



**Compliance
Game Changers**

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Alternative Payment Models

- MACRA loosened the downward financial risk did your organization join in?
- Challenges:
 - Aligning incentives to safeguard against misconduct
 - Reliability and validity of the underlying data
 - Designing, implementing, and assessing new models in development for proper outcomes and commercial reasonableness

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MACRA Reporting

Which Option did your practice choose?:

- Test the Quality Payment Program
- Partially Report
- Fully Report
- Participate in an Advanced APM



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MIPS

- MIPS reporting for Physician Quality Reporting System (PQRS), the Value Based Payment Modifier or Value Modifier and the Electronic Health Record Meaningful Use Program
- Four performance categories:
 - Quality (60%)
 - Advancing Care Information (25%)
 - Improvement Activities (15%)
 - Resource Use



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General-Impact of BPCI

- While we did not detect statistically significant changes in Medicare standardized allowed payments or quality between BPCI and comparison group episodes from the baseline to the intervention period for most clinical episodes groups, total standardized payments declined for clinical groups that constitute most of BPCI episodes. In this section, we highlight the key findings for the three clinical episode groups where we observed a statistically significant (at the 5% level) change in total payments.



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Generally-Failed

Impact of BPCI on Costs and Quality

"For most clinical episodes, there were no statistically significant differences in the change in Medicare standardized allowed payments between BPCI participants and comparison providers, although many of the participants we interviewed indicated that they had implemented efforts intended to reduce total episode costs."



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Model 3- Quality

- For Model 3 SNF EIs, quality outcomes were similar to those in the comparison group, with a few exceptions. For non-surgical cardiovascular clinical episodes, **there was a statistically significant increase in the unplanned readmission rate during the first 30 days of the episode**, equal to 7.0 percentage points, relative to the comparison group. Also, according to patient assessment data, there was a **statistically significant decline of 13.9 percentage points in the share of beneficiaries with improvement in self-care function** among those with orthopedic surgery episodes, relative to beneficiaries in comparison episodes.



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Model 2 Results

- **There was, however, a statistically significant increase in mortality for beneficiaries with cardiovascular surgery episodes in BPCI-participating hospitals relative to comparison hospitals.** This result was due to an increase in the mortality rate during the **30-days post-discharge** (1.6% to 1.9%) for beneficiaries in BPCI episodes at the same time that there was a decline in the mortality rate for beneficiaries with episodes in comparison hospitals (2.1% to 1.4%).—What??
- Because limited sample size did not allow us to match comparison and BPCI hospitals on baseline mortality rates, this outcome may be due to underlying provider differences not related to the initiative. (More recent results that incorporate an additional nine months of data did not indicate any statistically significant change in mortality.)



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Model 2 Results

- “There were no statistically significant changes in hospital readmissions within the 30-day or 90-day post-discharge periods, or any of the assessment-based quality measures between the BPCI and comparison populations. **Although emergency department use increased more for the BPCI than the comparison population during the 30-day post discharge period, there was no difference in the change during the 90-day period.**”—What??



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Drug Pricing and 340 B

- **Compliance/Audits**
- Overview:
- 340B Drug Pricing Program covered entities must ensure program integrity and maintain accurate records documenting compliance with all 340B Program requirements. HRSA has the authority to audit covered entities for compliance with 340B Drug Pricing Program (340B Program) requirements (42 USC 256b(a)(5)(C))
- Covered entities are subject to audit by the manufacturer or the federal government. Failure to comply may make the 340B covered entity liable to manufacturers for refunds of discounts or cause the covered entity to be removed from the 340B Program.



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FAQ

Q: What must a covered entity do if it finds 340B non-compliance (during an internal audit or through any other means)?

A: The covered entity must notify impacted manufacturers and attempt in good faith to resolve issues directly with manufacturers and wholesalers. Further, the covered entity must notify the HRSA Office of Pharmacy Affairs in writing of the compliance issue and include the following information:

- 340BID; the violation that occurred;
- scope of the problem;
- a corrective action plan (CAP) to fix the problem moving forward;
- a strategy to inform affected manufactures (if applicable); and
- a plan for financial remedy if repayment is owed..



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FAQ

- **To what extent is a registered 340B covered entity (parent) is responsible for outpatient facilities (child) it has registered?**

A: The covered entity is fully responsible for its registered outpatient facilities' compliance with all 340B Program requirements. The covered entity is also responsible for all contract pharmacy arrangements listed on the 340B database. Audits of 340B covered entities include a covered entity's outpatient facilities and contract pharmacies.



