Recent Legal Developments All Radiology Providers Should Know

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Disclosure

- None

Disclaimer

- These materials should not be considered legal advice
  - They are not intended to nor do they create an attorney-client relationship
    - The materials are general and may not apply to a particular individual legal or factual circumstance
      - Typical lawyer blah blah

Learning Outcomes

- Understand major changes to Stark Law and AKS and how those changes may impact radiology providers and suppliers.
- Understand new program initiatives that were recently made effective or will be going into effect soon (e.g., AUC program and Program Integrity Enhancements to the Provider Enrollment Process).
- Learn best practices for Cybersecurity in the Healthcare Industry.

Overview of Topics

1. Federal Stark Law
   - General Overview
   - Major Updates
2. Anti-Kickback Statute (AKS)
   - General Overview
   - Major Updates
3. Fraud and Abuse Compliance During COVID-19
4. Civil Monetary Penalties (CMP)
5. Appropriate Use Criteria (AUC) Program Requirements
6. Program Integrity Enhancements to the Provider Enrollment Process.
7. Prominent Cybersecurity Threats
8. Updates to Medicare Physician Fee Schedule (PFS)

Federal Stark Law

Federal Stark Law

The General Prohibition

- Physicians ***may not*** refer:
  - Medicare* patients
  - For certain specified "designated health services"
  - To an entity with which the "physician" or
  - An "immediate family member" has
  - A "financial relationship"
    - ***Unless an "exception" applies***
- Case law suggests that the Stark Law applies to Medicaid through application of the False Claims Act.

42 U.S. C. 1395nn; regulations at 42 CFR, Part 411, §§ 411.350 et seq.

Federal Stark Law: Key Terms

- **Designated Health Services (DHS) includes**:
  - Clinical laboratory services
  - Physical therapy services/occupational therapy services
  - Outpatient speech-language pathology services
  - **Radiology services, including MRI, CT, and ultrasound services**
  - **Radiation therapy services and supplies**
  - Durable medical equipment and supplies
  - Parental and enteral nutrients, equipment, and supplies
  - Prosthetics, orthotics, and prosthetic devices and supplies
  - Home health services
  - Outpatient prescription drugs
  - Inpatient and outpatient hospital services

Federal Stark Law: Key Terms

- **Designated Health Services (DHS)**
  - Radiology and certain other imaging services
  - Radiation therapy services and supplies
    - Defined by CPT/HCPCS Codes
    - Includes ***both*** professional & technical component (PC/TC)
    - **Does <u>not</u> include**:
      - X-ray, fluoroscopy, or ultrasound that require the insertion of a needle/catheter/probe/tube
      - Radiology procedures that are integral to the performance of a non-radiological procedure

Federal Stark Law: Key Terms

- "**Entity**" is defined as a person or entity that has performed a service billed as DHS or present a claim to Medicare for DHS.
- "**Physician**" and "**immediate family member**" are defined ***broadly***.

Physician "means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor, as defined in section 1861(r) of the Act. A physician and the professional corporation of which he or she is a sole owner are the same for purposes of this subpart."

Immediate Family Member "means husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild."

Federal Stark Law: Key Terms

- **"Financial Relationship"**
  - Includes direct/indirect ownership or ***compensation arrangements***
    - *Compensation arrangement*: "any arrangement involving ***remuneration***."
      - See § 411.354(c)
    - *Remuneration*: means any payment or other benefit made directly or indirectly, overtly, in cash or in kind ***except***:
      - The furnishing of items, devices, or supplies that are, in fact, used solely to collect, transport, process, or store specimens for the entity of furnishing the items, devices, or supplies or are used solely to order or communicate the results of tests or procedures for the entity
        - CMS recognized this exception in Advisory Opinion CMS-AO-2008-01
  - CMS Stark Overview: www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral

