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At the Bar: Balancing Compliance and Mission

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AGENDA

I. Agency Enforcement and Regulatory Updates

II. Hottest Compliance Risks

I. Agency Enforcement and Regulatory Updates

OIG ENFORCEMENT: RETURN ON INVESTMENT

	FY 2013	FY 2014	FY 2015	FY 2016
Individuals and entities excluded from Federal health care programs	3,214	4,017	4,112	3,635
Total health care fraud judgments and settlements	$2.6 billion	$2.3 billion	$1.9 billion	$2.5 billion
Total OIG expected recoveries (including investigations and audits)	$5.8 billion	$4.9 billion	$3.3 billion	$5.6 billion
Return on investment from various HCFAC activities	**$8 to $1**	**$7.7 to $1**	**$8 to $1**	**$8 to $1**

Sources: OIG Budget Requests to Congress (FY 2014, FY 2015, FY 2016; FY 2017); Health Care Fraud and Abuse Control Program Annual Report (FY 2013, FY 2014, FY 2015, FY 2016)

HHS OIG 2017 WORK PLAN

- Annually, the HHS OIG issues a work plan summarizing new and ongoing reviews and activities that the OIG plans to pursue with respect to HHS programs
- For FY 2017, the OIG announced the following priorities related to health centers:
  - HRSA's continued oversight of vulnerable health center grantees (defined as those with documented compliance or financial issues)
  - Health centers' compliance with grant requirements of the Affordable Care Act
  - **NEW:** OIG to investigate whether health services delivered to American Indians and Alaska natives met applicable federal requirements, issue a report reviewing a tribally operated FQHC in FY2018

340B DRUG DISCOUNT PROGRAM

- In response to a 2011 GAO report and Congressional interest, Office of Pharmacy Affairs (OPA) has begun:
  - Annual re-certification of all covered entities (CEs), including contract pharmacy arrangements
  - Targeted and random audits
    - Once an audit report is finalized by OPA, the findings are summarized on OPA's public website without input from the covered entity (CE)
    - Note: Significant uptick in 340B purchases and/or large contract pharmacy networks attract audits

340B DRUG DISCOUNT PROGRAM: AUDITS ON THE RISE

FY	TOTAL AUDITS	FQHC AUDITS	FQHCs WITH FINDINGS
2013	94	10 (11%)	7 (70%)
2014	99	14 (14%)	8 (57%)
2015	200	23 (12%)	19 (83%)
2016	182	32 (18%)	20 (63%)
2017 (as of 5/2/2017)	6	1 (16%)	0 (0%)
Total	**581**	**80 (14%)**	**54 (68%)**

Source: https://www.hrsa.gov/opa/programintegrity/auditresults/fy16results.html (last updated 5/02/2017)

HOT ISSUES IN 340B AUDITS

- Diversion
  - Contract pharmacy dispenses 340B drugs to non-patients
  - Prescription written by ineligible provider
  - No patient record documenting prescription
  - Delivery site not registered on OPA database
- Contract Pharmacies
  - No written contract
  - Actual delivery sites do not match OPA database
- Duplicate Discounts
  - Inaccurate record on OPA Medicaid Exclusion File
    - Billing Medicaid contrary to data on file
    - No NPI or Medicaid billing number registered
  - Using contract pharmacy to dispense to Medicaid fee-for service beneficiaries without method to prevent duplicate discounts
- Administrative
  - Registration of new health center sites with OPA
  - Wrong authorizing official or contact person
  - No, or inadequate, written policies and procedures for 340B program

HIPAA ENFORCEMENT ACTIVITY: UPDATES ON AUDITS

- **Phase 1** (2011- 2012): OCR conducted a pilot audit program to assess 115 covered entities' (CEs) compliance with HIPAA requirements
- **Phase 2 is HERE!**
  - Every covered entity and business associate is eligible for an audit
  - On July 11, 2016, 167 covered entities were notified that they had been selected for desk audits; business associate audits began in Fall 2016
  - OCR will conduct multiple sets or "rounds" of audits:
    - Desk audits of CEs and desk audits of business associates were scheduled to be completed by December 2016
    - **Onsite assessments** of either CEs or business associates – organizations receiving a desk audit may nonetheless be selected for an onsite audit
  - Updated protocol is available on website for review: http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/protocol/index.html
  - Additional Information and FAQs are also available through OCR's website: http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit#when