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340B Program Requirements

- Keep 340B database information accurate
- Recertify eligibility each year
- Prevent diversion to ineligible patients
- Prohibit duplicate discounts
- Maintain auditable records
- Undergo HRSA and manufacturer audits



• Be aware that error rates are running 60-70% for at least one material finding per audit. <http://www.pharmacytimes.com/publications/health-system-edition/2017/may2017/340b-audit-building-a-selfaudit-program>



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Privacy vs Care Coordination

- ACOs
- ACO light
- Bundled Payment programs
- Private network coordination
- Cell phones
- Tablets



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Privateers

- An armed ship owned and officered by private individuals holding a government commission and authorized for use in war, especially in the capture of enemy merchant shipping



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Other Risks



- Out-of-Network Litigation
- Media Driven Investigations
- Spotlight on Medicare Risk Adjustment
- Whistleblower Persistence in *Qui Tams*



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Out-of-Network Litigation



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Out-of-Network (OON) Litigation

Historically, patients and providers have litigated against payers in disputes over payments for OON services

Payers have started to file private actions for fraud against OON providers

- Claw back actions allege fraud and unjust enrichment by inducing physicians to refer patients to OON facilities, waiving payments due from patients and submitting false claims
- Payer avoidance of full payment theories



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Tale of Two Lawsuits --

- *Connecticut General Life Insurance Co. et al. v. Humble Surgical Hospital, LLC*, 4:13-cv-03291 (S.D. Tex., June 1, 2016)-overturned December 2017
 - In June 2016, Cigna ordered to pay more than \$13 million to Humble Surgical Hospital
- *Aetna Life Insurance Company v. Humble Surgical Hospital, LLC*, 4:12-cv-01206, 2016 BL 436734 (S.D. Tex., December 31, 2016)
 - In December 2016, Aetna wins \$41M in lawsuit against same hospital



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Aetna v. Humble

- Aetna can collect up to \$41.4 million from Humble Surgical Hospital that engaged in a dishonest billing scheme, a federal judge ruled on December 31, 2016
- In a heated opinion—which described the hospital as “filthy up to the elbows from lies and corrupt bargains”—the judge found that the hospital ran a kickback scheme with referring physicians that allowed it to submit inflated bills to Aetna



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Aetna v. Humble (cont.)

- The judge gave Aetna the option of recovering one of three remedies against the hospital:
 - \$41.4 million, representing everything it paid to the hospital;
 - \$20.2 million, representing the difference between what Aetna paid the hospital and what it would have paid if the hospital had been treated as in-network; or
 - \$12.4 million, representing the amount of kickback payments that the hospital gave to the referring physicians
- <https://www.bna.com/aetna-wins-41m-n73014449292/>



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North Cypress Medical Center v. Cigna

- “Based on the evidence on the record, the Court finds that Cigna abused its discretion. Although there is no undisputed evidence of a conflict of interest or a lack of internal consistency, there is strong evidence in the record that Cigna acted in bad faith. Cigna claims to have been concerned about eradicating fee forgiveness, relying on a Seventh Circuit decision from 1991. In fact, the evidence suggests that Cigna deliberately targeted North Cypress with its Fee-Forgiving Protocol in order to pressure it to negotiate an in-network contract. Given the strong evidence of bad faith, the Court finds that Cigna abused its discretion in violation of ERISA § 502(a)(1)(B). As a result, there is no need to reach the question of whether Cigna’s actions were based on substantial evidence.”
(*North Cypress Medical Center Operating Co., Ltd., et al. v. CIGNA Healthcare, et al.*, 4:09-cv-2556 (S.D. Tex. 2017))



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Rapid Tox Screen v. Cigna

- The “Fifth Circuit has held that exceptions to the exhaustion requirement are appropriate where the available administrative remedies either are unavailable or wholly inappropriate to the relief sought, or where the attempt to exhaust administrative remedies would be a patently futile course of action.” *Tex. Gen. Hosp.*, [2016 BL 208258], 2016 U.S. Dist. LEXIS 84082, [2016 BL 208258], 2016 WL 3541828, at *5.
- Plaintiff’s SAC contains allegations that “CIGNA has stated that any attempt by Rapid Tox to reprocess or appeal these claims to demonstrate the patients’ financial responsibility would be denied” and that Defendants delayed processing claims, failed to resolve underpayment issues on appeal, failed to provide a meaningful administrative processes and failed to comply with the substantive and procedural requirements of ERISA. Doc. 31, Pl.’s SAC ¶¶ 36, 39, 52.
- These are sufficient to infer that an exception to pursuing administrative remedies may apply. (*Rapid Tox Screen LLC v. Cigna Healthcare of Texas Inc., et al.*, 3:15-cv-03632 (N.D. Tex.))