Federal Stark Law: Key Terms

- "**Referral**"
  - Does include the referral of both components (TC/PC) of a diagnostic imaging test
  - Does **not** include personally performed services (e.g., orthopedic surgeon who orders and reads x-ray film)
  - **Excludes** certain requests by radiologists and radiation oncologists (the "Radiologist Referral Exception")
    - Requests by a radiologist for diagnostic services when initiated from another physician and tests/services furnished by or under the supervision of the radiologist (group)

Federal Stark Law: Penalties

- **Statutory Penalties**:
  - For ***knowing*** or ***unknowing*** violations:
    - Denial of payment
    - Refund of amounts collected from beneficiary as a result of improper billing
  - For ***knowing*** violations, potentially:
    - Civil Money Penalties of $15,000 per item or service plus 2X the amount claimed
    - Civil Money Penalties of $100,000 for "Circumvention Schemes"
    - Exclusion
    - Potential False Claims Act Liability
      - Min. Penalty: $11,665; Max Penalty: $23,331 (per single false claim)
      - Damages Multiplier: 3X amount claimed
      - Attorney Fees

Federal Stark Law: Application

- **Does the Stark Law apply to radiologists**?
  - Am I a DHS entity?
    - As a result of the arrangement, does a referring physician receiving **something of value** from a DHS entity?
      - **Think broadly!**
- Common exceptions potentially applicable to common arrangements with radiologists:
  - In-Office Ancillary Services Exception
  - Non-Monetary Compensation Exception
  - Fair Market Value (FMV) Exception

Federal Stark Law: Exceptions

In-Office Ancillary Exception (IOASE) (42 CFR 411.355)

- Permits a physician practice to provide certain DHS (*e.g.*, diagnostic imaging services) referrals within their own practice.
- ***To rely on the IOASE, the practice must meet the definition of a "group practice" under the Stark Law***.
- To meet the IOASE, the following requirements must be met:
  - The DHS are personally performed by:
    - The referring physician;
    - A physician in the same group practice; or
    - An individual under the supervision of the referring physician or another physician in the same group practice;
  - The DHS are performed in the same centralized building in which the referring physician or members of the group practice regularly practice medicine; and
  - The DHS are billed by the physician performing or supervising the service or his/her group practice.

Federal Stark Law: Major Update

CMS's Stark Law Final Rule revised the rules regarding ***group practices*** and their distributions of ***profit shares***.

- CMS clarified that a group practice's "overall profits" means the profits derived from all DHS of any component of the group (if the group is composed of at least five physicians).
  - This requires group practices to first ***aggregate*** their DHS profits ***before*** making any profit-based payments (*i.e.*, profit share payments).
  - This effectively prohibits group practices from distributing DHS profits on a split-pool (*i.e.*, service-by-service) basis.
    - Should a group practice distribute profits on a split-pool basis, CMS will consider them not to be unified business, and thus fail to meet the applicable definition of "group practice."
- This update will go into effect on **January 1, 2022**.

Federal Stark Law: Major Update

CMS also revised the Stark Law rules pertaining to **productivity bonuses**

- CMS clarified productivity bonuses may continue to be paid to a group practice's physicians based on services ***personally performed*** or services "***incident to***" such personally performed services, so long as the bonus is not determined in a manner directly related to the volume or value of the physician's referrals.
  - Production bonuses paid to a physician, based on the physician's total patient encounters or RVUs will be deemed to ***not*** take into account the volume or value of the physician's referrals.
  - CMS also added a new rule that productivity bonuses will be deemed to not take into account the volume or value of a physician's referrals if the services are ***not*** DHS.
- The group practice updates will go into effect on **January 1, 2022**.
- ***Practices relying on the IOASE should ensure their internal policies comply with the new rules pertaining to profit shares and productivity bonuses***.

