Arkansas HFMA

Regulatory Update
2024

Amie K. Schoeppel Wilcox

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- Medical Malpractice
- Healthcare
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- Employee Benefits
- Real Estate/Commercial Transactions
- Merger & Acquisitions

Overview

- 2024 Updates
  - Surprise Billing
  - Information Blocking
- 2024 Upcoming
  - HIPAA Revisions Expected

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Overview

- Reviewing the Big Ones
  - Stark Law
  - Anti-Kickback Statute
  - HIPAA

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Surprise Billing Rules

- Two Interim Final Rules were published, implementing the provisions of the No Surprises Act (signed into law as a part of the Consolidated Appropriations Act of 2021).
- Effective January 1, 2022
- Certain Provisions Effective January 1, 2023
- Update – enforcement for some of these provisions has been stopped pending further regulation

Surprise Billing Rule Application

- Applies to "balance billing" – billing the patient for the difference between the billed charge and the amount paid by their plan or insurance (usually for out-of-network charges)
- Does not apply to people with coverage such as Medicare, Medicaid, VA, Tricare (already prohibited balance billing)

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Surprise Billing Rule Application

Applies to facility or facilities

In most cases, this is a Hospital, HOPD, or Ambulatory Surgery Center

Physician Offices *are not* covered unless furnished in connection with a service from a covered facility

Limited Exception

- Consent Exception – may apply in limited cases; will not apply in some situations where surprise bills are likely (for example, ancillary services connected to non-emergency care such as anesthesia or radiology).
- Where it does apply, specific requirements exist regarding the content of notices and consents.

Requirements of Surprise Billing Rule

Generally, Requires 3 Things:

1. No Surprise Billing (Commercial Pay)
2. Good Faith Estimates (Self-Pay or Uninsured)
3. Required Notices (Commercial Pay)

45 CFR § 149.430

1. No Surprise Billing

Patients receiving:

- Emergency services at *any* covered facility (network status does not matter)
- Non-emergency services at an *in-network* facility
- Air Ambulance Services

May not be billed more than the patient would be billed had the patient and service been in-network

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1. No Surprise Billing

Non-emergency service at *in-network* facility

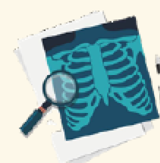
- Is the facility in-network?
- Is the specific provider that provided the services at the in-network facility out-of-network?
- Were the services provided "ancillary services?"

No Surprise Billing

Ancillary Services

Ancillary services include items and services related to:

- Emergency medicine
- Anesthesiology
- Neonatology
- Pathology
- Radiology
- Diagnostic services, including radiology and laboratory services
- Items and services provided by assistant surgeons, hospitalists, intensivists
- Items and services provided by a nonparticipating provider if there is no participating provider who can furnish the item or service at that facility.



Good Faith Estimates

Good Faith Estimates Required – for uninsured or self pay patients. The Rule sets forth specific time frames this estimate is required to be furnished within. If patient is billed substantially in excess (at least $400 in excess) of estimate, will be subject to arbitration process.

Obligation is for the Good Faith Estimates to be furnished *by the facility.*

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Good Faith Estimates

Co-Providers

- patients should receive on GFE of their procedure

- No Surprises Act requires Co-Providers to be included in the GFE (example – laboratory, anesthesia), however, this is currently not being enforced

-Co-Providers should cooperate with facility to provide estimates of care

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Required Notice and Disclosure

Required Notice – requires providers and facilities to make publicly available, post on a public website, and provide to individuals a one-page notice about the requirements of this Rule and how to report a violation. Should include any applicable state laws as well.

This includes providers who furnish services at a covered facility (example – physician performs procedure at ASC)

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Required Notice and Disclosure

1. Public signage posted prominently at provider's or facility's location
2. Posting on easily accessible portion of website
3. One-page notice provided directly to individuals enrolled in group health plan or individual health insurance coverage must be delivered in person, by email, or by mail based on individual's preference (no later than when payment is requested).

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Your Rights and Protections Against Surprise Medical Bills

When you get emergency care or are treated by an out-of-network provider at an in-network hospital or ambulatory surgical center, you are protected from **balance billing. In these cases, you** shouldn't be charged more than your plan's copayments, coinsurance and/or deductible.

What is "balance billing" (sometimes called "surprise billing")?

When you see a doctor or other health care provider, you may owe certain out-of-pocket costs, like a copayment, coinsurance, or deductible. You may have additional costs or have to pay the entire bill if you see a provider or visit a health care facility that isn't in your health plan's network.

