam filtering and virus protection are automatically enabled, we expect you to check your junk or spam email folder for emails from OCR."

Fox Rothschild LLP
ATTORNEYS AT LAW

Alert: Phishing Email Disguised as Official OCR Audit Communication - November 28, 2016

It has come to our attention that a phishing email is being circulated on mock HHS Departmental letterhead under the signature of OCR's Director, Jocelyn Samuels. This email appears to be an official government communication, and targets employees of HIPAA covered entities and their business associates. The email prompts recipients to click a link regarding possible inclusion in the HIPAA Privacy, Security, and Breach Rules Audit Program. The link directs individuals to a non-governmental website marketing a firm's cybersecurity services. In no way is this firm associated with the U.S. Department of Health and Human Services or the Office for Civil Rights. We take the unauthorized use of this material by this firm very seriously.

OCR would like to further share that this phishing email originates from the email address OSOCRAudit@hhs-gov.us and directs individuals to a URL at http://www.hhs-gov.us. This is a subtle difference from the official email address for our HIPAA audit program, OSOCRAudit@hhs.gov, but such subtlety is typical in phishing scams.

Covered entities and business associates should alert their employees of this issue and take note that official communications regarding the HIPAA audit program are sent to selected auditees from the email address OSOCRAudit@hhs.gov. In the event that you or your organization has a question as to whether it has received an official communication from our agency regarding a HIPAA audit, please contact us via email at OSOCRAudit@hhs.gov

https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/

Fox Rothschild LLP
ATTORNEYS AT LAW

What Is the Status of Audits?

- **DESK Audits**
  - Auditees submitted documentation via a "*secure audit portal*"
  - **Round 1 = Covered Entities**
  - **Round 2 = Business Associates**
  - Round 1 desk audits are complete
  - No information yet from OCR about generalized findings

- **ONSITE Audits** – **Round 3.**
  - **Covered Entities and Business Associates**
  - Onsite Audits slated to commence in 2017
  - Might request certain information be submitted **via OCR portal**
  - Will examine a **broader scope** of requirements

Fox Rothschild LLP
ATTORNEYS AT LAW

OCR's Focus for 2017

- Continuation with HIPAA Audits – Onsite Visits
- Modernizing HIPAA and Supporting Innovation in Healthcare –
  - Efforts to "modernize" health information privacy and security protections through expanded guidance and regulatory change
  - Enable further advances in health care, research, and technology that will improve health outcomes and improve ability to detect and prevent cyber-attacks
    - OCR Guidance on HIPAA and Cloud Computing (October 2016) – identifying cloud services providers (CSPs) as business associates (to extent they receive or maintain PHI) and addressing situations in which CSPs experience security events

Fox Rothschild LLP
ATTORNEYS AT LAW

Select 2017 Compliance Areas: (1) Access Rights

- HHS FAQs (https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/access/#newlyreleasedfaqs) and Audit item 3 of 7 emphasize focus on individual right to access PHI
- Access v. Authorization (don't use latter when request is for Access!)
- Right to access (most) PHI in Designated Record Set
- May require request to be in writing, if CE informs individual of the requirement
- Reasonable verification – cannot create barriers or unreasonable delay
  - May not require individual to physically come to office if mailing requested
  - May not require use of web portal

Fox Rothschild LLP
ATTORNEYS AT LAW

Select 2017 Compliance Areas: (1) Access Rights, cont.

- May provide summary, if individual agrees in advance
- Expected that all CEs can readily produce and provide via email
  - Must send via unencrypted email, if requested by individual
  - Must provide brief warning that there is "some level of risk" while in transit
- Form and format of request
  - Paper records must be provided electronically, if so requested, if "readily producible" (i.e., can scan)

Fox Rothschild LLP
ATTORNEYS AT LAW

Select 2017 Compliance Areas: (1) Access Rights, cont.

- Acceptable fees include ONLY:
  - Cost of labor for copying PHI requested, whether paper or electronic
  - Cost of supplies for creating copy
  - Postage, when request for PHI to be mailed
  - Cost of preparation of summary or explanation, where requested, and individual agrees to cost in advance.

May not charge any additional amounts, even if authorized by State law!

Fox Rothschild LLP
ATTORNEYS AT LAW

Select 2017 Compliance Areas: (2) Texting PHI

- Mobile devices and texting
  - Spring of 2016: Joint Commission publishes reversal of 2011 FAQ prohibiting physicians/practitioners from using texts to order care.
  - Texting is permitted if a secure platform is used that includes:
    - Secure sign-in process
    - Encrypted messaging
    - Delivery and read receipts
    - Date and time stamp
    - Customized message retention time frames
    - Specified contact list for individuals authorized to receive and record orders

Correction: the Joint Commission took an about-face on this issue in late 2016 and now, once again, prohibits the use of text messaging (even secure) for transmission of orders.

