

Healthcare Industry Update/ Stump the Lawyer

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What is Compliance?

- Doing what is right?
- Doing whatever the government says?
- Doing what's legal?

What Will Get You On TV?

- Relationships between physicians and hospitals, between physician groups, and between health care professionals/facilities and drug/device companies that run afoul of the law.
- Coding problems.
- Confidentiality snafus.

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Medicare Antikickback Statute

- It is illegal to offer, solicit, make or receive any payment intended to influence referrals under a federal health care program.
- The government applies the “one purpose” test. If one purpose of the payment is to influence referrals, the payment is illegal.
- Can payments inside an organization violate the law?

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56 F.R. 35952 (July 29, 1991)

“Comment: Many commenters requested the OIG to clarify that payments between corporations which have common ownership are not subject to the statute. Commenters cited as examples intracorporate discounts and payments between two wholly-owned subsidiaries. Some commenters argued that referral arrangements between two related corporations do not constitute "referrals" within the meaning of the statute, and suggested that the OIG define the word "referral" to exclude such activity.

Response: We agree that much of the activity described in these comments is either not covered by the statute or deserves safe harbor protection. **We believe that the statute is not implicated when payments are transferred within a single entity, for example, from one division to another. Thus, no explicit safe harbor protection is needed for such payments.**

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Potential Antikickback Problems

- Relationships with pharmaceutical/device manufacturers:
 - Research studies;
 - Freebies:
 - Lunches;
 - Super Bowl tickets.
- Joint ventures.
- Investment in outside organizations.
- Professional courtesy discounts (“don’t charge him, he’s a good referral source”).

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Baptist Medical Center

- Medical director agreements between a hospital and two physicians.
- Physicians were paid \$60,000 year.
- Hospital executives sent emails explaining they didn't want to impose a large burden on the physicians.

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Baptist Jury Instruction

In order to sustain its burden of proof against the hospital executives for the crime of violating the antikickback statute, the government must prove beyond a reasonable doubt that the defendant under consideration offered or paid remuneration with the specific criminal intent “to induce” referrals.

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Baptist Jury Instruction

To offer or pay remuneration to induce referrals means to offer or pay remuneration with intent to gain influence over the reason or judgment of a person making referral decisions. The intent to gain such influence must, *at least in part*, have been the reason the remuneration was offered or paid.

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Baptist Jury Instruction

On the other hand, defendants Anderson, Keel, and McClatchey cannot be convicted merely because they hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes. Likewise, mere oral encouragement to refer patients or the mere creation of an attractive place to which patients can be referred does not violate the law. There must be an offer or payment of remuneration to induce, as I have just defined it.

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You're Training Physicians On E&M Coding. What Should You Tell Them Happens If They Err?

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Role of Documentation: The Law

“No payment shall be made to any provider of services or other person under this part **unless there has been furnished such information** as may be necessary in order to determine the amounts due such provider or other person under this part for the period with respect to which the amounts are being paid or for any prior period.”

Social Security Act § 1833(e)

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Role of Documentation: Guidance from CPT and CMS

- The CPT Assistant explains: “it is important to note that these are *Guidelines*, not a law or rule. Physicians need not modify their record keeping practices at all.”

CPT Assistant Vol. 5, Issue 1, Winter 1995

- Then HCFA, now CMS publicly stated that physicians are not required to use the Documentation Guidelines.

Avoid the Clash! Don't Train in Vain

Compliance Training Tips

- Distinguish between fraud and mistakes.
- Don't exaggerate.
- Track training.
- Get semi-annual certifications.

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Salary Surveys: Death of Common Sense (and Math)?

- Survey says?
 - Is 50th percentile a ceiling? What about 75th? 90th?
- Conventional wisdom in this area is awful. True analysis seems rare.
- FMV is supposed to ignore presence of referrals. Is that even possible?

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Surveying the Environment

- Meghan Wong at MGMA has explained "the data are not intended to be used as an academic data set for extrapolating to the U.S. population of physicians," and are not a "one-to-one representation of the universe of medical practices that are in the country."*
- High and low responses are thrown out.
*Thanks to Tim Smith, Ankura Consulting, and Forthcoming BVR/AHLA Guide to Valuing Physician Compensation and Healthcare Service Arrangements

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Surveying the Environment

- Do people understand "total compensation?"
- Is there an inverse relationship between productivity and per RVU compensation?
- Do groups comply with the "professional data only, no technical fees" request?