"Out-of-network" means providers and facilities that haven't signed a contract with your health plan to provide services. Out-of-network providers may be allowed to bill you for the difference between what your plan pays and the full amount charged for a service. This is called **"balance billing."** This amount is likely more than in-network costs for the same service and might not count toward your plan's deductible or annual out-of-pocket limit.

"Surprise billing" is an unexpected balance bill. This can happen when you can't control who is involved in your care—like when you have an emergency or when you schedule a visit at an in-network facility but are unexpectedly treated by an out-of-network provider. Surprise medical bills could cost thousands of dollars depending on the procedure or service.

You're protected from balance billing for:

Emergency services
If you have an emergency medical condition and get emergency services from an out-of-network provider or facility, the most they can bill you is your plan's in-network cost-sharing amount (such as copayments, coinsurance, and deductibles). You **can't** be balance billed for these emergency services. This includes services you may get after you're in stable condition, unless you give written consent and give up your protections not to be balanced billed for these post-stabilization services.

Certain services at an in-network hospital or ambulatory surgical center
When you get services from an in-network hospital or ambulatory surgical center, certain providers there may be out-of-network. In these cases, the most those providers can bill you is your plan's in-network cost-sharing amount. This applies to emergency medicine, anesthesia, pathology, radiology, laboratory, neonatology, assistant surgeon, hospitalist, or intensivist services. These providers **can't** balance bill you and may **not** ask you to give up your protections not to be balance billed.

If you get other types of services at these in-network facilities, out-of-network providers **can't** balance bill you, unless you give written consent and give up your protections.

You're never required to give up your protections from balance billing. You also aren't required to get out-of-network care. You can choose a provider or facility in your plan's network.

When balance billing isn't allowed, you also have these protections:

- You're only responsible for paying your share of the cost (like the copayments, coinsurance, and deductible that you would pay if the provider or facility was in-network). Your health plan will pay any additional costs to out-of-network providers and facilities directly.
- Generally, your health plan must:
  - Cover emergency services without requiring you to get approval for services in advance (also known as "prior authorization").
  - Cover emergency services by out-of-network providers.
  - Base what you owe the provider or facility (cost-sharing) on what it would pay an in-network provider or facility and show that amount in your explanation of benefits.
  - Count any amount you pay for emergency services or out-of-network services toward your in-network deductible and out-of-pocket limit.

If you think you've been wrongly billed, you may file a complaint with the federal government at https://www.cms.gov/nosurprises/consumers or by calling *1-800-985-3059.*

Visit *www.cms.gov/nosurprises/consumers* for more information about your rights under federal law.

The law in your state may provide additional protections to you that are not provided by federal law. For more information regarding your protections against Surprise Medical Billing to to learn about making a complaint, please see the state-specific resources on the enclosed page.

Burden Shifting Allowed

To the extent a provider furnishes services at a covered facility (hospital, surgery center, etc.), the provider may satisfy the notice requirements if a written agreement between the provider and facility requires the facility to provide the required notice.

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Continuity of Care

Continuity of Care requirements may come into play if your hospital is at risk of going out-of-network with carrier

In some situations, patients undergoing treatment for serious or complex condition may still qualify for in-network rates after the provider-payer contract expires

Further rulemaking pending on this provision. Be sure to understand your Continuity of Care obligations if contract negotiations may progress toward termination.

Provider Directory Errors

Providers and Facilities should submit provider directory information to health plans at the time of contracting *and make sure they send notification of update upon termination of network agreement.*

Otherwise, Providers and Facilities may be required to reimburse enrollees who relied upon the incorrect information and were billed out-of-network

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Who pays the difference?

Independent Dispute Resolution Process Established

- Provider or Facility and Payers
  - To determine amount of payment owed to provider/facility as a result of treating patients as in-network for out-of-network charges
- Provider or Facility and Self Pay Patient
  - To determine amount of payment owed if substantially in excess of good faith estimate

Further clarification pending 2023 Proposed Rule

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Surprise Billing Rule

Independent Dispute Resolution Action	Timeline
Initiate 30-business-day open negotiation period	30 business days, starting on the day of initial payment or notice of denial of payment
Initiate independent dispute resolution process following failed open negotiation	4 business days, starting the business day after the open negotiation period ends
Mutual agreement on certified independent dispute resolution entity selection	3 business days after the independent dispute resolution initiation date
Departments select certified independent dispute resolution entity in the case of no conflict-free selection by parties	6 business days after the independent dispute resolution initiation date
Submit payment offers and additional information to certified independent dispute resolution entity	10 business days after the date of certified independent dispute resolution entity selection
Payment determination made	30 business days after the date of certified independent dispute resolution entity selection
Payment submitted to the applicable party	30 business days after the payment determination

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Enforcement

CMS will only enforce a provision if CMS determines that a state is not substantially enforcing that provision.

