Five Current Issues in Hospital/Physician Relationships

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Agenda

- Recent Stark and AKBS Updates
- Physician Contracting & Physician Compensation Issues
- Specific Issues in Physician/Hospital Relationships
- Privacy and Security Enforcement
- Provider-Based Updates

Recent Stark and AKBS Statute Updates

- **Stark Updates - the following Stark Updates were issued pursuant to 80 Fed. Reg. 70886 on November 16, 2015 to become effective January 1, 2016.**
- **Anti-Kickback Statute Updates - the following Anti-Kickback Statute Updates were issued pursuant to 81 Fed. Reg. 88368 on December 7, 2016 to become effective January 6, 2017.**

Recent Stark and AKBS Updates: Stark Updates

- **Clarification of Writing Requirement [80 Fed. Reg. 70886, 71314] –**
  - **Many Stark exceptions require the financial arrangement to be documented in writing.**
  - **Uncertainty in provider community related to use of the terms "arrangement" and "agreement" with respect to the writing requirement. Some providers interpreted "agreement" to mean a single written agreement is required to satisfy the writing requirement.**
  - **To ensure uniformity among the compensation exceptions, CMS removed the term "agreement" from §411.354(d)(1), (d)(4)(i), (a)(1), (b)(1), (e)(4)(i) and (l)(i). CMS replaced "agreement" with "lease arrangement" at §411.354(a)(2), (a)(4), (a)(5), (a)(6), (b)(3), (b)(4) and (b)(5). CMS replaced "agreement" with "arrangement" in §411.354(c)(3) and (f)(2). CMS made similar revisions to other exceptions where the language suggested a formal contract or specific writing is required.**
  - **Uncertainty in provider community regarding whether the arrangement needs to be documented in a single formal agreement.**
  - **To satisfy the writing requirement the facts and circumstances of the arrangement must be sufficiently documented to permit the government to verify compliance with the applicable exception.**

Recent Stark and AKBS Updates: Stark Updates (cont'd)

- **CMS clarified that a collection of documents, including contemporaneous documents evidencing a course of conduct between the parties, may satisfy the writing requirement.**
  - **Examples of documents that may be part of the "collection of documents" include:**
    - **Board meeting minutes or other documents authorizing payments for specified services**
    - **Written communication between the parties including hard copy and electronic communication**
    - **Fee schedules for specified services**
    - **Check requests or invoices identifying items or services provided, relevant dates, and/or rate of compensation**
    - **Time sheets documenting services performed**
    - **Call coverage schedules or similar documents providing date of services to be provided**
    - **Accounts payable or receivable records documenting date and rate of payment and reason for payment**
    - **Checks issued for items, services or rent**
  - **List is <u>not</u> exhaustive. Fact-based analysis. Party could have all of the documents listed above and still not satisfy the writing requirement if the documents do not clearly relate to one another and evidence one and the same arrangement between the parties.**
  - **Safest course of action to comply with the writing requirement is to execute a single written document outlining the arrangement between the parties.**
  - **<u>Note</u>: CMS noted that the use of a collection of documents to evidence course of conduct between the parties was its existing policy and its proposal to substitute "arrangement" for "agreement" throughout exceptions for compensation arrangements was merely intended to clarify and confirm existing policy.**

Recent Stark and AKBS Updates: Stark Updates (cont'd)

- **Remember –**
  - **Entities have the burden of proof to establish that services were not furnished as a result of prohibited referrals and that all requirements of an exception were met at the time a referral is made.**
  - **If an arrangement with a physician does not comply with the applicable exception's writing requirement at the time the arrangement commences, the entity cannot bill for DHS furnished as a result of the physician's referrals until the arrangement is sufficiently documented.**
  - **Contemporaneous documents cannot be relied on to protect referrals that predate the documents.**

Recent Stark and AKBS Statute Updates: Stark Updates (cont'd)

- **Clarification of One Year Term Requirement [80 Fed. Reg. 70886, 71317] –**
  - **The following exceptions require the compensation arrangement between the DHS entity and referring physician to have a term of at least one year:**
    - **Rental of Office Space**
    - **Rental of Equipment**
    - **Personal Services Arrangements**
  - **Providers have incorrectly interpreted the one year requirement to mean that a formal written contract identifying the term of the arrangement is required to satisfy the one year term requirement.**
  - **CMS clarified that an arrangement that lasts as a matter of fact for at least one year satisfies the requirement. CMS requires that the parties have contemporaneous writings establishing that the arrangement last for at least one year or demonstrate that the arrangement was terminated during the first year and the parties did not enter into a new arrangement for the same space, equipment, or service during the first year.**
  - **A "collection of documents" can be used to evidence that the arrangement lasted for at least one year.**
  - **CMS revised 42 CFR 411.357(a)(2), (b)(3) and (d)(1)(iv) to reflect CMS' policy that the arrangement need only last at least one year as a matter of fact.**