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Media Driven Investigations



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Media Driven Investigations

Secret deaths: CNN finds high surgical death rate for children at a Florida hospital

A CNN investigation, a closed heart surgery program, a resigned CEO: What happened at St. Mary's Medical Center?

Locked On The Psych Ward
Lock them in. Bill their insurer. Kick them out. How scores of employees and patients say America's largest psychiatric chain turns patients into profits.



"Federal regulators have been looking into whether [the hospital] misused Florida's involuntary commitment laws to hold patients at the hospital who did not need treatment."

Media Driven Investigations

In last few years, media has become more involved in uncovering healthcare "fraud" and quality of care issues

- Coupled with government push for transparency and release of more healthcare payment, utilization and quality data
- Can create public relations issues, government investigations and potential litigation

A few examples include:

- CNN investigation into surgical death rates of children at a Florida hospital
- BuzzFeed investigation into the nation's largest psychiatric hospital chain that was already under federal civil and criminal investigation

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MEDICARE

Spotlight on Medicare Risk Adjustment

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Spotlight on Medicare Risk Adjustment

<p>CHUCK GRASSLEY United States Senator</p> <p>Grassley Presses Federal Agencies on Scrutiny of Payments to Medicare Advantage Plans May 21, 2015</p>	<p>Modern Healthcare</p> <p>Feds expand probe into DaVita's Medicare Advantage practices By Lisa Schencker June 24, 2015</p>
<p> United States Department of Justice</p> <p>FOR IMMEDIATE RELEASE Friday, March 4, 2016</p>	
<p>Doctor Who Falsely Diagnosed Hundreds Of Patients As Part of a Medicare Fraud Scheme Pleads Guilty</p>	
<p>HHS / OIG Work Plan Fiscal Year 2017</p> <p>Risk Adjustment Data – Sufficiency of Documentation Supporting Diagnoses</p>	<p>npr</p> <p>Justice Department Joins Second Lawsuit Against UnitedHealth March 26, 2017 1:50 PM ET</p>

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Spotlight on Medicare Risk Adjustment

Medicare Risk Adjustment (RA) is the process by which CMS reimburses Medicare Advantage (MA) plans and is based on the health status of their members, rather than on demographics alone

Dual purpose of any risk adjustment model is to:

- Mitigate selection of healthier enrollees
- Increase competition between plans based on quality and efficiency

In Medicare Advantage, the CMS-HCC model was rolled out in 2003 with full implementation in 2007

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MRA Risk Adjustment Factors

Patient #123-45-6789			Patient #123-45-6789		
Female 70-74 years	<input type="checkbox"/>		Female 70-74 years	<input type="checkbox"/>	
Male 70-74 years	<input type="checkbox"/>		Male 70-74 years	<input type="checkbox"/>	
Metastatic cancer and acute leukemia	<input type="checkbox"/>		Metastatic cancer and acute leukemia	<input type="checkbox"/>	
Lung, upper digestive tract, and other severe cancers	<input type="checkbox"/>		Lung, upper digestive tract, and other severe cancers	<input type="checkbox"/>	
Breast, prostate, colorectal and other cancers and tumors	<input type="checkbox"/>		Breast, prostate, colorectal and other cancers and tumors	<input type="checkbox"/>	
Diabetes with renal or peripheral circulatory manifestation	<input type="checkbox"/>		Diabetes with renal or peripheral circulatory manifestation	<input type="checkbox"/>	
Diabetes with acute complications	<input type="checkbox"/>		Diabetes with acute complications	<input type="checkbox"/>	
Diabetes without complication	<input type="checkbox"/>		Diabetes without complication	<input type="checkbox"/>	
Drug/alcohol dependence	<input type="checkbox"/>		Drug/alcohol dependence	<input type="checkbox"/>	
Major depressive, bipolar and paranoid disorders	<input type="checkbox"/>		Major depressive, bipolar and paranoid disorders	<input type="checkbox"/>	
ANNUAL RATE	RISK SCORE	RISK ADJUSTED RATE	ANNUAL RATE	RISK SCORE	RISK ADJUSTED RATE
\$9,600	0.336	\$3,226	\$9,600	1.562	\$14,995

Source: The Center for Public Integrity, using 2011 data and code released by CMS, <http://www.publicintegrity.org/2014/06/04/14867/how-risk-scores-work>, accessed 4/3/2017.