Could be enforced by State Insurance Department

Look for further development here.

Further Resources

https://www.cms.gov/nosurprises/policies-and-resources/overview-of-rules-fact-sheets

https://www.cms.gov/nosurprises/consumer-advocate-toolkit

Overview of Rules

FAQ

Decision Trees for all Requirements

Fact Sheets

Guidance and Technical Resources

Disclosures, Notice & Consent

Question 1

The Surprise Billing Rules Require:

1. Covered Providers to Post Required Notices on Website
2. Covered Providers to Provide Required Notices to Patients
3. Good-Faith Estimates to Uninsured or Self Pay Patients
4. All of the Above

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Polling Question 2

The No Surprises Act Applies To:

1. Emergency Services
2. Physician Clinic Services
3. Out-of-Network Facilities
4. None of the Above

What is Information Blocking?

Engaging in any practice that is likely to interfere with the Access Exchange, or Use of Electronic Health Information (EHI)

Unless the practice is covered by an exception (we'll cover these!)

Examples of Information Blocking

- A health care provider has the capability to provide same-day access to EHI in a form and format requested by a patient or patient's health care provider, but takes several days to respond.
- A health care provider charges unnecessary and unsubstantiated fees for access to EHI.
- A health care provider has the ability to make test results available via a patient portal, but improperly delays making these results available

Information Blocking Rule

- This new rule was implemented (effective April 5, 2021) as a result of the 21st Century Cures Act
- The Rule *does not* require the Provider to disclose EHI if doing so would violate another applicable law, such as HIPAA.
- OIG has authority to take enforcement actions beginning September 1, 2023 – Providers not included in "entities subject to penalty" at this time (unless also a health IT developer, health information exchange or health information network)

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Who does this policy apply to?

- Workforce Members
  - Employees
  - Associates
  - Officers
  - Medical staff
  - Residents / Fellows
  - Students
  - Volunteers
  - Vendors
  - Contractors
  - Agents

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When does this policy apply?

- When a request to access, use, or exchange EHI is *denied* or *limited*, an exception must apply.
  - What does limited mean?
    - By content
    - Pursuant to a condition (like a fee)
- If a request to access, use, or exchange is *granted,* this policy does not apply.

Procedure in Practice

If a request for access, use, or exchange of EHI is being denied or limited, an exception *must* apply.

1. Identify the exception that applies.
2. Satisfy the conditions of the exception (set forth in the Policy).
3. Document the results of your determination.
4. Implement all exceptions in a consistent and non-discriminatory manner.

EXCEPTIONS

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Exceptions for Denying Access

1. Necessary to Prevent Harm – practice is reasonable and necessary to prevent harm to a patient or another person
   a) Reasonable belief that the practice will substantially reduce a risk of harm;
   b) Practice must be no broader than necessary;
   c) Must classify risk of harm or type of harm

Example: Data (such as lab results) are reasonably suspected to be misunderstood.

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Exceptions for Denying Access

2. Necessary to Protect Privacy

a) If denying a request because it would violate HIPAA policies, this exception should be documented.

Example: denying request for psychotherapy notes.

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Exceptions for Denying Access

3. Necessary for Security – necessary to interfere with access, exchange, or use of EHI in order to protect security of EHI

a) Directly related to safeguarding the confidentiality, integrity, and availability of EHI

b) Example: after a security incident or ransomware incident, the patient portal is temporarily unavailable.

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Exceptions for Denying Access

4. Infeasibility – legitimate practical challenges may limit ability to comply with a request for access

a) Example: Medical records personnel not available to respond to requests due to COVID-19 diagnosis or exposure;

b) Example: An electronic system is temporarily unavailable due to a security incident;

c) Example: the data requested cannot be separated from data that may not be disclosed (under a separate exception)

Exceptions for Denying Access

5. Health IT Performance – reasonable and necessary measures to make health IT system temporarily unavailable for the benefit of overall performance of system

Example: software update of EMR system makes information temporarily unavailable

Exceptions when Limiting Access

1. Content and Manner – may limit the content of its response or the manner in which it fulfills a request, exchange, or use of EHI.
   a) Example – may respond in alternative manner if requested manner is technically unavailable

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Exception - Licensing

It is not information blocking to impose terms and conditions (e.g. a license or a non-disclosure agreement) in situations that meet the exception's specific requirements.