Fox Rothschild LLP
ATTORNEYS AT LAW

Select 2017 Compliance Areas: (3) Security Policies

- Enterprise-wide Risk Analysis and Security Policies
  - Media and Device Policies & Procedures (BYOD restrictions; secure network use)
  - Security Awareness and Training for Workforce
  - User attestations
  - Encryption!
- MAPFRE Life – 2017 $2.2M "Resolution Amount" and CAP
  - Unencrypted pen drive stolen from IT department overnight results in breach affecting 2,209 individuals

Fox Rothschild LLP
ATTORNEYS AT LAW

Select 2017 Compliance Areas: (4) Health Apps

Mobile Health App: is App Developer Your BA?

- "Fact and circumstance specific" (https://www.hhs.gov/hipaa/for-professionals/special-topics/developer-portal/index.html?language=es)
- Patient downloads health app to smartphone and inputs health information – HIPAA does not apply, because app developer is not creating, receiving, maintaining or transmitting PHI as a CE or BA/Subcontractor
- Patient downloads health app to smartphone because provider makes app available to patients – HIPAA applies because developer is BA of provider

Fox Rothschild LLP
ATTORNEYS AT LAW

Select 2017 Compliance: (5) Cloud Service Providers

- Encryption is not enough – CSP maintaining PHI is a Business Associate, as per HHS
- The "blindfolded Business Associate": CSP may not know it holds PHI – must verify the type of data it holds, particularly if encrypted
- Service Level Agreement must be consistent with HIPAA and Business Associate Agreement

(https://www.hhs.gov/hipaa/for-professionals/special-topics/cloud-computing/index.html?language=es)

Fox Rothschild LLP
ATTORNEYS AT LAW

Select 2017 Compliance Areas: (6) Telehealth/Telemedicine

- Effective 1/1/17, CMS using new POS code 02 for telehealth and reimburse using facility rate for Method II Critical Access Hospital
- Consider Joint Commission requirements for secure texting as possible model for secure telehealth platform

Fox Rothschild LLP
ATTORNEYS AT LAW

Select 2017 Compliance Areas: (7) BAs and Big Data

- Does BAA permit Data Aggregation?
- Is BA performing Data Aggregation *on behalf of* CE?
  - "Data Aggregation" means, with respect to BA, combining of CE's PHI with PHI of another CE "to permit data analyses that relate to the health care operations of the respective" CEs (45 CFR 164.501)
  - "Health Care Operations" means activities of CE including quality assessment and improvement; review of competence of health care professionals; medical review, legal services, auditing; business management activities of CE (45 CFR 164.501)

Fox Rothschild LLP
ATTORNEYS AT LAW

HIPAA Settlements

Fox Rothschild LLP
ATTORNEYS AT LAW

OCR Resolution Agreements

www.hhs.gov/hipaa/for-professionals/compliance-enforcement/agreements/index.html

1. **July 16, 2008: Providence Health & Services ($100K)**
2. **January 16, 2009: CVS Pharmacy, Inc. ($2.25M)**
3. **July 27, 2010: Rite Aid Corporation ($1M)**
4. **December 13, 2010: MSO Washington, Inc. ($35K)**
5. **February 4, 2011: Cignet Maryland ($4.3M) [CMP]**
6. **February 14, 2011: Gen Hospital & Mass General Phys ($1.5M)**
7. **July 6, 2011: UCLA Health System ($865,500K)**
8. **March 13, 2012: BCBS Tennessee ($1.5M)**
9. **April 13, 2012 : Phoenix Cardiac Surgeons ($100K)**
10. **June 26, 2012: Alaska DHSS($1.7M)**
11. **September 17, 2012: Mass Eye & Ear Associates ($1.5M)**
12. **December 31, 2012: Hospice of Northern Idaho ($50K)**

Fox Rothschild LLP
ATTORNEYS AT LAW

Case Examples & Resolution Agreements *(continued)*

13. **May 21, 2013: Idaho State University ($400K)**
14. **June 13, 2013: Shasta Regional Medical Center ($275K)**
15. **July 11, 2013: WellPoint ($1.7M)**
16. **August 14, 2013: Affinity Health Plan ($1,215,780)**
17. **Dec 20, 2013: Adult/Pediatric Dermatology P.C. ($150K)**
18. **March 7, 2014: Skagit County, Washington ($215K)**
19. **April 22, 2014: QCA Health Plan Inc. ($250K)**
20. **April 22, 2014: Concentra Health Services ($1,725,220)**
21. **May 7, 2014: NY and Presbyterian Hospital ($3.3M)**
22. **May 7, 2014: Columbia University ($1.5M)**
23. **June 23, 2014: Parkview Health System ($800K)**
24. **Dec 2, 2014: Anchorage Comm. Mental Health ($150K)**