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MRA Data Submission Process



1. Provider documents member visit in the medical record
2. Provider's office or hospital assigns diagnosis codes
3. Provider submits claim or encounter to MA plan



1. MA plan processes and filters claims and encounter data from providers
2. MA plan submits risk adjustment data to CMS via claims and encounter data files



1. CMS processes data for risk adjustment factor calculation and payment
2. CMS returns data to MA plans with accepted or error code status



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MRA Legal Standards

- MA plans sign annual attestation that:
"The CEO, CFO, or an individual delegated ... must certify (based on best knowledge, information, and belief) that the data it submits under §422.310 are accurate, complete, and truthful." (42 C.F.R. §422.504(i)(2))
- 60-Day Overpayment Rule
"The MA organization has identified an overpayment when the MA organization has determined, or should have determined through the exercise of reasonable diligence, that the MA organization has received an overpayment." (42 C.F.R. §422.326)
- Civil False Claims Act and Swobden Decision (31 U.S.C. §3729-3733 and USA, ex rel. Swobden v. United Healthcare, No. 13-56746 (9th Cir. 2016))



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MRA Regulatory Environment

CMS sets policy and rules for MRA

CMS is also charged with performing Risk Adjustment Data Validation (RADV) Audits

- Targeted audits of 30 plan contracts each year
- Samples of 201 members, stratified by low, medium and high risk scores
- Results are extrapolated across contract membership
- Audits of contract year 2011 and 2012 currently underway
- Future of RADV process:
 - CMS released SOW in March 2016 seeking equivalent of Part A and B Recovery Audit Contractors
 - Scope of RADV audits would be significantly expanded



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MRA Enforcement Environment

- *USA, ex rel. Oliva Graves, M.D., v. Plaza Medical Centers, et al.*, 1:10-cv-23382 (S.D. Fla.)
- *USA, ex rel. Becky Ramsey-Ledesma v. CenseoHealth, LLC*, 3:14-cv-00118-M (N.D. Tex.)
- *USA, ex rel. Valdez v. Aveta Inc, et al.*, 3:15-cv-01140-CCC (D. Puerto Rico) (orig. 2:11-cv-03343)
- *USA, ex rel. Benjamin Poehling v. UnitedHealth Group, et al.*, 2:16-cv-08697-MWF-SS (C.D. Cal.)
- *USA, ex rel. James M. Swoben v. Secure Horizons, et al.*, 2:09-cv-05013-JFW-JEM (C.D. Cal.)
- *USA v. Thompson*, 9:15-cr-80012 (S.D. Fla.)



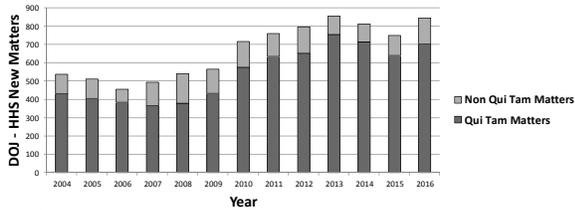
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MRA Other Interested Parties



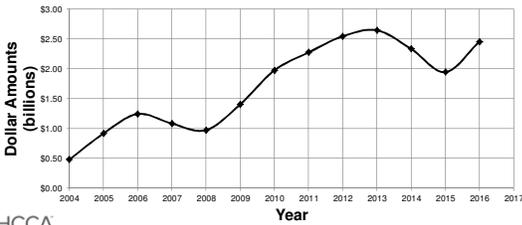
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Yearly Qui Tam and Non Qui Tam New Matters under the FCA



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Total Health Care Settlements and Judgments in Federal Qui Tam Cases



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Developing an Effective Compliance Program



The Shift

- DOJ Sentencing requirements
- ACO statute requirements
- OIG recommendations (requirements)
- ACA requirements
- Government focus on compliance: Yates and 60 Day and the need for compliance and ethics training versus the dangers of ineffective training, and the use of data to help prove “effectiveness”.

U.S. Sentencing Guidelines



§8B2.1. Effective Compliance and Ethics Program

(a) To have an effective compliance and ethics program, for purposes of subsection (f) of §8C2.5 (Culpability Score) and subsection (b)(1) of §8D1.4 (Recommended Conditions of Probation - Organizations), an organization shall—

- (1) exercise due diligence to prevent and detect criminal conduct; and
- (2) **otherwise promote an organizational culture that encourages ethical conduct and a commitment to compliance with the law.**

DOJ

(4) (A) The organization shall take reasonable steps to communicate periodically and in a practical manner its standards and procedures, and other aspects of the compliance and ethics program, to the individuals referred to in subparagraph (B) **by conducting effective training programs** and otherwise disseminating information appropriate to such individuals' respective roles and responsibilities.