Federal Stark Law: Exceptions

Non-Monetary Compensation Exception (42 CFR 411.357(k))

- Allows a hospital or other DHS Entity
- To furnish something of value (no cash/cash equivalents)
  - (e.g., advertising, meals, entertainment, non-cash gifts such as tickets, pre-authorization assistance)
- To a referring physician up to an annual limit (updated annually)
  - 2017 - $398; 2018 - $407; 2019 - $416; 2020 - $423; 2021 - $429
- The Stark Law Final rule removed the prior condition that a compensation arrangement under this exception cannot violate the AKS.
  - Still cannot violate the AKS, but that analysis is now separated from the Stark analysis.

Federal Stark Law: Exceptions

- Inadvertent compensation provided in excess of the annual limit can be corrected if:
  - The value of excess compensation is not more than 50% of the limit; and
  - The physician returns the excess to the entity by the end of the calendar year or within 180 days following the date received, whichever is earlier.
  - The ability to pay back excess non-monetary compensation and remain in compliance with the exception may be used by a DHS entity only once every 3 years with respect to the same referring physician

Federal Stark Law: Exceptions

- **Applies only to non-monetary compensation provided to individual physicians**
  - (Phase I) (66 Fed. Reg. 920, 2001)
    - Can a gift to a group practice be considered a gift to each physician in the group practice / should full value be accounted for??
    - No mention in the regulation or preamble of "immediate family member"
  - Examples of non-monetary compensation: meals, tickets for sporting or entertainment events, transportation to events, golf, flowers congratulating a physician (*e.g.*, new office, birth of child, or birthday).
- **Does not apply to cash and cash equivalents**
  - Gift certificates and gift cards that are not redeemable for cash are not considered "cash equivalents"
  - Exception applies only to "items and services"

Federal Stark Law: Major Updates

New Exception for Limited Remuneration to a Physician

- CMS issued a new exception for certain arrangements, in which a physician receives limited remuneration ***for items or services actually provided by the physician***.
- Compensation under such an arrangement may not:
  - Exceed an aggregate of **$5,000** per calendar year (adjusted annually for inflation);
  - Take into consideration the volume or value of referrals by the physician; or
  - Exceed fair market value
- CMS clarified that the exception permits a physician to provide items/services through the physician's employees hired for such purposes (*e.g.*, locums tenens physicians).
- CMS clarified that arrangements under the exception ***must be commercially reasonable*** even if no referrals are made between the parties.
  - CMS also finalized a new definition of "commercially reasonable" under the Stark Law to mean an arrangement that furthers a legitimate business purpose of the parties and is sensible considering the characteristics of the parties (e.g., size, type, specialty).

Federal Stark Law: Exceptions

- **FMV Exception** (42 CFR 411.357(l))
  - This can apply when services or items are being exchanged between the physician/DHS entity
  - Per the Stark Law Final Rule, this exception now covers the lease of office space or equipment by a physician or group of physicians.
- Signed writing
- Specific timeframe
- Compensation set in advance, FMV, not related to referrals
- Can't violate Anti-Kickback Statute (AKS)
  - The Stark Final Rule removed language prohibiting an agreement under the exception from violating any Federal or State law/regulation re billing or claims submission.
    - Still must adhere to these laws, but this analysis is now separated from the Stark analysis.

Federal Stark Law: Major Updates

- CMS also created three new exceptions to the Stark Law for value-based arrangements (**VBAs**) in its Stark Law Final Rule.
  - VBAs with full financial risk;
  - VBAs with substantial or meaningful downside financial risk for the participating entity; and
  - Remuneration paid under a VBA.
- A ***VBA*** is an arrangement that provides at least one value-based activity (*i.e.*, an action or inaction designed to achieve a value-based purpose designed to meet the needs of a target patient population).
  - ***Value-based purposes*** include improving the quality of health care or reducing the costs of health care for a specific target population.
- Remuneration paid under VBAs must be commercially reasonable.