This exception is really more applicable for developers and researchers.

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Exception - Fees

Ensure you are accurately assessing all fees in compliance with HIPAA policies – if these fees are not appropriate, could be information blocking violation and HIPAA violation.

Refresher: Records Requests

HIPAA Right of Access

- Covered entities may require request to be in writing
- No unreasonable measures allowed
  - For example – may not require all individuals to request access via web portal, because all individuals may not have this access.
- In the form and format requested, if readily producible
- Within 30 days (but earlier if possible)

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Refresher: Fees for Records Requests

The Privacy Rule permits a Covered Entity to impose a reasonable, cost-based fee to provide the individual (or personal representative) or designated third party with the requested records.

The reasonable, cost-based fee may only include:

- Certain labor,
- Supplies, and
- Postage.

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Refresher: Fees for Records Requests

Certain Labor:

- Includes *only* labor for creating and delivering electronic or paper copy in the form and format requested, once PHI that is responsive to the request has been identified, retrieved or collected and is ready to be copied.
- *Does not include* reviewing the request for access or searching for and retrieving PHI.
- May include cost of labor to prepare a summary or explanation, if the individual in advance *both* chooses to receive the explanation or summary and agrees to the fee that may be charged.

Supplies:

- Supplies for creating paper copy or electronic media in the form and format requested (ex. Paper, toner, USB drive, CD, etc.)

Postage: can include only if the individual requests that the copy be mailed.

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Refresher: Calculating Fees

- Actual Costs – may calculate actual cost associated with criteria on last slide so long as individual is informed in advance of approximate fee
- Average Costs – can develop schedule of costs for labor based on average labor costs; may add supply cost.
- Flat fee for electronic copies of PHI maintained electronically – may charge a flat fee that does not exceed $6.50, which includes all labor, supplies, and postage.

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Fees for Records Requests

Ciox Health, LLC v. Azar (D.D.C. January 23, 2020)

- Federal Court vacated the “third-party directive” within the individual right of access as expanded by HHS in the 2013 Omnibus Rule, which broadened the third-part directive to PHI contained in any format, not just electronic records.
- The Patient Rate fee limitation will now apply only to an individual’s request for access to their own records, and does not apply to an individual’s request to transmit records to a third party.

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Cybersecurity and HIPAA

Most Common Threats

1. Email Phishing Attacks
2. Ransomware Attacks
3. Loss or theft of equipment or data
4. Inside, accidental or intentional data loss
5. Attacks against connected medical devices

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HIPAA Common Compliance Issues

- Business Associate Agreements
- Risk Analysis
- Failure to Maintain Identified Risk, e.g. Encrypt
- Lack of Appropriate Auditing
- Insider Threat
- Insufficient Cybersecurity Measures
- Insufficient Data Backup and Contingency Planning

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Takeaways

1. Perform a Risk Assessment – Engage a 3rd Party
2. Follow-up on the results of the Risk Assessment
3. Encryption is now the standard – not an option
4. Make sure you have written Business Associate Agreements in place! (these are necessary if sharing PHI with non-clinic)
5. Cyber Liability Coverage
6. Enforcement - https://www.hhs.gov/hipaa/for-professionals/compliance-enforcement/index.html

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Polling Question 3

If my organization does not run a Security Risk Assessment:

1. It won't matter as long as there is no breach;
2. I can defend an unfavorable finding if the Security Risk Assessment would have been too expensive;
3. It's okay if we ran one last year;
4. None of the above.

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HIPAA PROPOSED REVISIONS

A Notice of Proposed Rule Making (NPRM) for modifications to the HIPAA Privacy Rule was published by the Department of Health and Human Services (HHS) in the Federal Register on January 21, 2021 closed commenting in 2022. The purpose of the proposed changes is to improve individual access to protected health information (PHI) and increase permissible disclosures of PHI with the intent of improving care coordination and case management.

Expected in 2023 – coming in 2024?

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Expected HIPAA Provisions in 2024

- Allowing patients to inspect their PHI in person and take notes or photographs of their PHI.
- Changing the maximum time to provide access to PHI from 30 days to 15 days.
- Requests by individuals to transfer ePHI to a third party will be limited to the ePHI maintained in an EHR.