HIPAA ENFORCEMENT: COMMON THEMES

- Common themes emerging from HIPAA enforcement cases:
  - Lost or stolen backup tapes, laptops, and thumb drives
  - Unencrypted storage of ePHI or otherwise inadequately protected PHI (*e.g.*, hospital network accessible by a default password on a wireless router)
  - No Business Associate Agreement or an outdated agreement
  - No risk assessment or an inadequate risk assessment conducted
  - Significant delay in implementing measures to address any vulnerabilities discovered in a risk assessment or after an actual breach
  - Failure to develop and implement appropriate policies and procedures to safeguard PHI (prior to or after a breach)
  - Lack of appropriate authorizations to use/disclose PHI

2017 HIPAA ENFORCEMENT HIGHLIGHTS

- CardioNet **($2.5 million):** a company laptop containing the ePHI of 1,391 individuals was stolen from a parked vehicle outside of an employee's home. OCR's investigation revealed insufficient risk analysis and risk management processes in place at the time of the theft. Additionally, CardioNet's policies and procedures implementing the standards of the HIPAA Security Rule, including safeguards for ePHI on mobile devices, were in draft form and had not been implemented or finalized.
- Center for Children's Digestive Health (CCDH) **($31,000)**: the HHS Office for Civil Rights (OCR) initiated a compliance review of CCDH following an investigation of CCDH's business associate, FileFax, Inc., which stored records containing protected health information (PHI) for CCDH. Neither party could produce a signed Business Associate Agreement (BAA).
- Metro Community Provider Network (MCPN) **($400,000)**: due to a lack of a security management processes, a hacker was able to access employee email accounts and obtain electronic protected health information (ePHI) for 3,200 individuals through a phishing incident. MCPN's subsequent risk analysis was insufficient and did not meet the requirements of the Security Rule.
- Memorial Healthcare System (MHS) **($5.5 million)**: a former employee's log-in credentials were used by other staff members to improperly access patient PHI on a *daily basis* for at least one year without detection primarily because MHS failed to implement procedures with respect to reviewing, modifying and/or terminating users' right of access.

2016 HIPAA ENFORCEMENT HIGHLIGHTS

- Children's Medical Center of Dallas **($3.2 million)**: Children's submitted breach notification reports for multiple incidents including the loss of an unencrypted, non-password protected BlackBerry device and the theft of an unencrypted laptop. Children's implemented some physical safeguards to the laptop storage area, but did not properly restrict access to workforce not authorized to access ePHI and failed to implement risk management plans for lost devices.
- MAPFRE Life Insurance Company of Puerto Rico **($2.2 million)**: MAPFRE submitted a breach notification report for a USB data storage device stolen from its IT department, where it was left unprotected overnight, which contained the unsecured PHI of 2,209 individuals. MAPFRE also failed to conduct a risk analysis and implement risk management plans, despite representing to OCR that it had, and did not take timely measures to encrypt or otherwise protect ePHI.
- Presence Health Network **($475,000)**: Presence failed to notify OCR within 60 days of a breach affecting 500 or more individuals. On October 22, 2013, a hospital in the Presence system realized that paper operating room schedules containing the PHI of 836 individuals were missing. OCR was not notified until January 31, 2014.
- University of Massachusetts Amherst **($650,000)**: a workstation with ePHI for 1,670 individuals was infected with a malware program, because UMass failed to implement technical security measures (*e.g.*, a firewall) to guard against unauthorized access.

FEDERAL TORT CLAIMS ACT (FTCA) SITE VISITS

- HRSA may conduct a FTCA site visit during the deeming application process and/or as part oversight responsibilities to ensure appropriate implementation of FTCA requirements
  - HRSA states that site visit results will not affect current deeming status; however, should respond to findings prior to next deeming cycle
  - Common Findings:
    - Credentialing & Privileging
      - Lack of Board involvement/oversight in privileging/credentialing
      - Failure to follow peer review policy as part of credentialing and privileging