Fox Rothschild LLP
ATTORNEYS AT LAW

Case Examples & Resolution Agreements *(continued)*

25. April 22, 2015: Cornell Prescription Pharm ($125K)
26. June 10, 2015: St Elizabeth Medical ($218,400)
27. August 31, 2015: Cancer Care Group ($750K)
28. November 24, 2015: Lahey Hospital ($850K)
29. November 30, 2015: Triple-S Corp ($3.5M)
30. December 14, 2015: Univ of Washington ($750K)
31. February 3, 2016: Lincare, Inc ($239,800)
32. February 16, 2016: Pool & Land PT ($25K)
33. March 16, 2016: North Memorial Health Care ($1.55M)
34. March 17, 2016: Feinstein Institute ($3.9M)
35. April 14, 2016: Raleigh Ortho Clinic ($750K)
36. April 21, 2016: NY Presbyterian ($2.2M)

Fox Rothschild LLP
ATTORNEYS AT LAW

Case Examples & Resolution Agreements *(continued)*

37. June 29, 2016: Catholic Health Services (BA) ($650K)
38. July 18, 2016: Oregon Health & Science Univ ($2.7M)
39. July 21, 2016: Univ of Mississippi Medical ($2.75)
40. August 4, 2016: Advocate Health ($5.55M)
41. September 23, 2016: Care New England Health ($400K)
42. October 17, 2016: St. Joseph Health ($2.14M)
43. November 22, 2016: Univ of Massachusetts Amherst ($650,000)

Fox Rothschild LLP
ATTORNEYS AT LAW

Case Examples & Resolution Agreements *(continued)*

42. **January 9, 2017: Presence Health ($475,000)**
43. **January 18, 2017: MAPFRE Life Insurance Company of Puerto Rico ($2.2M)**
44. **February 2, 2017: Children's Medical Center of Dallas ($3.2M)**
45. **February 16, 2017: Memorial Healthcare Systems ($5.5M)**

Fox Rothschild LLP
ATTORNEYS AT LAW

Rise in Enforcement Activity

- Over 7 years of enforcement. As of Feb. 28, 2017:
  - OCR has received over 150,000 HIPAA complaints
  - OCR has investigated and resolved almost 25,000 cases, requiring corrective action
  - OCR has settled 47 cases, resulting in total penalties of over $67.2 Million
- 2016 was a record setting year:
  - HIPAA Enforcement actions: 13
    (prior record: 7 in 2014)
  - Collections on HIPAA enforcement: $23 Million
    (prior record: $7.4 Million in 2014)
  - Single largest fine for HIPAA violations: $5.5 Million
    (prior record: $4.8 Million in 2011 (Cignet Health: $4.3M -- $1.3M for violations & $3M for failing to cooperate with investigation))

Fox Rothschild LLP
ATTORNEYS AT LAW

OCR Enforcement

- Compliance issues investigated most are, in order of frequency:
  - Impermissible uses and disclosures of protected health information;
  - Lack of safeguards of protected health information;
  - Lack of patient access to their protected health information;
  - Use or disclosure of more than the minimum necessary protected health information; and
  - Lack of administrative safeguards of electronic protected health information.

OCR Enforcement

- The most common types of covered entities that have been required to take corrective action are, in order of frequency:
  - Private Practices;
  - General Hospitals;
  - Outpatient Facilities;
  - Pharmacies; and
  - Health Plans (group health plans and health insurance issuers).

Enforcement Lessons Learned From OCR

- **Encrypt laptops and mobile devices, including thumb drives!**
  - Providence Health ($100K)
  - Idaho Hospice($50K)
  - Mass Ear/Eye MDs ($1.5 M)
  - Alaska DHSS ($1.7M)
  - Concentra ($1.725M) (if you don't, document the alternative used)
  - QCA ($250K)
- **Dispose of PHI properly, including wiping leased copiers of ePHI!**
  - CVS ($2.25M)
  - Rite Aid ($1M)
  - Affinity Health ($1.2M) (purge ePHI from copiers & devices!)
  - Parkview Health System ($800K) (don't leave PHI in driveways!)
- **Don't take PHI off-site!** (Gen Hospital Corp. & Mass Gen MD Org ($1.5M))
- **Enter into BA Agreements with vendors who store or secure your PHI!**
  - BCBS Tennessee ($1.5M)
  - AZ Cardiologists ($100K)