Federal Stark Law: New VBA Exceptions

- **Full Financial Risk VBA Exception**
  - Requires the value-based entity ("**VBE**") (*i.e.*, the collaborating participants in the VBA) to assume full financial risk for patient care services for the entire duration of the VBA.
  - Greatest amount of flexibility.
- **VBAs with Meaningful Downside Financial Risk Exception**
  - Requires the participating physician in a VBA to assume financial risk (at least 10% of the total value of the VBA's remuneration) for failure of achieving the value-based purposes of the VBA.
  - Provides a moderate level of flexibility.
- **Remuneration Paid Under a VBA Exception**
  - Acts as a catch-all to protect remuneration under VBAs not covered by the other exceptions.
  - Does not require any participant to take on financial risk.
  - Most stringent requirements, including signed writing requirements detailing the purpose of the VBA.

Federal Stark Law: Major Updates

Compensation for DHS from VBAs

- The Stark Law generally prohibits remuneration for DHS referrals, unless an exception applies.
- To spur innovation and adoption of VBAs, CMS revised the Stark Law to permit physicians to share in profits from their group practices that are directly attributable to the physician's participation in a VBE.
- CMS clarified that profits distributed directly to the physician under this new rule will be deemed to not take into account the volume or value of the physician's referrals.
    - Ex: A 100-physician group practice has two physician members which participate with a hospital as a VBE. The group practice may distribute profits derived from the VBE ***only*** to the two physicians that participated in the VBE.

ANTI-KICKBACK STATUTES (AKS)

Anti-Kickback Statute: Overview

- **Elements of the Prohibition**:
  - Knowing and willful
  - Solicitation, receipt or offer of payment
  - Of ***remuneration***
  - In return for referring a Federal program patient, or
  - To induce the purchasing, leasing, or arranging for or recommending or leasing items or services paid by a Federal program.
- **Applicability**: The AKS applies much more broadly than the Stark Law, it applies to everyone.

Anti-Kickback Statute: Key Definitions

- **Remuneration**
  - Anything of Value – Tangible or Intangible
  - A reduction or discount
  - Direct payment of cash or loans
  - Free items or services
- **Federal Program Business**
  - Medicare, Medicaid, TRICARE, Veterans Administration, etc.

Anti-Kickback Statute: Penalties

- AKS Penalties (42 USC § 1320a-7b(b); 42 CFR § 1003.102)
  - No more than 10 years in prison
  - No more than $100,000 criminal fine
  - $50,000 penalty
  - Exclusion from Medicare/Medicaid
- Anti-Kickback Violation = False Claims Act Violation (42 USC § 1320a-7a(a)(7))
  - Lower standard of proof
  - Subject to False Claims Act penalties
  - Subject to qui tam suit
- OIG Self-Disclosure Protocol
  - Minimum $50,000 Settlement

Anti-Kickback Statute: Exceptions/Safe Harbors

- ***11 Statutory Exceptions*** – Congress
  - "Because the law is broad on its face, concerns arose among health care providers that some relatively innocuous – and in some cases even beneficial – commercial arrangements are prohibited by the anti-kickback law. Responding to these concerns, Congress in 1987 authorized the Department to issue regulations designating specific 'safe harbors' for various payment and business practices that, while potentially prohibited by the law, would not be prosecuted."
- ***37 Regulatory Safe Harbors*** – OIG
  - No liability if all requirements of a safe harbor are satisfied
  - Not required to fit within safe harbor because ultimate question is whether "one purpose" of remuneration is to induce or reward referrals
  - The closer you come to satisfying the regulatory requirements, the safer you will be.

Anti-Kickback Statute: Safe Harbors

The Personal Service Safe Harbor (42 CFR § 1001.952(d))

- Protects certain arrangements in which one party performs services pursuant to an agreement with another party.
  - May be relied upon for arrangements which do ***not*** qualify as a bona fide employment relationship
- Only applies if ***all*** requirements of the safe harbor are satisfied.
- OIG updated the Personal Service Safe Harbor in its AKS Final Rule to revise certain requirements of the safe harbor and expand its applicability.