FTCA SITE VISITS: COMMON FINDINGS

- Quality Improvement & Assurance Systems
  - Failure to have QI/QA Plan with specific clinical/business plan measures
  - Failure to have QI Committee meeting minutes reflect specific information to PDSA processes and projects or other process improvement
  - Board minutes do not reflect discussion of QI activities
  - Failure to conduct peer review appropriately
- Risk Management
  - QI Committee does not review claims
  - Failure to inform Board of claims (both pending and settled)
  - Issues with diagnostic tracking policy
  - Issues with hospitalization tracking policy
  - No system to analyze claims to identify training needs
  - No tracking to demonstrate provider attendance at risk management training
  - Failure to notify patients about FTCA deemed status
  - Limited number of staff review claims for standard of care
  - No process for clinical review of claims

II. Hottest Compliance Topics

DRAFT HEALTH CENTER PROGRAM COMPLIANCE MANUAL

- On August 23, 2016, the Bureau of Primary Health Care (BPHC) released the long-awaited **DRAFT** Health Center Program Compliance Manual
  - The Manual describes the Health Center Program Requirements, integrating policies described in PINs and PALs and providing concrete examples for demonstrating compliance with each requirement
  - The draft Manual will not be used during upcoming OSVs: reviewers have been instructed to use only current guidance (*e.g.*, the Site Visit Guide, PINs, and PALs)
- With the new Administration and new Secretary of Health and Human Services, Tom Price, the final content, form, and date of release for the Compliance Manual remain uncertain

BPHC GUIDANCE THAT WOULD BE SUPERSEDED BY THE COMPLIANCE MANUAL

- If finalized as proposed, the Compliance Manual would **supersede** the following policies:
  - PIN 1994-07: Migrant Voucher Program Guidance
  - **PINs 1997-27 and 1998-24: Affiliation Agreements of Community & Migrant Health Centers and Amendment to PIN 97-27**
  - **PINs 2001-16 and 2002-22: Credentialing and Privileging of Health Center Practitioners and Clarification of PIN 2001-16**
  - PAL 2006-01: Dual-Status Health Centers
  - PIN 2010-01: Confirming Public Agency Status
  - **PIN 2014-01: Health Center Program Governance**
  - **PIN 2014-02: Sliding Fee Discount Program**
  - PAL 2014-08: Health Center Program Requirements Oversight
  - PAL 2014-11: Applicability of PAL 2014-08 to Look-Alikes

BPHC GUIDANCE REMAINING IN EFFECT

- If finalized as proposed, the following policies would remain in effect and would **NOT** be superseded by the final Compliance Manual:
  - **PIN 2007-09: Service Area Overlap**
  - PIN 2007-15: Emergency Management Program Expectations
  - **PIN 2008-01: Defining Scope of Project and Policy for Requesting Changes** and additional related resources
  - **PIN 2009-02: Specialty Services and Scope of Project**
  - PIN 2009-05: Special Population-Only Grantees Requesting a Change in Scope to Add a New Target Population
  - **PIN 2013-01: Budgeting and Accounting Requirements**
  - Federal Tort Claims Act Health Center Policy Manual
  - **Site Visit Guides**
  - Uniform Data System (UDS) Resources

DRAFT HEALTH CENTER PROGRAM COMPLIANCE MANUAL

- Key issues to watch:
  - Patient definition from PIN 2014-01 altered to require that both the service and the site be in-scope for a consumer board member's visit to qualify
  - Prohibition regarding Board member-employee relationships extended to individual contractors
  - Grantees receiving only Health Care for the Homeless and/or Public Housing Primary Care funding no longer exempted from certain governance requirements
  - Ability to have a contracted CEO/management team
  - Heightened expectation to demonstrate accessibility (*e.g.*, distance and travel time)
  - Procurement rules appear to apply to all contracts, not just grant-supported contracts
  - Under the Sliding Fee Discount Program, a referral provider for in-scope services has to offer equal or greater discounts, but there is no mention of referral with payment

OVERVIEW OF SECTION 330 GOVERNANCE HIGH RISK AREAS

Services

- #16: Scope of Project
- #2: Required & Additional Services

- #7: Sliding Fee Discounts
- #10 & #11: Collaborations & Affiliations
- #12: Financial Management and Control Policies
- #14: Budget

Governance

- #17: Board Authority
- #18: Board Composition
- #19: Conflict of Interest Policy