Fox Rothschild LLP
ATTORNEYS AT LAW

Enforcement Lessons Learned

- **Perform** and **Update Security Risk Assessments, especially with system upgrades**
  - BCBS Tenn ($1.5M)
  - Idaho State Univ ($400K)
  - Wellpoint ($1.7M)
  - Columbia ($1.5) / NY Presbyterian ($3.3M)
  - Anchorage ($150K) (don't use outdated software, and fail to update patches)
- Ensure you have Control Policies over your Devices and Media (Cancer Care)
- Apply **Minimum Necessary** to disclosure within organization! (Shasta Medical)
- **Train & Sanction Employees, Including executives** (Shasta Medical ($275K)
- **CORRECT** Violations!
  - Cignet Maryland ($4.3M)
  - UCLA ($865K)
- **Cooperate with OCR!** Cignet Maryland ($4.3M)

Fox Rothschild LLP
ATTORNEYS AT LAW

Enforcement Lessons Learned *(continued)*

- **Have written Policies, and Implement effectively**
  - Providence Health ($100K)
  - CVS ($2.25M)
  - Rite Aid ($1M)
  - MSO Washington ($35K)
  - Cignet Maryland ($4.3M)
  - General Hospital Corp. & Massachusetts General Physicians ($1.5M)
  - UCLA ($865,500K)
  - BCBST ($1.5M)
  - AZ Cardiac MDs ($100K)
  - Alaska DHSS ($1.7M)
  - Mass MDs ($1.5 M)
  - Idaho Hospice($50K)
  - A&P Dermatology ($150K)
  - Shasta ($275)
  - Wellpoint ($1.7M)
  - Affinity ($1.2M)
  - Skagil ($275K)

Fox Rothschild LLP
ATTORNEYS AT LAW

HIPAA as the "Standard of Care"

- At least 10 States (Delaware, Connecticut, Kentucky, Maine, Minnesota, Montana, North Carolina, Tennessee, Utah, West Virginia) have published judicial decisions and precedent supporting that a court may *at least look* to HIPAA when considering the relevant standard of care for State privacy violation claims brought by individuals.

- *Byrne v. Avery Center for Obstetrics and Gynecology,* the Connecticut Supreme Court went one step further and concluded that HIPAA regulations can establish the standard of care in certain situations!

Fox Rothschild LLP
ATTORNEYS AT LAW

Bryne v. Avery Center for Obstetrics and Gynecology, P.C.

- Facts: Emily Byrne, asked Avery Center for Obstetrics and Gynecology not to provide her PHI to her significant other (HIPAA's Request for Restriction). The Center received **a subpoena** from her significant other's attorneys in a paternity suit, and **promptly turned over the information without alerting the patient or fighting the subpoena in court**.
  - **Byrne sued Avery Center for negligence**, but a lower court ruled that HIPAA preempted the negligence suit. Byrne then appealed.
- Holding: **November 2014, the Connecticut Supreme Court overruled** the lower court and pointed to language in the preamble to the final HIPAA to permit privacy lawsuits based on State law to go forward. **HIPAA does not preempt State law cases of action.**
- **Impact:** De facto right of action under HIPAA, which could subject health care providers to more lawsuits for breaching patient confidentiality.

Fox Rothschild LLP
ATTORNEYS AT LAW

Developments on the Horizon

- ***Premera*** *(currently ongoing)*
  - Insurer suffered data breach that went undetected for over a year, leading to dissemination of sensitive information for approx. 11 million individuals
  - Plaintiffs argue, in part, that NPP is a contract between insurer and consumers
  - In August, Court dismissed certain negligence and breach of contract claims; however, certain claims still unsettled:
    - Fraud allegations regarding statements in the company's privacy notice, code of conduct and other materials provided to consumers; and
    - Breach of contract claims for the statements in the company's privacy notice and "Preferred Select" policy (under Oregon law; claims based on Washington law dismissed)
    - Unjust enrichment claim, alleging that it was unjust for Premera to retain fees for health insurance without securing sensitive data

Fox Rothschild LLP
ATTORNEYS AT LAW

HIPAA Take-Aways and Reminders

- *Due diligence for sale of covered entity: beware of Data Room disclosures!*
- *Data aggregation in the "big data" era: does your BAA permit it?*
- *Patient access rights v. authorization and preemption of state laws regarding copy charges*
- *Medical device hacking*
- *Health apps: is it PHI?*

Fox Rothschild LLP
ATTORNEYS AT LAW

Thank You. Any Questions?

Elizabeth G. Litten, Esq.

Fox Rothschild LLP

elitten@foxrothschild.com

https://hipaahealthlaw.foxrothschild.com

609.895.3320

Fox Rothschild LLP
ATTORNEYS AT LAW