Anti-Kickback Statute: Major Updates

OIG Updates the Personal Service Safe Harbor

- The OIG revised the Personal Services Safe Harbor to no longer require the aggregate compensation under a personal service arrangement to be set in advance. Instead, the methodology for determining the compensation is all that must be included.
- The OIG also eliminated the prior requirement that a personal service arrangement on a periodic, sporadic, or part-time basis must specify the schedule, length and exact charge for such intervals.
- The OIG further revised the safe harbor to protect outcomes-based payment arrangements between a principal and an agent.
  - The safe harbor will now protect payments to an agent based on achieving an outcomes-based measurement which results in improvement to a patient's health or reduced costs to the patient.
  - Such arrangements ***must*** include a written description of the arrangement.
  - The parties ***must*** also periodically assess and revise (as necessary) all benchmarks to ensure it remains consistent with fair market value.

Anti-Kickback Statute: Major Updates

Revised Personal Service Safe Harbor Requirements:

- Signed, written agreement;
- Agreement covers (and specifies) all of the services the agent provides to the principal for the term of the agreement;
- The term of the agreement is for not less than one (1) year;
- The compensation methodology for remuneration paid under the agreement must be set out in advance;
- The services performed do not involve the counseling or promotion of a business arrangement; and
- The aggregate services contemplated by the agreement do not exceed those services which are reasonably necessary to accomplish the commercially reasonable business purpose of the agreements.

Anti-Kickback Statute: Major Updates

The Office of Inspector General ("**OIG**") issued two final rules concurrently with CMS' Stark Law Final Rule to update the AKS.

- The first rule (the "**AKS Final Rule**") provided the bulk of the updates to the AKS, including many similar updates as the Stark Law Final Rule.
  - The AKS Final Rule included three new safe harbors for VBAs, similar to the Stark Law Final Rule.
- The second rule (the "**PBM Final Rule**") was issued separately and amended the process by which prescription drug discounts and payments to pharmacy benefit managers ("**PBMs**") could be paid out.
  - The Biden Administration issued a Memo directing a 60-day regulatory freeze *(i.e.*, until March 22, 2021), aimed primarily at revisions under the PBM Final rule.
  - Subsequently a federal court issued an order to postpone the implementation of the PBM Final Rule's revisions of the Discount Safe Harbor until January 1, 2023, pending a review by the Biden Administration.
  - Certain other revisions under the PBM Final Rule went into effect on March 22, 2021.

Anti-Kickback Statute: Major Updates

New Safe Harbor for VBA with full financial risk

- VBE must assume full financial risk from a payor for a target patient population.
- Protects in-kind and monetary remuneration.
- More flexible requirements than the other VBA safe harbors

New Safe Harbor for VBA with substantial downside financial risk

- VBE must assume substantial downside financial risk, which includes one of the following:
  - 30% of any shared losses of the VBE,
  - A repayment obligation to the payor of at least 20% of total losses in more than one care setting, or
  - A partially capitated methodology on a per-patient payment to cover losses.
- Protects in-kind and monetary remuneration.
- Moderate level of flexibility

New Safe Harbor for Care Coordination

- Catch-all safe harbor for ***in-kind remuneration*** paid under a VBA not covered above.
- Lowest level of flexibility of the new VBAs as participants are not required to take on risk.
- Has additional requirements (*e.g.*, signed writing describing the VBA, monitoring outcomes).

Fraud and Abuse Compliance During COVID-19

Fraud and Abuse Compliance During COVID-19

CMS issues blanket waivers to the Stark Law

- Due to the burden that COVID-19 had placed on healthcare providers nationwide, CMS issued 18 blanket waivers to the Stark Law, available here.
- **The Stark Waivers only apply to financial relationships and referrals solely related to COVID-19**.
- The Stark Waivers increased regulatory flexibility and waived sanctions for certain actions that would otherwise trigger the Stark Law.
- Examples of Stark Waivers that may be applicable to arrangements with radiologists include:
  - rental charges
  - the purchase of items/services
  - certain compensation agreements
  - group practices for in-office ancillary services