Recent Stark and AKBS Statute Updates: Stark Updates (cont'd)

- **Extension on Holdover Arrangements [80 Fed. Reg. 70886, 71318] –**
  - **Historically, the Rental of Office Space Exception, Rental of Equipment Exception, and Personal Services Arrangement Exception permitted holdovers for up to six months if an arrangement of at least one year expires.**
  - **CMS revised these exceptions to permit an indefinite holdover provided:**
    - **The arrangement lasted for at least one year;**
    - **The holdover arrangement immediately followed the expiration of the arrangement;**
    - **The arrangement met the conditions of the exception when it expired;**
    - **The holdover arrangement is on the same terms and conditions as the immediately preceding arrangement; and**
    - **The holdover arrangement continues to satisfy the conditions of the exception.**

Recent Stark and AKBS Statute Updates: Stark Updates (cont'd)

- **Please note that CMS also issued the following two new Stark exceptions via 80 Fed. Reg. 70886: (1) the Assistance to Compensate a Nonphysician Practitioner Exception; and (2) the Timeshare Arrangements Exception. We discussed these exceptions during our presentation last year.**

Recent Stark and AKBS Statute Updates: Anti-Kickback Updates

- **Clarification of the Old and Addition of the New**
  - **A technical correction to the existing safe harbor for referral services**
  - **Protection for certain cost-sharing waivers, including: pharmacy waivers of cost-sharing for financially needy beneficiaries; and waivers of cost-sharing for emergency ambulance services furnished by State- or municipality owned ambulance services**
  - **Protection for certain remuneration between Medicare Advantage organizations and federally qualified health centers**
  - **Protection for discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program**
  - **Protection for free or discounted local transportation services that meet specified criteria**

Recent Stark and AKBS Statute Updates: Anti-Kickback Updates (cont'd)

- **Technical correction to the safe harbor for referral services [42 CFR 1001.952(f)]**
  - **1999 – finalized modification to language of referral services safe harbor to clarify that the safe harbor precludes protection for payments from participants to referral services that are based on the volume or value of referrals to, or business otherwise generated by, *either party for the other party*.**
  - **Subsequently – revisions were made to the safe harbor which were intended to make a technical correction clarifying that exclusion authority applied to all Federal health care programs rather than only to Medicare and State health care programs. Language was inadvertently changed to "or business otherwise generated by either party for the referral services."**
  - **Now – CMS made a technical correction and reverted to the language used in the 1999 final rule.**

Recent Stark and AKBS Statute Updates: Anti-Kickback Updates (cont'd)

- **Protection for certain cost-sharing waivers, including: pharmacy waivers of cost-sharing for financially needy beneficiaries; and waivers of cost-sharing for emergency ambulance services furnished by State- or municipality owned ambulance services**
  - **Subparagraphs added to protect certain cost-sharing waivers that pose a low risk of harm.**
  - **Pharmacy Waiver [42 CFR 1001.952(k)(3)] - If the cost-sharing amounts are owed to a pharmacy for cost-sharing imposed under a Federal health care program, the pharmacy may reduce or waive the cost-sharing amounts if:**
    - **The waiver or reduction is not offered as a part of an advertisement or solicitation; and**
    - **Except for waivers or reductions offered to subsidy-eligible individuals to which only the requirement in paragraph (k)(3)(i) of 1001.952 applies:**
      - **The pharmacy does not routinely waive or reduce cost-sharing amounts; and**
      - **The pharmacy waives the cost-sharing amounts only after determining in good faith that the individual is in financial need or after failing to collect the cost-sharing amounts after making reasonable collection efforts.**

Recent Stark and AKBS Statute Updates: Anti-Kickback Updates (cont'd)

- **Ambulance Waiver [42 CFR 1001.952(k)(4)] – If the cost-sharing amounts are owed to an ambulance provider or supplier for emergency ambulance services for which a Federal health care program pays under a fee-for-service payment system and all of the following conditions are met:**
  - **The ambulance provider or supplier is owned and operated by a State, a political subdivision of a State, or a tribal health care program;**
  - **The ambulance provider or supplier is engaged in an emergency response;**
  - **The ambulance provider or supplier offers the reduction or waiver on a uniform basis to all of its residents or (if applicable) tribal members, or to all individuals transported; and**
  - **The ambulance provider or supplier must not later claim that amount reduced or waived as a bad debt for payment purposes under a Federal health care program or otherwise shift the burden of the reduction or waiver onto a Federal health care program, other payers, or individuals.**

Recent Stark and AKBS Statute Updates: Anti-Kickback Updates (cont'd)