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Expected HIPAA Provisions in 2024

- Individuals will be permitted to request their PHI be transferred to a personal health application.
- States when individuals should be provided with ePHI at no cost.
- Covered entities will be required to inform individuals that they have the right to obtain or direct copies of their PHI to a third party when a summary of PHI is offered instead of a copy.

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Expected HIPAA Provisions in 2024

- HIPAA-covered entities will be required to post estimated fee schedules on their websites for PHI access and disclosures.
- HIPAA-covered entities will be required to provide individualized estimates of the fees for providing an individual with a copy of their own PHI.
- Pathway created for individuals to direct the sharing of PHI maintained in an EHR among covered entities.

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Expected HIPAA Provisions in 2024

- Healthcare providers and health plans will be required to respond to certain records requests from other covered healthcare providers and health plans, in cases when an individual directs those entities to do so under the HIPAA Right of Access.
- The requirement for HIPAA-covered entities to obtain written confirmation that a Notice of Privacy Practices has been provided has been dropped.
- Covered entities will be allowed to disclose PHI to avert a threat to health or safety when harm is “seriously and reasonably foreseeable.” The current definition is when harm is “serious and imminent.”

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Expected HIPAA Provisions in 2024

- Covered entities will be permitted to make certain uses and disclosures of PHI based on their good faith belief that it is in the best interest of the individual.
- The addition of a minimum necessary standard exception for individual-level care coordination and case management uses and disclosures, regardless of whether the activities constitute treatment or health care operations.
- The definition of healthcare operations has been broadened to cover care coordination and case management.

Expected HIPAA Provisions in 2024

- The Armed Forces' permission to use or disclose PHI to all uniformed services has been expanded.
- A definition has been added for electronic health records.

Navigating Fraud and Abuse Laws

- Stark and Anti-Kickback address financial incentives and over-utilization
- Two distinct laws – overlapping applications
- Financial relationships are highly regulated
- Both carry severe penalties for violations
- State laws limiting mark ups and other medical billing techniques

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Stark Law

Purpose: limits physician referrals for when there is a financial relationship with the entity (includes anything of value provided).

Analysis:

1. Is there a referral from a physician for a designated health service (DHS)?
2. Does the physician (or an immediate family member) have a financial relationship with the entity providing the DHS?
3. Does the financial relationship fit within an exception?

Penalties – payment denial, monetary penalties, exclusion, and possible violation of the False Claims Act

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Stark Law Compliance

1. Meet a Stark Law exception
2. Document financial relationships with referring physicians.
3. Have systems to ensure properly structured payments.
4. Watch out for lease problems.
5. Gifts can implicate the Stark Law too.

Anti-Kickback Statute

Purpose: prohibits asking for or receiving anything of value to induce or reward referrals of Federal health care program business.

Analysis:

1. Is there a referral relationship?
2. Is there something of value being exchanged?
3. Are there Federal health care program patients?
4. Is there intent to induce referrals?

Penalties: fines, program exclusion, prison time

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Anti-Kickback Compliance

1. Use a Safe Harbor
2. The test is a "One Purpose" Test
   - the statute is violated if one purpose of the remuneration is to induce referrals, even if there are other legitimate purposes.
3. FMV for actual/necessary services

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False Claims Act

Purpose: prohibits the submission of false or fraudulent claims to the Government.

Types of False Claims

- False Claim – patient does not exist, services not rendered
- Reverse False Claim – retained overpayments
  - A strong compliance program is necessary to identify potential overpayments.
  - An overpayment must be reported and refunded within 60 days of quantification.
  - Tasked with "reasonable diligence" to identify overpayments.

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Safe Harbors

Stark

- Bona fide employment
- Personal services
- Rental of office space and equipment
- Isolated Transaction
- Physician Recruitment
- Indirect Compensation
- Fair Market Value (FMV)
- In-Office Ancillary Services
- Bona Fide Employment Relationships

Anti-Kickback

- Employment
- Personal Services and Management Contracts
- Rental of Office Space and Equipment
- Sale of Practice
- Practitioner Recruitment

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Polling Question 4

If my organization comes close to meeting a Stark Exception, that's okay, as substantial compliance is all that is required.

1. True
2. False

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Recent Stark Law Developments

Generally, Provider-Friendly

- Hospitals can pay a physician up to $5,000 per year without a written agreement;
- “Commercially reasonable” clarification – takes into account the type of entity
- “Volume/Value of Referrals” Clarification – becomes a mathematic equation consideration
- 90-day compliance period for written agreement

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Recent Stark Law Developments

Value Based Arrangements

- Greater Risk = Greater Flexibility
- No fair market value requirement.

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