

Regulatory Agency Updates

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Federal Government Enforcement

- ▶ Enrollment & Certification:
 - Provider enrollment safeguards
 - Temporary moratoria on enrollment (HHAs, ambulances)
 - Provider-based changes
- ▶ Quality/Patient Safety/Confidentiality Investigations:
 - Surveys/Termination Actions (hospitals, ASCs, SNFs)
 - System Improvement Agreements (transplant programs, hospitals, NFs)
 - Corporate Integrity Agreements with quality component
 - HIPAA Audits by the Office of Civil Rights
- ▶ Fraud & Abuse (Follow the Money!):
 - Data analysis & analytics applied to claims
 - Repayments of overpayments/recoveries
 - Civil monetary penalties & fines/False Claims Act
 - Exclusion
 - Criminal fines/recoveries and jail time

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Provider Enrollment

- ▶ Part A and Part B through Medicare Administrative Contractors (MACs)
- ▶ Rules since 2006 - 42 CFR §§ 424.500-424.570 (www.ecfr.gov)
- ▶ Effective date of new enrollment for physicians - later of date of filing or date begin furnishing services
- ▶ Contractors check on operations
- ▶ Keep enrollment information updated
- ▶ Consequences:
 - Deactivation:
 - No claims for 12 months, failure to report changes or to submit requested information timely
 - Reactivate with submission of new application or recertification of information for failure to submit claims
 - Revocation:
 - Noncompliance, exclusion, felony, false information, misuse of billing number, prescribing issues, **no longer operational**
 - 1 to 3-year bar to re-enrollment

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Provider Based Change

- ▶ Bipartisan Budget Act of 2015 passed on 11/2/2015 (Public Law 114-74, <https://www.congress.gov/bill/114th-congress/house-bill/1314/text>) includes section 603 (amending 42 USC § 1395I(t)) to require lower payments for services furnished in provider-based hospital departments:
 - Effective on 1/1/2017
 - Payment per Medicare Physician or ASC Fee Schedule
 - Applies to outpatient departments that are NOT:
 - On campus;
 - Within 250 yards of a hospital remote location; or
 - An off-campus dedicated emergency department.
 - Grandfathers departments billing as provider-based as of 11/2/2015

HIPAA Phase 2 Audits

- ▶ Office of Civil Rights (OCR) likely to begin Phase 2 HIPAA audits in 2016
- ▶ OCR contracted with FCI Federal, Inc. to conduct desk and on-site data security audits over 3 years of:
 - 350 covered entities (232 providers, 109 health plans, & 9 clearinghouses) for compliance with security standards (150), privacy standards (100), and breach notification standards (100)
 - 50 business associates (35 IT-related vendors & 15 non-IT-related vendors) for compliance with security standards
- ▶ Audit protocol may be found at: <http://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/audit/protocol-current/index.html>

Parts A & B Overpayments Final Rule

- ▶ Affordable Care Act requires prompt repayment of identified overpayments (section 6402(a), creating section 1128J(d) of Social Security Act)
- ▶ Final rule published 2/12/2016, effective 3/14/2016 (<https://www.gpo.gov/fdsys/pkg/FR-2016-02-12/pdf/2016-02789.pdf>):
 - Overpayment must be reported and returned by later of (i) 60 days after being identified, or (ii) date corresponding cost report is due (if applicable).
 - When is an overpayment "Identified"? When person using "reasonable diligence" has/should have determined he has received and quantified the overpayment
 - How far back does obligation go? Applies to overpayments within 6 years of their receipt

Fraud & Abuse Development

- ▶ “Yates Memo” from DOJ Deputy Attorney General Sally Quillian Yates to all DOJ attorneys on 9/9/2015
(<http://www.justice.gov/dag/file/769036/download>)
- ▶ Applies to all civil & criminal investigations and enforcement efforts
- ▶ When dealing with corporations, government lawyers are encouraged “to most effectively pursue the individuals responsible for corporate wrongs”

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Yates Memo – 6 key steps:

- ▶ “To be eligible for *any* cooperation credit, corporations must provide to the [DOJ] all relevant facts about the individuals involved in the corporate misconduct.”
 - But government attorneys should proactively investigate individuals even when corporation is cooperating.
- ▶ “Both criminal and civil corporate investigations should focus on individuals from the inception of the investigation.”
- ▶ “Criminal and civil [government] attorneys handling corporate investigations should be in routine communication with one another.”

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Yates Memo – 6 key steps (cont):

- ▶ “Absent extraordinary circumstances, no corporate resolution will provide protection from criminal or civil liability for any individuals.”
- ▶ “Corporate cases should not be resolved without a clear plan to resolve related individual cases before the statute of limitations expires and declinations as to individuals in such cases must be memorialized.”
- ▶ “Civil [government] attorneys should consistently focus on individuals as well as the company and evaluate whether to bring suit against an individual based on considerations beyond that individual’s ability to pay.”

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