- **Protection for certain remuneration between Medicare Advantage (MA) organizations and federally qualified health centers (FQHCs) [42 CFR 1001.952(z)]**
  - **"Remuneration" does not include any remuneration between a federally qualified health center (or an entity controlled by such a health center) and a Medicare Advantage organization pursuant to a written agreement described in section 1853(a)(4) of the Act.**

Recent Stark and AKBS Statute Updates: Anti-Kickback Updates (cont'd)

- **Protection for discounts by manufacturers on drugs furnished to beneficiaries under the Medicare Coverage Gap Discount Program [42 CFR 1001.952(aa)]**
  - **"Remuneration" does not include a discount in the price of a drug when the discount is furnished to a beneficiary under the Medicare Coverage Gap Discount Program if the following conditions are met:**
    - **The discounted drug meets the definition of "applicable drug" set forth in section 1860D-14A(g) of the Act;**
    - **The beneficiary receiving the discount meets the definition of "applicable beneficiary" set forth in section 1860D-14A(g) of the Act; and**
    - **The manufacturer of the drug participates in, and is in compliance with the requirements of, the Medicare Coverage Gap Discount Program.**

Recent Stark and AKBS Statute Updates: Anti-Kickback Updates (cont'd)

- **Protection for free or discounted local transportation services [42 CFR 1001.952(bb)]**
  - **"Remuneration" does not include free or discounted local transportation made available by an eligible entity if all requirements are met.**
    - **Availability of free or discounted local transportation must:**
      - **Be set forth in a policy that is applied uniformly and consistently**
      - **Not be determined in a manner related to the past or anticipated volume or value of Federal health care program business**
    - **Available only to an individual who is:**
      - **An established patient of the eligible entity that is providing the transportation, if the eligible entity is a provider or supplier of health care services; and**
      - **An established patient of the provider or supplier to or from which the individual is being transported**
    - **Must be within 25 miles of the health care provider or supplier to or from which the patient would be transported, or within 50 miles if the patient resides in a rural area**
    - **Must be for the purpose of obtaining medically necessary items and services**

Recent Stark and AKBS Statute Updates: Anti-Kickback Updates (cont'd)

- **Other Key Restrictions:**
  - **Cannot be air, luxury or ambulance-level transportation**
  - **Cannot be publically marketed or advertised**
  - **No marketing of health care items/services occurs during the course of the transportation or at any time by drivers who provide the transportation**
  - **Drivers and others arranging transportation cannot be paid on a per-beneficiary basis**
  - **Eligible entity cannot shift the costs of the transportation to any Federal health care program, other payors or individuals**
- **Protects use of "shuttle services" if:**
  - **The shuttle service is not air, luxury or ambulance-level transportation**
  - **The service is not marketed or advertised and no marketing of health care items/services occurs during the course of transportation and drivers and others arranging transportation are not paid on a per-beneficiary transported basis**
  - **The service is only available within the eligible entity's local area (no more than 25 miles from any stop on the route to any stop at a location where health care items/services are provided, except that if a stop on the route is in a rural area, the distance may be up to 50 miles between that stop and all providers/suppliers on the route)**
  - **Eligible entity must bear the cost of the shuttle service and must not shift the burden to any Federal health care program, other payors or individuals.**

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- ❑ Physician Contracting & Physician Compensation Issues
- ❑ Specific Issues in Physician/Hospital Relationships
- ❑ Privacy and Security Enforcement
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Physician Contracting & Physician Compensation Issues

- **Regulatory Requirements Relating to Contracting for Employed Physicians versus Independent Contractor Physicians**
- **Compensation Risk Areas**
- **Other Compensation Issues**
- **Importance of Valuations**
- **Issues in Practice**

Physician Contracting & Physician Compensation Issues:

Regulatory Requirements Relating to Contracting for Employed Physicians versus Independent Contractor Physicians

Bona Fide Employment Relationships	
<u>Stark Exception</u> i. Arrangement is for identifiable services; ii. Amount of remuneration must be consistent with fair market value and not determined in a manner that takes into account the volume or value of referrals; and iii. Amount of remuneration must be commercially reasonable even if no referrals were made to the employer. 42 CFR §411.357(c)	<u>AKBS Safe Harbor</u> "Bonafide Employee" Safe Harbor.

Physician Contracting & Physician Compensation Issues:

Regulatory Requirements Relating to Contracting for Employed Physicians versus Independent Contractor Physicians (cont'd)

Personal Services and Management Contracts (Independent Contractors)

Stark exception related to compensation arrangements for personal services or management:

i. The arrangement must be set out in writing, signed by the parties and specify the services covered by the arrangement;
ii. The arrangement must cover all services to be furnished by the physician to the entity (may incorporate by reference or cross-reference a Master List of contracts that is maintain and updated centrally);
iii. Aggregate services contracted for must not exceed those that are reasonable and necessary for the legitimate business purpose of the arrangement;
iv. The term of the arrangement must be for at least one year;
v. The compensation must be set in advance, not exceed FMV, and not be determined in a manner that takes into account the volume or value of referrals or any other business generated between the parties;
vi. Services furnished under the arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any Federal or State law.