Fraud and Abuse Compliance During COVID-19

OIG Issues Policy Statement re Application of Certain Administrative Enforcement Authorities and FAQ Guidance During re COVID-19

- On April 3, 2020 the OIG issued a Policy Statement regarding the application of its administrative enforcement authorities during the COVID-19 outbreak, available here.
  - The Policy Statement provided that the OIG would not impose administrative sanctions under the AKS with respect to remuneration covered by Stark Waivers #1-11.
  - Should an arrangement fall outside the types of remuneration covered by Stark Waivers #1-11, the OIG Policy Statement would not apply. The Provider would need to assess whether the arrangement complies with the AKS.
- In response to COVID-19, the OIG invited providers to submit inquiries regarding the application of OIG's administrative enforcement authorities during the pandemic.
- The OIG issued several FAQ responses, available at https://oig.hhs.gov/coronavirus/authorities-faq.asp
- The FAQ responses clarify whether certain arrangements that would otherwise violate the AKS and/or CMP present a low-level risk of fraud and abuse during the pandemic.
  - Note: the arrangements often have specific elements to be met to be deemed a low-level risk of fraud and abuse by OIG.

Fraud and Abuse Compliance During COVID-19

Hypothetical: A group practice meets the Stark Law definition of a "group practice." The group practice's patients would normally receive MRI services at the hospital but have been instructed not to go to the hospital due to COVID-19. The group practice would like to hire a radiologist to provide MRI services to their patients in a mobile van in the group practice's parking lot in order to ensure patients are receiving necessary care during the pandemic. Is this permissible?

- The Stark Law's In-Office Ancillary Services Exception (IOASE) requires physicians billing and providing imaging services in their office to perform the imaging services in certain required locations. A mobile van in a group practice's parking lot would not qualify for the IOASE.
- *Stark Waiver 15*: The referral by a physician in a group practice for medically necessary designated health services furnished by the group practice in a location that does not qualify as a "same building" or "centralized building" for purposes of 42 CFR 411.355(b)(2).
- *OIG Policy Statement re the Stark Waivers* – the OIG Policy Statement clarified that it would not impose administrative sanctions under the AKS with respect to remuneration covered by Stark Waivers #1-11.
    - The above arrangement is covered under Stark Waiver #15 and will not be covered by the OIG Policy Statement.

Civil Monetary Penalty (CMP)

Civil Monetary Penalty: Overview

- **General Prohibition on Beneficiary/Patient Inducement**
  - Prohibited
    - From offering or transferring remuneration
    - To any individual eligible for Medicare or Medicaid
    - Knows, or should know, is likely to influence the individual to order or receive any item or service for which payment may be made under Medicare or Medicaid

See **42 USC §1320a-7a**

Civil Monetary Penalties: Guidance

- OIG Special Advisory Bulletin on "Offering Gifts and Other Inducements to Beneficiaries"
  - Remuneration Does Not Include:
    - Gifts of nominal value are permitted
      - $15/$75 limits
    - Incentives tied to promote preventive care services are permitted (e.g., mammography screenings)
    - Non-routine, unadvertised waivers of copayments or deductible amounts are permitted
    - Financial hardships

Civil Monetary Penalties: Remuneration

- Remuneration Includes:
  - Waiver of coinsurance and deductible amounts
  - Transfers of items or services for free or for a value other than FMV
- Co-Pay Waiver
  - Marketer pays?
  - Waiving?
  - “Patient Assistance” programs?