(B) The individuals referred to in subparagraph (A) are the members of the governing authority, high-level personnel, substantial authority personnel, the organization's employees, and, as appropriate, the organization's agents.

The Seven Core Elements of a Compliance Program

The seven core elements, required by the USSCG, include:

- Standards and Procedures
- Oversight - Compliance Officer or Compliance Committee
- Delegation of Authority: Screening of Employees and Contractors, etc.
- Training and Education
- Auditing and Monitoring
- Enforcement and Disciplinary
- Corrective Action Procedures (Response and Prevention)



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Liability From Inaction-Per CMS

It was also apparent from some commenters that they do not currently engage in compliance efforts to ensure that the claims they submitted to Medicare were accurate and proper and that payments received are appropriate.

We advise those providers and suppliers to undertake such efforts to ensure they fulfill their obligations under section 1128J(d) of the Act.

We believe that undertaking no or minimal compliance activities to monitor the accuracy and appropriateness of a provider or supplier's Medicare claims would expose a provider or supplier to liability under the identified standard articulated in this rule based on the failure to exercise reasonable diligence if the provider or supplier received an overpayment.



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60 Day Time Period

The 60-day time period begins either when

- A. the reasonable diligence is completed and the overpayment is identified (180 +60 max) or
- B1. on the day the person received credible information of a potential overpayment if the person fails to conduct reasonable diligence AND
- B2. the person in fact received an overpayment.



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60 Day Rule

The final rule states that a person

- has identified
- an overpayment
- when the person has, or should have through the exercise of reasonable diligence,
- determined that the person has received an overpayment and
- quantified the amount of the overpayment.



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60 Day Rule



"Reasonable diligence" includes :

- both **proactive compliance activities** conducted in good faith **by qualified individuals** to monitor for the receipt of overpayments
- and investigations conducted in good faith and in a timely manner by **qualified individuals** in response to obtaining credible information of a potential overpayment.



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Yates Memo-DOJ Policy

- The guidance in this memo will also apply to civil corporate matters. In addition to recovering assets, civil enforcement actions serve to redress misconduct and deter future wrongdoing. Thus, civil attorneys investigating corporate wrongdoing should maintain a **focus on the responsible individuals, recognizing that holding them to account is an important part of protecting the public ...**



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Elements

The guidance in this memo reflects six key steps to strengthen our pursuit of individual corporate wrongdoing, some of which reflect policy shifts and each of which is described in greater detail below:

- (1) in order to qualify for any cooperation credit, corporations must provide to the Department all relevant facts relating to the individuals responsible for the misconduct;
- (2) criminal and civil corporate investigations should focus on individuals from the inception of the investigation;
- (3) criminal and civil attorneys handling corporate investigations should be in routine communication with one another;



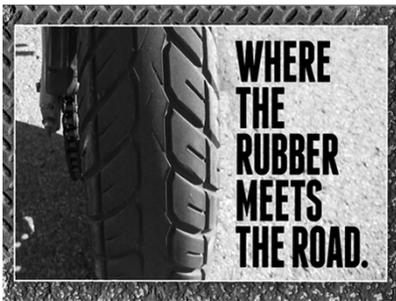
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Elements (Cont'd)

- (4) absent extraordinary circumstances or approved departmental policy, the Department will not release culpable individuals from civil or criminal liability when resolving a matter with a corporation;
- (5) department attorneys should not resolve matters with a corporation without a clear plan to resolve related individual cases, and should memorialize any declinations as to individuals in such cases; and
- (6) civil 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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Section 2- Training



- "I have been trained on and understand the compliance requirements and responsibilities as they relate to the Company"- CEO CIA certification
- "I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert department functional areas], an area under my supervision. My job responsibilities include ensuring compliance with regards to the _____ [insert name of the department or functional area]. – Management CIA certification



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Ten Tips for Effective Compliance



1. Culture is key
2. Messaging is crucial
3. Governance integrity is essential
4. Get it right up front – focus on underlying conditions
5. Build a certification trail



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Ten Tips for Effective Compliance (Cont'd)

6. Coordinate among participants
7. Leverage existing efforts
8. Integrate quality and compliance
9. Don't forget about privacy and security
10. Proactively audit new and existing issues and address identified problems



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Thank You!

Discussion and
Questions



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