NOTE: holdover arrangement for indefinite period following the expiration of the agreement after a year that meets all of the above conditions is OK, so long as the arrangement is on the same terms and conditions as the preceding agreement.
42 CFR §411.357(d)

AKBS - safe harbor for remuneration from an entity under a personal service arrangement or management contract:

i. The agreement is in writing and signed by the parties;
ii. The agreement covers all of the services provided and specifies the services provided;
iii. If services are intended to be provided on a periodic, sporadic or part-time basis rather than on a full-time basis, the agreement must specify the schedule of such intervals, the length of time of the internals and the charge for such intervals;
iv. The term of the agreement must be for at least 1 year;
v. The aggregate compensation paid over the term is set in advance, consistent with FMV and is not determined in a manner that takes into account the volume or value of any referrals or business generated between the parties for which payment may be made in whole or in part under Medicare or a State healthcare program;
vi. Services performed under the agreement do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law;
vii. The aggregate services contracted for do not exceed those that are reasonably necessary to accomplish the commercially reasonable business purpose of the services.

42 CFR §100.952(d)

Physician Contracting & Physician Compensation Issues:

Regulatory Requirements Relating to Contracting for Employed Physicians versus Independent Contractor Physicians (cont'd)

Topic Area	Stark	AKBS
Equipment Lease	42 CFR 411.357(b)	42 CFR 1001.952(c)
Space Lease	42 CFR 411.357(a)	42 CFR 1001.952(b)
Fair Market Value	42 CFR 411.357(l)	None
Isolated Transactions	42 CFR 411.357(f)	None
Recruitment	42 CFR 411.357(e)	42 CFR 1001.952(n)
Non-monetary Compensation	42 CFR 411.357(k)	None
Medical Staff Incidental Benefits	42 CFR 411.357(m)	None
Compliance Training	42 CFR 411.357(o)	None
Professional Courtesy	42 CFR 411.357(s)	None
Electronic Prescribing items & services	42 CFR 411.357(v)	42 CFR 1001.952(x)
Electronic Health Records items& services	42 CFR 411.357(w)	42 CFR 1001.952(y)

Physician Contracting & Physician Compensation Issues:

Regulatory Requirements Relating to Contracting for Employed Physicians versus Independent Contractor Physicians (cont'd)

- **Relevant Definitions under Stark and AKBS:**
  - **a. Fair Market Value**
    - **The value in arm's-length transactions, consistent with the "general market value"**
    - **"General Market Value" - the compensation that would be included in a services agreement as a result of bona fide bargaining between well-informed parties to the agreement who are not otherwise in a position to generate business for the other party, at the time of the service agreement**
    - **The market may be different in different areas - one size does not fit all!**
  - **b. Commercially reasonable**
    - **Commercial Reasonableness – an arrangement is commercially reasonable if it is: a sensible, prudent business arrangement from the perspective of the parties involved, even in the absence of potential referrals.**
    - **Determining Commercial Reasonableness - "Is the transaction consistent with fair market value?" Standard definition of FMV addresses many of the issues thought to require a commercial reasonableness assessment. Any transaction that fails to be consistent with fair market value is commercially unreasonable. However, if a transaction meets the FMV standard, it may be commercially unreasonable for other reasons.**
    - **Underlying Principles - All business transactions should aid organizations in accomplishing their strategic, operational, and/or financial objectives; assess the overall arrangement, including qualitative considerations such as strategy and operations,**
    - **Whereas fair market value primarily assesses the financial aspects of the arrangements (range of dollars only), commercial reasonableness considers the aggregate terms of the overall arrangements and asks the question: "Does this deal make sense?"**

Physician Contracting & Physician Compensation Issues: Compensation Risk Factors

- **Compensation Risk Factors:**
  - **Is compensation in excess of FMV?**
  - **Is compensation commercially reasonable?**
  - **Are employment/compensation decisions driven by patient referrals?**
  - **Are physicians compensated in excess of what they would earn in private practice and/or in excess of collections? If so, why?**
  - **Is the compensation model unique, as compared to other similar hospitals/health systems?**
  - **Do referral patterns shift often and/or dramatically?**
  - **Does the practice operate at a loss?**

Physician Contracting & Physician Compensation Issues: Other Compensation Issues

- **Other Compensation Issues:**
  - **wrVUS – ensure consistency in determining initial wRVUS and throughout the term of the Agreement**
  - **Quality payments – MACRA**
  - **Supervision of midlevels**
  - **Integration of EMR systems**
  - **Potential delays in credentialing**