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Analyze This

- 90th Percentile Interv. Card. CF in 2012:
 AMGA: \$102.06 MGMA: \$86.47
- 90th Percentile RVU IC.:

2009	16,758
2010	18,316
2011	16,136
2012	15,208 (20% swing from 2010!)

“We Lose Money on Every Physician.”

- If true, is this a problem?
- Is it true?
 - How is overhead calculated and allocated?
 - How is revenue allocated?
- What about ancillaries?

Beware of Bad Lawyering!!

- 4 cases discuss Medicare Manual language from 1992 that was “written with Stark in mind.”
- The discussion relates to hospital services.
- Stark I (1989) only applied to lab. Hospital services were added in Stark II. Stark II was passed in??

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Fraud, Waste and Abuse and Compliance Training

- Lots of lingo, very complicated regulations.
- Plans say hospitals and clinics are “first tier downstream and related entities” (“FDR”).
- Plans may expect you to perform fraud, waste and abuse training and compliance training.
- They cite 42 C.F.R. 422.503 (b)(4)(vi)(C) and 423.504 (b)(4)(vi)(C).

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42 C.F.R. 422.503 (b)(4)(vi)(C)

(b) Conditions necessary to contract as an MA organization. Any entity seeking to contract as an MA organization must:

(4) Have administrative and management arrangements satisfactory to CMS, as demonstrated by at least the following:

(vi) Adopt and implement an effective compliance program, which must include measures that prevent, detect, and correct non-compliance with CMS' program requirements as well as measures that prevent, detect, and correct fraud, waste, and abuse. The compliance program must, at a minimum, include the following core requirements:

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42 C.F.R. 422.503 (b)(4)(vi)(C)

(C) (1) Each MA organization must establish and implement effective training and education between the compliance officer and organization employees, the MA organization's chief executive or other senior administrator, managers and governing body members, and the MA organization's first tier, downstream, and related entities. Such training and education must occur at a minimum annually and must be made a part of the orientation for a new employee, new first tier, downstream and related entities, and new appointment to a chief executive, manager, or governing body member.

(2) First tier, downstream, and related entities who have met the fraud, waste, and abuse certification requirements through enrollment into the Medicare program are deemed to have met the training and educational requirements for fraud, waste, and abuse.

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42 C.F.R. 422.503 (b)(4)(vi)(C)

(3) An MA organization must require all of its first tier, downstream, and related **entities** to take the CMS training and accept the certificate of completion of the CMS training as satisfaction of this requirement. MA organizations are prohibited from developing and implementing their own training or providing supplemental training materials to fulfill this requirement.

Things to Note

- Regulations refer to “the CMS training” without defining it.
- Regulations say Medicare suppliers and providers are exempt from FWA training.
- The reference to “CMS training” comes after this waiver.
- How does an “entity” train?

General Compliance Training

Sponsors must ensure that general compliance information is communicated to their FDRs. The sponsor's compliance expectations can be communicated through distribution of the sponsor's Standards of Conduct and/or compliance policies and procedures to FDRs' employees. Distribution may be accomplished through Provider Guides, Business Associate Agreements or Participation Manuals, etc.

- Medicare Managed Care Manual Ch. 21 Sec. 50.3.1

The Complication

- The Manuals haven't been updated since the regulations.
- The regulations and Manuals don't really apply directly to you.
- "Your contract controls!"

Who “Must” Train?

In order to prevent unnecessary burden on FDRs, Sponsors should work with their FDRs and specify which positions within an FDR must complete the training. There will be certain FDRs where not every employee needs to take the training based on their duties.

Below are examples of the critical roles within an FDR that should clearly be required to fulfill the training requirements:

Positions/Roles

Senior administrators or managers directly responsible for the FDR’s contract with the Sponsor (e.g. Senior Vice President, Departmental Managers, Chief Medical or Pharmacy Officer);

Individuals directly involved with establishing and administering the Sponsor’s formulary and/or medical benefits coverage policies and procedures;

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Who “Must” Train?

Individuals involved with decision-making authority on behalf of the Sponsor (e.g. clinical decisions, coverage determinations, appeals and grievances, enrollment/disenrollment functions, processing of pharmacy or medical claims);

Reviewers of beneficiary claims and services submitted for payment; or,

Individuals with job functions that place the FDR in a position to commit significant noncompliance with CMS program requirements or health care FWA.

- CMS Memo; Additional Guidance – Compliance Program Training Requirements and Audit Process Update – December 28, 2015

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Do Medicare Rules Apply to MA Patients?

- No regulation expressly suggests this.
- Each program points a finger at the other.
- Review your payer agreement and provider manual.
- Stark may be a different story.