SECTION 330 HIGH RISK AREAS

- **Scope of Project**
  - Maintain accurate and up to date Scope of Project
  - Ensure Board review and approval of: needs assessment findings; service area and target population; health center sites, services, and locations; and new grant application(s)
- **Required and Additional Services**
  - Ensure mix and level of services is consistent with needs assessment / strategic plan
  - Determine most effective mode of delivery for each in-scope service; can vary by site
  - Ensure contracted service arrangements, hospitalization and other referral arrangements are formalized and compliant

SECTION 330 HIGH RISK AREAS

- **Sliding Fee Discount Program**
  - Schedule of Charges should be consistent with locally prevailing charges and designed to cover the health center's costs
  - Evaluate Schedule of Discounts annually to ensure discount levels and/or nominal fee amounts do not create a barrier to care
  - Ensure discounts offered by in-scope referral providers or pay the difference
  - Establish and/or review policies and procedures regarding:
    - Eligibility / income verification documentation
    - Waiver or reduction of fees for individuals who do not otherwise qualify for discounts
    - Partial payment / discount schedules and policies
    - Bad debt write offs and collection from self-pay patients
- **Collaborations & Affiliations**
  - Structure affiliations / collaborations in compliance with all Section 330-related requirements and, as appropriate, procurement rules
  - Address concerns regarding potential service area overlap with other health centers

SECTION 330 HIGH RISK AREAS

- **Financial Management and Control Policies**
  - Ensure financial policies and procedures safeguard health center resources and prevent fraud, waste, and abuse
  - Maintain up-to-date grants management practices
    - Federal dollars and non-federal resources should be tracked separately and allocated appropriately
    - Procurements with federal dollars must be consistent with 45 C.F.R. Part 75
- **Budget**
  - Actively monitor health center budget and expenditures
    - Review monthly reports detailing cash/investments, assets, and liabilities
    - Follow up with the CFO to ensure that any known issues have been resolved
    - Routinely evaluate whether the board-approved budget supports the approved scope, locations, and schedule of services

SECTION 330 HIGH RISK AREAS

- **Board Authority**
  - Ensure bylaws are up to date with required provisions (see PIN 2014-01 and the Site Visit Guide)
  - Hold monthly meetings (no more waivers)
  - Determine which policies must be Board-approved, determining method and frequency for review and update, and **document** approval
  - Provide regular training on appropriate exercise of authorities
- **Board Composition**
  - Ensure compliance with Section 330 composition requirements:
    - 51% consumers , demographically representative of patients served by the health center (see PIN 2014-01 definition)
    - Representation of special populations (*e.g.*, health care for the homeless)
    - No more than 50% of the non-consumer board members may derive more than 10% of their annual income from the health care industry
  - Adopt recruitment and selection procedures in order to maintain a Board with at least 9, but no more than 25 members

SECTION 330 HIGH RISK AREAS

- **Conflict of Interest Policy (or "Standards of Conduct")**
  - Adopt policies that define "conflict of interest"
  - Establish prohibitions regarding: gifts and gratuities, nepotism, and bribery
  - Establish procedures to disclose and manage potential or actual conflicts of interest and include a clear description of the consequences for violating the policies
  - Specifically consider the following risks:
    - Board members or immediate family members providing services to the health center
    - Confidentiality

DISTINGUISHING BETWEEN LOBBYING AND POLITICAL ACTIVITY

- **Lobbying**: written or oral communication that is an attempt to influence (for or against) specific legislation, including referenda, initiatives, or similar ballot measures
  - Tax law: Health centers may lobby, within certain limits
  - Federal cost principles: federal grant funds may not be used to support the cost of lobbying activities
  - Education is not lobbying!
- **Political activity**: Health centers may not intervene in any election for public office or attempt to influence the outcome of any federal, state or local election
  - Board members can support or oppose candidates and engage in political process as individuals, **PROVIDED THAT** they do not act on behalf of the health center or use any health center resources

ADDITIONAL HIGH RISK AREAS

- **CEO compensation packages & wage and benefit scales for other personnel:**
  - Health centers may pay reasonable compensation
  - Comply with IRS requirements and the grant-related cost principles, as well as the HHS salary cap (applicable to expenditure of Federal grant funds)
    - Documentation of comparability
    - Include all compensation, including fringe benefits, incentives, *etc.*
    - No conflicts of interest
  - Remember, ALL compensation must be considered, including: fringe benefits, insurance, car allowances, incentives, *etc.*

QUESTIONS?

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