Physician Contracting & Physician Compensation Issues: Other Compensation Issues

- **Quick MACRA Primer**

1) **What is it?**
   - **The Medicare Access and CHIP Re-Authorization Act**

2) **What does it do?**
   - **Repeals the SGR**
   - **Locks in provider payment rates at near zero growth**
   - **Provides for the development of 2 new payment tracks under the Quality Payment Program: (i) Merit-Based Incentive System (MIPS) and (ii) Advance Alternative Payment Models (AAPM)**
   - **Starting in 2019**

3) **Who does it apply to?**

The following payments and clinicians are included:

- **Any services billed under the MPFS; adjustments will apply to the work, practice expense and physician malpractice RVUs**
- **Physicians, PAs, NPs, Clinical nurse specialists, CRNAs (and groups that include these clinicians)**

Physician Contracting & Physician Compensation Issues: Other Compensation Issues

4) **Who does it NOT apply to:**

The following payments are clinicians are excluded

- **IPPS**
- **OPPS**
- **ASC Payment System**
- **Clinicians or groups that fall below $30,000 or less in Medicare charges OR fewer than 100 Medicare patients**
- **Clinicians in their 1st year of billing**

5) **What is the timeline?**

- **January 1, 2019 based on 2017 performance data**

6) **What are the key differences between MIPS and APMs?**

- **Under MIPS, Medicare consolidates the 3 pay for performance programs (Meaningful Use, the Value-Based Payment Modifier, and PQRS) into 1 system. Under the new system, CMS will score clinicians and groups on their performance in 4 categories: Quality (50%), Cost (10%), Improvement Activities (25%), and Advancing Care Information (15%)**
  - **NOTE: These are 2020 percentage allocations**
  - **Can result in penalties from (4%) to bonuses of 12%; ultimately growing to reductions of (9%) and bonuses of 27%.**
- **Under AAPM can earn favorable financial rewards, but have to participate in a risk-based payment model.**
- **NOTE: there is a straddle group called Partial Qualifying APM Participants.**

7) **What Track will most clinicians be in?**

- **Significant majority – upwards of 90% - are expected to be in MIPS.**

Physician Contracting & Physician Compensation Issues: Importance of Valuations

- **Importance Of Valuations:**
  - **Good to have, but not required**
  - **Many Stark Exceptions and AKBS Safe Harbors require FMV**
  - **Shows intent to comply, but actually have to look behind the data**

Physician Contracting & Physician Compensation Issues: Issues in Practice

- What if the agreement is not in writing?
- What if the agreement has expired?
- Does de minimus compensation have to be in writing?
- Can a hospital require the physician to refer to the hospital?
- What if the agreement is signed AFTER the physician starts providing services?

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Specific Issues in Physician/Hospital Relationships

- **Coding and Billing**
  - **Ensure knowledge of appropriate billing and coding requirements for site-specific services**
  - **Determine who is responsible for what – are physicians responsible for coding? Are they responsible for providing documentation of services to hospital for hospital to code?**
    - **Coding training for physicians**
  - **Regular internal audits/reviews**
- **Opportunities for Additional Compensation**
  - **Medical Director Opportunities**
  - **Medical Staff appointments**
  - **Service line consultants**
  - **Participation in Community Assessments**
  - **Call coverage**

Specific Issues in Physician/Hospital Relationships

- **Participation in Decision Making**
  - **EMR Systems**
  - **Hospital Global Strategic Planning**
  - **Hospital Service-Line Strategic Planning**
- **Education of Regulatory Limitations/Requirements**
- **Recent settlements (DOJ & OIG):**
  - **There have been numerous settlements by hospitals over the past year relating to a variety of issues involving physician relationships including:**
    i. **compensation tied to referrals**
    ii. **upcoding of services**
    iii. **compensation in excess of FMV and not commercially reasonable**
    iv. **rent to physicians in excess of FMV**
    v. **providing marketing services resulting in undue benefits**
    vi. **billing for unnecessary services from referrals from physicians**
    vii. **inappropriate supervision**

Specific Issues in Physician/Hospital Relationships

- **May 2017 - Mercy Hospital in Chesterfield Missouri (and affiliate Mercy Clinic Springfield) paid a $34mm settlement for allegedly submitting false claims to Medicare for chemotherapy services between 2009 and 2014 by taking into account patient referrals to its infusion center when it paid its oncologists. Mercy indicated that the error occurred in 2009 when Mercy transferred its infusion center from its clinic to its hospital in order to participate in a federal drug pricing program. (NOTE: In August 2015, Mercy also paid $5.5mm to settle claims it gave its doctors bonuses for referrals to its clinics.)**
- **July 28, 2016 - Lexington Medical Center in South Carolina agreed to pay a $17mm settlement based on allegations that entered into asset purchase agreements for the acquisition of physician practices or employment agreements with 28 physicians that violated the Stark Law because they took into account the volume or value of physician referrals, were not commercially reasonable, and provided compensation in excess of fair market value.**
- **June 30, 2017 - Charlotte-Mecklenburg Hospital Authority (d/b/a Carolinas Healthcare System) agreed to pay $6.5mm to resolve charges it violated the False Claims Act by up-coding claims for urine drug tests.**