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Does the FCA Apply to Claims to MA Plans?

- Assume the answer is yes but ...
- Fight vigorously to argue the answer is no.

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Does the 60-Day Report and Return Provision Apply to MA?

- It definitely applies to payments received by the plan from the government.
- Less clear whether it applies to payments from plans to providers and suppliers.
- Better safe than sorry?

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60 Day Rule: 42 CFR § 401.305(a)(2)

“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. A person should have determined that the person received an overpayment and quantified the amount of the overpayment if the person fails to exercise reasonable diligence and the person in fact received an overpayment.”

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What Is Knowingly?

“While we acknowledge the terms ‘knowing’ and ‘knowingly’ are defined but not otherwise used in Section 1128J(d) of the Act, we believe that Congress intended for Section 1128J(d) of the Act to apply broadly. If the requirement to report and return overpayments only applied to situations where the providers or suppliers had actual knowledge of the existence of an overpayment, then these entities could easily avoid returning improperly received payments and the purpose of the section would be defeated.”

- 81 FR 7660

Is Six Years Right?

“*Overpayment* means any funds that a person has received or retained under title XVIII of the Act to which the person, after applicable reconciliation, is not entitled under such title.”

- 42 CFR 401.303

•If the contractor can't reopen the claim, doesn't that mean you are entitled to keep the money?

Six Years From When?

- Remember “identify” includes quantification.
- The six years runs from the date the overpayment is quantified not from the first suspicion of an overpayment.
- Operationally, this may be challenging.

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The Malingerer

- A nurse comes to you worried that a colleague is “faking” an illness to get out of work.
- She asks a physician to check the hospital medical record.

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Medicaid Audits

- Medicaid audits you. Your documentation does not meet the Guidelines, but you have good evidence you provided the service. Should you worry?

The Public Complaint

- A patient is very upset with care.
- The family writes a letter to the local paper.
- The paper calls you and offers you a chance to respond.

The Subpoena

An employee receives a grand jury subpoena from Atlanta that says "The United States Attorney requests that you do not disclose the existence of this subpoena. Any such disclosure would impede the investigation being conducted and thereby interfere with the enforcement of the law."

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Off-Label Use

- A drug is approved for a particular use. The company asks physicians to give a speech describing an off-label use for the drug. Any issues?
- Must a physician tell the patient a use is off label?
- Must an insurer cover it?

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A Patient Walks In With Fake I.D.

- What do you do if a patient comes in with an insurance card and you **KNOW** that the card is for someone else?
- **CAN** you report the patient? **MUST** you report the patient?

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855 Issues

- Forms matter
- Penalties for non-compliance with enrollment and claims requirements
- Medicare enrollment forms (855A and 855B)
- Reporting requirements and timeframes
- Pitfalls of Medicare claim forms
- Responding to written inquiries from the government

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“Background Questionnaire”

- A safeguard contractor asks you to list model, manufacturer, etc. of all diagnostic equipment in your practice.”
- You “certify” that the information is “complete and accurate.”
- You agree to “advise” them of “changes that subsequently occur with respect to any of the information provided.”

Deactivation of Billing Privileges

- CMS may “deactivate” billing privileges for the following reasons:
 - Provider/supplier does not submit Medicare claims for 12 consecutive months.
 - Provider/supplier does not report a change to information supplied on the enrollment application within 90 days of the change (e.g., change in managing employee or billing services).
 - Provider/supplier does not report a change in ownership or control within 30 days.
- No bar on reactivation.

Revocation of Billing Privileges

- CMS may “revoke” billing privileges for the following reasons:
 - **“Noncompliance” with enrollment requirements or the enrollment application.**
 - Exclusion of provider/supplier or owner, managing employee, authorized or delegated official, medical director, supervising physician or other healthcare personnel of provider/supplier.
 - Certain felonies.
 - Certifying as “true” false or misleading information on the enrollment application.
 - Failure to furnish within 60 days complete and accurate information requested by CMS in connection with enrollment or revalidation.

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Revocation of Billing Privileges

- Grounds for revocation (continued):
 - Failing an on-site review.
 - Misuse of billing number.
 - Abuse of billing privileges.
 - Failure to report a final adverse action or change in practice location within 30 days.
 - Failure to document or provide CMS access to documentation of certain lab, home health, DMEPOS, imaging and specialist services.

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Revocation of Billing Privileges

- Once CMS has revoked billing privileges, the provider/supplier is barred from re-enrollment for at least 1 year and no longer than 3 years, based on the severity of the non-compliance.
- Upon re-enrollment, must submit a new application and be resurveyed and recertified, if applicable.