Specific Issues in Physician/Hospital Relationships

- **June 28, 2017 - PAMC Ltd. and Pacific Alliance Medical Center Inc., which together own and operate Pacific Alliance Medical Center, an acute care hospital located in Los Angeles, agreed to pay $42mm to settle charges they violated the False Claims Act and the Stark Law by engaging in improper financial relationships with referring physicians in the form of (1) arrangements under which the physicians were paid above-market rates to rent office space in the physicians' offices, and (2) marketing arrangements that allegedly provided undue benefit to the physicians' practices.**
- **June 2, 2017 - Fredericksburg Hospitalist Group, P.C. agreed to pay approximately $4.2mm to settle charges it violated the False Claims Act by upcoding E&M codes to the highest code levels in providing hospitalist services to patients at Mary Washington Hospital and Stafford Hospital.**
- **April 27, 2017 - Indiana University Health Inc. (IU Health) and HealthNet Inc. agreed to pay a total of $18mm to resolve allegations they violated the False Claims Act by engaging in an illegal kickback scheme related to the referral of HealthNet's OB/GYN patients to IU Health's Methodist Hospital by providing HealthNet with an interest-free line of credit with a balance in excess of $10 million.**

Specific Issues in Physician/Hospital Relationships

- **April 24, 2017 - Crittenton Hospital Medical Center and the Crittenton Cancer Center, together with their current owners Ascension Michigan and Ascension Health, agreed to pay roughly $790,000 to resolve allegations they violated the False Claims Act by billing for medically unnecessary laboratory testing for patients who had been referred to Crittenton by Dr. Farid Fata and physicians in his office.**
- **April 11, 2017 - Norman Regional Hospital Authority (d/b/a Norman Regional Health System) a former hospital administrator and six radiologists agreed to pay roughly $1.6mm to settle charges of violating the False Claims Act by submitting false claims to Medicare for radiological services performed without the proper supervision by a physician.**
- **February 9, 2017 - University Behavioral Health of El Paso agreed to pay $860,000 to resolve allegations it violated the False Claims Act relating to making payments to a physician above fair market value or for services not rendered.**
- **February 6, 2017 - TeamHealth Holdings (as successor in interest to IPC Healthcare Inc., f/k/a IPC The Hospitalists Inc.), agreed to pay $60mm to resolve allegations it violated the False Claims Act by requiring its physicians to upcode.**

Specific Issues in Physician/Hospital Relationships

- **December 7, 2016 - South Miami Hospital agreed to pay approximately $12mm to settle allegations it violated the False Claims Act by submitting false claims to federal healthcare programs for medically unnecessary electrophysiology studies and other procedures allegedly performed by Dr. John R. Dylewski.**
- **October 3, 2016 - Tenet Healthcare Corporation and two of its Atlanta-area subsidiaries, Atlanta Medical Center Inc. and North Fulton Medical Center Inc., agreed to pay over $513mm to resolve charges they violated the False Claims Act and Anti-Kickback statute through illegal kickbacks it paid to a pre-natal clinic to unlawfully refer over 20,000 Medicaid patients to the hospitals.**
- **September 28, 2016 - Pennsylvania-based hospital chain Vibra Healthcare LLC agreed to pay $32.7mm in conjunction with admitting numerous patients to five of its long term care hospitals and one of its inpatient rehab facilities who did not demonstrate signs or symptoms that would qualify them for admission. In addition, Vibra allegedly extended the stays of its long term care patients without regard to medical necessity, qualification and/or quality of care. In some instances, Vibra allegedly ignored the recommendations of its own clinicians, who deemed these patients ready for discharge.**

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Privacy and Security Enforcement

- **Top Five Issues in OCR Investigated Cases**
- **Recent OCR Enforcement Activity**
- **Preparation is Key**
- **Ransomware**

Privacy and Security Enforcement: Top Five Issues in OCR Investigated Cases

- **Impermissible Uses & Disclosures**
- **Safeguards**
- **Administrative Safeguards**
- **Access**
- **Technical Safeguards**