A Visitor: What Would You Do?

- A typo-filled email requests access to your clinic.
- The person arrives and asks to take a bunch of pictures of your clinic, including your DME inventory?

Advanced Imaging Notice

- Give written notice to all MR/CT/PET pts. (E-mail is ok.)
- At time of referral (i.e. NOT registration).
- Must indicate patient can go elsewhere.
- Address/phone for at least 5 “suppliers” within 25 miles. (If fewer than five, list them. If none, no notice necessary.)
- Can say more; may wish to warn about insurance coverage.

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Every Violation Isn't Fraud: Universal Health Services v. United States ex rel. Escobar

“Likewise, if the Government required contractors to aver their compliance with the entire U. S. Code and Code of Federal Regulations, then under this view, failing to mention noncompliance with any of those requirements would always be material. The False Claims Act does not adopt such an extraordinarily expansive view of liability.”

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Can I Have Different Prices For Different Patients?

- One might argue every attendee has multiple charges for identical services.
- Beware of catchy phrases like “you can’t discriminate.”
- Inconsistent pricing for services isn’t “illegal”, but it may have collateral consequences.

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Can I Have Different Prices For Different Patients?

- Note that Robinson-Patman prohibits price discrimination for goods.
- If you provide a discount to a cash paying walk-in, why is an auto insurer not entitled to the same rate?
- Many seemingly logical justifications run afoul of the law or your contracts.

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Can Our Group Have Different Rates For Different Physicians?

- You CAN, the question is what will it mean.
- Unclear if U&C is by code or practitioner.
- If you bill as a group, probably best to assume it is by code.

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I Have To Give Medicare My Lowest Price, Right?

- Wrong. Medicare pays the lower of:
 - actual charge.
 - fee schedule amount.
 - usual and customary charge.
- Usual and customary charge is defined as your median (50th percentile) charge.

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I Have To Give Medicaid My Lowest Price, Right?

- Maybe. Depends on state law.
- In some states the “usual and customary” charge is defined as the charge that you charge most often.
- Some states follow Medicare.
- Some states require Medicaid to be the lowest.

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Can I Require Patients To Pay More Than Their Insurer Reimburses?

- Do you have a contract with the insurer?
 - If yes, then you will need to review the contract.
 - If no, then you can charge the patient what you want.
 - Remember concepts of implied contract.

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Can I Require Patients To Pay More Than Their Insurer Reimburses?

- What if the payor is Medicare?
 - If participating, then you must accept Medicare.
 - If nonparticipating, then limited by Medicare Limiting Charge (15% over Medicare's approved amount).
 - If opted out, then do what you want.
- Medicaid – state by state.

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Can I Charge A Patient For “Extras” Like Phone Calls?

- Each payor has different rules.
- Medicare prohibits charging patients for covered services. Phone calls are “covered.”
- Most insurers include similar prohibitions in their contracts.
- Absent a contract, almost anything goes.

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Are Coders Personally Liable?

- Almost never.
- Indemnification governed by state law, corporate documents.
 - Good faith.
 - Conduct legal.
 - Believe actions in company's best interest.

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Can I Adjust My Fees to Out-of-Network Patients to Mirror the Network?

- Extremely controversial issue.
- Insurers want the network to mean something.
- There may be no contract between you and the insurer, but there is a contract between the patient and the insurer.

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Can I Adjust My Fees to Out-of-Network Patients to Mirror the Network?

- How the insurer reimburses out-of-network services may affect the analysis.
 - Fee schedule.
 - Percentage of charges.
 - Percentage of fee schedule.
- New Jersey court ruled against Health Net and for the physicians in an ASC dispute where ASC waived co-insurance. State law forbids dentists from waving co-insurance.

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Can We Charge Interest On Outstanding Balances?

- Payor/state law dependent.
- Know your contracts.
- Medicare claims the answer is no.
- Medicare's claim is wrong.

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Medicare Cites:

- "To collect only the difference between the Medicare approved amount and the Medicare Part B payment (for example, the amount of any reduction in incurred expenses under Sec. 410.155(c), any applicable deductible amount, and any applicable coinsurance amount) for services for which Medicare pays less than 100 percent of the approved amount."

But Interest Isn't A Charge For The Service.