Privacy and Security Enforcement: Recent OCR Enforcement Activity

- **Center for Children's Digestive Health - $31,000 settlement for alleged failure to have a signed Business Associate Agreement in place with a third party vendor that stored the practice's inactive paper medical records.**
- **North Memorial Health Care - $1.55 million settlement for alleged failure to implement a Business Associate Agreement with Accretive. North Memorial provided access to PHI to Accretive around March 21, 2011 and did not enter into a Business Associate Agreement until October 14, 2011. North Memorial also allegedly failed to conduct an accurate and thorough risk analysis of its IT equipment, applications and data systems using ePHI.**

Privacy and Security Enforcement: Recent OCR Enforcement Activity

- **Feinstein Institute for Medical Research – $3.9 million settlement that started with a breach notification to OCR regarding a stolen unencrypted laptop. Upon investigation OCR alleged that:**
  - **PHI of 13,000 individuals was impermissibly disclosed when company owned computer containing PHI was left unsecured in employee's car;**
  - **Feinstein failed to conduct an accurate and thorough risk analysis of potential risks and vulnerabilities of ePHI;**
  - **Feinstein failed to implement policies and procedures for granting access to ePHI to its workforce;**
  - **Feinstein failed to implement physical safeguards for a laptop containing ePHI;**
  - **Feinstein failed to implement policies and procedures that govern receipt and removal of hardware and electronic media that contains ePHI into and out of the facility and movement of items within the facility; and**
  - **Feinstein failed to implement mechanism to encrypt ePHI.**

Privacy and Security Enforcement: Recent OCR Enforcement Activity

- **Memorial Healthcare System - $5.5 million settlement related to allegedly impermissibly accessed PHI. Login of former employee of an affiliated physician practice was used to access ePHI for a year without detection. MHS allegedly failed to implement policies/procedures regarding reviewing, modifying, and/or terminating users' right of access (even though MHS had workforce access policies/procedures in place).**
- **Memorial Hermann Health System - $2.4 million settlement related to alleged disclosure of PHI to the media. MHHS allegedly disclosed a patient's PHI through press releases issued to 15 media outlets/reporters. MHHS senior leadership allegedly further disclosed patient's PHI in meetings with an advocacy group, state representative and state senator. MHHS also allegedly disclosed the patient's PHI in a statement on its website.**

Privacy and Security Enforcement: Recent OCR Enforcement Activity

- **Oregon Health & Science University – $2.7 million settlement following investigation by OCR that allegedly found:**
  - **Disclosure of PHI to an entity without a Business Associate Agreement;**
  - **Failure to implement policies and procedures to prevent, detect, contain and correct security violations;**
  - **Failure to implement an mechanism to encrypt and decrypt ePHI; and**
  - **Failure to implement policies and procedures to address security incidents.**
- **Presence Health – $475,000 settlement to settle allegations that Presence untimely reported a breach of unsecured PHI.**
  - **Discovery of breach on October 22, 2013 and notified affected individuals February 3, 2014 (104 calendar days after the breach). Required to notify affected individuals without unreasonable delay and no later than 60 calendar days after discovery of breach per the Breach Notification Rule. Each extra day is counted as a separate violation of the Breach Notification Rule.**
  - **Alleged failure to provide timely written notification of the breach to prominent media outlets in area in which more then 500 of the individuals affected by the breach resided. Presence notified the media on February 5, 2014 (106 calendar days after discovery of the breach).**
  - **Alleged failure to provide timely written notification of the breach to HHS. Presence did not notify HHS until January 31, 2014 (101 calendar days after discovery of the breach).**

Privacy and Security Enforcement: Recent OCR Enforcement Activity

- **Complete PT – $25,000 settlement related to disclosure of PHI when it posted patient testimonials using full names and full face images on its website without valid HIPAA-compliant authorization. OCR investigation allegedly found that Complete PT:**
  - **Failed to reasonably safeguard PHI;**
  - **Impermissibly disclosed PHI without an authorization; and**
  - **Failed to implement policies/procedures with respect to PHI.**
- **University of Massachusetts Amherst - $650,000 settlement related to malware infection. UMass notified HHS of a workstation infected by malware that may have resulted in breach of unsecured ePHI. HHS' investigation indicated that UMass:**
  - **Allegedly did not conduct an accurate and thorough risk analysis of potential risks and vulnerabilities of its ePHI;**
  - **Allegedly did not implement technical security measure to guard against authorized access to ePHI over a network by ensuring that firewalls were in place; and**
  - **Allegedly provided access to the ePHI of patients whose information was on the workstation infection by malware.**

Privacy and Security Enforcement: Preparation is Key

- Executed Business Associate Agreements
- Policies and Procedures
- Training
- Risk Assessments
- Responsiveness