- "The charge for a missed appointment is not a charge for a service itself (to which the assignment and limiting charge provisions apply), but rather is a charge for a missed business opportunity. Therefore, if a physician's or supplier's missed appointment policy applies equally to all patients (Medicare and non-Medicare), then the Medicare law and regulations do not preclude the physician or supplier from charging the Medicare patient directly."
 - MLN MM5613

Can We Charge Interest On Outstanding Balances?

- Consider both federal and state law.
- Federal Truth in Lending Act.
 - Applies if you extend credit to patients.
 - Must make periodic disclosures.
- State usury laws.

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Can We Give Free Care To Medicare Recipients?

- Hospital requires EKG before surgery but denied by Medicare.
- Poor patient.
- Mad patient.

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Can We Release Medical Records We Received From A Third Party?

- Under HIPAA, “PHI” is any health information, created, received, or maintained by a covered entity.
- HIPAA lets a covered entity disclose PHI in a designated record set.
- Alcohol and drug abuse records protected by federal law should NOT be redisclosed.
- Remember state law considerations.

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Can We Give Prompt Pay Discounts?

- What rationale supports the discount?
 - insurance contracts prohibit “a billing fee.”
 - is it interest?
- I love my dentist.

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Is Mailing A Letter To The Wrong Patient A HIPAA Breach?

- Under the old “breach” definition, maybe not.
- New “breach” definition, breach is “presumed” and the information in most misaddressed letters is probably “compromised” if someone opens it.
- What if it was the mayor?

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Can I Share The Legal Advice I Get With Others?

- Risks waiving the privilege.
- May be able to use “common interest” privilege.
- Its validity is far from clear.
- Share at your own risk.

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Does HIPAA Require Us To Encrypt PHI?

- The regulation says encryption is “addressable.” That means you have to be reasonable. Industry standards will determine what is reasonable.
- The guidance strongly recommends encryption.
- My unsolicited advice: encrypt laptops and devices that store PHI.

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Can Physicians Get Credit For Ordering Ancillaries?

- Stark: Not for Medicare (Medicaid??)
- State law?
- Stark doesn't apply to private pay, but...
- How do you divide the revenue?
 - Equally.
 - Production.
 - Anything else that isn't who ordered it.

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Can We Send Emails To Patients?

- Yes – there is no law preventing it.
- The new HIPAA rules changed the answer to the encryption question.
 - If a patient asks for a copy of his/her PHI, can send in an unencrypted email IF the patient consents to it after hearing about the risk. Document the conversation.
 - Advice: encrypt email to patients; check the address three times before sending.

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Does Stark Cover Medicaid?

- Darn good question.
- Some strong arguments it does not.
- This is not an area where we are inclined to tempt fate.

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Can We Pay The Exchange Premium Of A Patient?

- K. Sebulius has said antikickback law doesn't apply.
- CMS has said they don't like the idea.
- Seems legal to us.
- Insurers may try to challenge it, but under what theory?

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How Often Do We Have To Check The OIG Excluded List?

- There is no law that requires you to check.
- CMS's current position is that you must check the OIG List of Excluded Individuals and Entities monthly.
 - “New” Medicare Advantage manual language supports this.
- What about the System for Award Management (“SAM”), formerly GSA list?
- Watch out for attestations/certifications to payors.

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Can I Give Discounts To Non-Medicare Patients?

- It depends.
- Not if one purpose is to influence referrals.
- Beware of impact on Usual and Customary.
 - Medicare: Median Charge.
 - Medicaid: State defined.
 - Private Payors: Contractually defined.
- Need-based or complaint-based discounts probably fine.

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Is My Consultant Covered By The Attorney/Client Privilege?

- Attorney/client privilege covers employees.
- Unless you have a broad state law definition of “employee,” your consultant probably isn’t covered.
- Only works if your attorney engages the consultant up front.
- Work product doctrine issues.

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Does The Anti-Markup Rule Apply To Professional Component?

- CMS says yes.
- They lack the legal authority to do so.
- Authorizing law is SSA 1861(s)(3). That law applies to diagnostic tests. Reads are physician services under 1861(s)(1).
- CMS knows this, but says that Congress' omission was "inadvertent."

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Do I Have To Use The OIG Disclosure Protocol To Refund Overpayments?

- This is a voluntary disclosure protocol.
- The OIG is the last place to raise a refund, except in certain special and rare circumstances.
- Report and return law says to go to the most appropriate entity (e.g., MAC, Medicaid agency, etc.)

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Must All Charts Be Signed?

- Conditions of Participation will require it for most providers.
- Life is easier if the chart is signed.
- Payment shouldn't be denied for an unsigned chart.

QUESTIONS?



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