Privacy and Security Enforcement: Ransomware

- Combination of unwanted encryption and a demand for ransom for release
  - Fastest growing malware threat (estimated 4,000 attacks daily since early 2016)
  - Estimated $1 Billion in Losses in 2016 (per FBI)
- Attacks from websites, email attachments, software
- Not all ransomware is the same – some can extract data from affected computers
- A quick response is critical – have ransomware response plan and backups ready

Privacy and Security Enforcement: Ransomware

- **HHS Guidance on Ransomware (July 11, 2016)**
  - **Ransomware on a Covered Entity's or Business Associate's computer system is a security incident under the HIPAA Security Rule**
  - **Any encryption of PHI by ransomware is presumed to be a breach because PHI that was encrypted was acquired (i.e., unauthorized individuals took possession/control of information)**
    - **Control of data, even if it can't be viewed, is a disclosure**
    - **Must report unless there is a low probability that the PHI has been compromised based on –**
      - **Nature and extent of PHI involved**
      - **The unauthorized person to whom the disclosure was made**
      - **Whether the PHI was actually acquired or viewed**
      - **The extent to which the risk to the PHI has been mitigated**

Agenda

- [x] Recent Stark and AKBS Updates
- [x] Physician Contracting & Physician Compensation Issues
- [x] Physician/Hospital Relationships
- [x] Privacy and Security Enforcement
- [ ] Provider-Based Updates

Provider-Based Updates

- **Final Regulations came out 11/14/16**
- **Recap:**

  An off-campus provider-based department (OPBD) is an outpatient department of a hospital that is located off of the hospital's main campus and meets all of the provider-based requirements found in the regulations at 42 C.F.R. § 413.65. Historically, Medicare has paid hospitals for services delivered in OPBDs just as it reimburses hospitals for on-campus outpatient services, with no distinction in the payment rates for on- and off-campus services.

  Issue - concerns that OPBDs were paid as hospital sites even though they may do little to provide patient care that goes beyond that which is furnished by free-standing, non-hospital-based operations.

  "New" off-campus provider-based locations – locations that come into operation after November 2, 2015 are no longer to be paid the outpatient prospective payment system (OPPS) rates for services furnished beginning January 1, 2017.

  Exceptions: Specifically, OPPS will continue to be used to pay for services furnished: (i) in dedicated emergency departments; (ii) in *on-campus* provider-based departments (i.e., within 250 yards of the main hospital buildings); (iii) at, or within 250 yards of, remote hospital locations; and (iv) by an OPBD that billed for services provided as of November 2, 2015.

- **Why do we care? May impact decisions on (i) acquisition of physician practices; (ii) location of such practices; (iii) expansion of already acquired practices; and (iv) billing for services**

Provider-Based Updates

- **"Answers to Unanswered Questions"**
  - **How to pay for non-excepted locations – under the proposed rule, non-excepted OPBDs would not be paid under OPPS but instead would be paid "under the applicable payment system." Congress, however, did not identify what that applicable payment system would be, leaving this for CMS to address in its rule. Concern: What happens if there is no applicable payment system – parties don't get paid?**

    Solution: In response, CMS decided not to adopt the proposal. Instead, in the final rule CMS provided that payment for calendar year (CY) 2017 will be made to the physician or practitioner for his/her professional fee, and payment will be made to the OPBD for the facility fee (the technical component). Payment to the non-excepted OPBD will be at 50 percent of the OPPS rate, with some exceptions. Hospitals will be required to bill on a UB-04, the uniform billing form for hospitals, using a modifier "PN" to indicate a non-excepted item or service. CMS will apply a geographic adjustment factor to the site-specific technical component rates. CMS anticipates that it will continue the same payment mechanism for CY 2018 to allow time to develop a new system to be applied thereafter. Although the system being adopted in CY 2017 is meant to be a stop gap provision to allow CMS to consider what system it would like to put in place in the future, CMS provided no guidance on what that new future system would be.

Provider-Based Updates

- **Prohibition on relocation – Under the proposed rule, grandfathered facilities could not change location or they would lose provider-based status. Concern: What if a move is required for reasons outside the control of the hospital?**

  Solution: In the final rule, CMS adopted one modification to the proposed relocation bar, it will allow an exceptions process limited to extraordinary circumstances outside a hospital's control, such as natural disasters, significant seismic building code requirements or significant public health and public safety issues. CMS expects that these will be rare occurrences and stated that it will provide sub-regulatory guidance on the extraordinary circumstances process.

- **Service line expansions – Under the proposed rule, grandfathered facilities could not expand service lines or they would lose provider-based status (limited to 19 clinical families of hospital outpatient services).**

  Solution: CMS decided not to adopt this proposal to limit service line expansions. Therefore, an OPBD will receive payments under OPPS for all billed items and services, regardless whether it furnished them prior to the enactment of Section 603, as long as the OPBD remains excepted, i.e., meets the relocation and change of ownership requirements.

Agenda

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Any Questions?

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