Civil Monetary Penalties: Remuneration

Remuneration

- Does ***NOT*** Include:
  - Waiver of coinsurance and deductible amounts ***if***:
    - The waiver is not as part of any advertisement or solicitation; offered
    - The physician does not routinely waive coinsurance or deductible amounts; and
    - The physician waives coinsurance and deductible amounts after determining, in good faith, that the individual is in financial need or failure by the physician to collect coinsurance or deductible amounts after making reasonable collection efforts

Civil Monetary Penalties: Remuneration

Remuneration

- Does ***NOT*** Include:
  - Any practice permitted under the AKS safe harbors (e.g., discount)
  - Incentives given to individuals to promote the delivery of preventive care services
  - PPACA - any item or service "which promotes access to care and poses a low risk of harm to patients and Federal health care programs. . ."
    - Items or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by—
      - (i) Being unlikely to interfere with, or skew, clinical decision making;
      - (ii) Being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and
      - (iii) Not raising patient safety or quality-of-care concerns;
  - **OIG Example**: A provider incentivizes pediatric patients who have missed two or more preventive care appointments by: (1) contacting the patient's guardian by telephone; (2) notifying them of an opportunity to receive a $20 gift card to reschedule and attend the appointment; and (3) furnishing the gift card after checkout regardless of their insurance status or ability to pay for services.
    - ***OIG Adv. Opinion No. 20-06*** *– OIG found this would pose a low risk of harm and promote care*

APPROPRIATE USE CRITERIA (AUC)

Appropriate Criteria Use (AUC): Mandate

- As of January 1, 2020, a provider:
  - referring advanced diagnostic imaging to a Medicare beneficiary must consult AUC through a qualified Clinical Decision Support Mechanism (CDSM) and communicate this information to the provider or facility furnishing the advanced diagnostic imaging services.
  - furnishing advanced diagnostic imaging will be required to report the AUC consultation information when making Medicare claims.
- CY 2020-2021 are deemed Educational/Operations Testing Periods
  - There are no payment consequences associated with the AUC during CY 2020 or 2021.
  - **Full implementation of the AUC program will begin on January 1, 2022.**
- List of Qualified CDSMs - https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/Appropriate-Use-Criteria-Program/CDSM.html
- CMS AUC claims processing guidance – https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNMattersArticles/Downloads/MM10481.pdf

Appropriate Use Criteria: Consultation Assistance

- ***HHS specifically requires the ordering professional (physician),*** or the ordering physician's clinical staff, to consult AUC.
  - ***Clinical staff*** are defined as individuals that may perform care management services, such as: chronic care management, behavioral health integration, and transitional care management.
- ***Burdens*** of AUC Consultation.
  - ***Cost*** – The AUC consultation is not a billable service. Therefore, as the ordering physician (or his/her clinical staff) is required to complete the consultation, the ordering physician alone shall bore the costs of the consultation.
  - ***Time Consumption*** – The ordering physician (or his/her clinical staff) must spend time consulting AUC that could be used to perform other necessary tasks.

Appropriate Use Criteria: Consultation Assistance

- ***Furnishing professionals*** (e.g., radiology and imaging providers) may perform their own AUC consultation, however, this **will not** satisfy the AUC requirement.
- **Could a third-party (e.g., a furnishing professional) performing the consultation *for* the ordering physician implicate the AKS?**
  - By fulfilling the consultation, the third-party would relieve the ordering physician of the obligation to perform the consultation, resulting in remuneration.
- **Look to OIG pre-authorization assistance guidance**
  - OIG released four favorable opinions regarding preauthorization assistance (***OIG Advisory Opinions 10-4, 10-13, 10-20,*** and ***12-10***)
    - Each Advisory Opinion reviewed a proposed arrangement involving a radiology or imaging provider providing free pre-authorization services to referral sources.

PROGRAM INTEGRITY ENHANCEMENTS TO THE PROVIDER ENROLLMENT PROCESS

Program Integrity Enhancements: Overview

- In September 2019, CMS published the Final Rule regarding Program Integrity Enhancements to the Provider Enrollment Process.
  - The Final Rule became effective November 4, 2019.
- Important Updates
  - The Final Rules requires certain providers (*i.e.*, Medicare, Medicaid, and CHIP providers) to disclose certain current and previous affiliations with other providers/suppliers.
  - The Final Rule also expands CMS' authority to deny/revoke a provider's/supplier's Medicare enrollment in a number of circumstances.

Program Integrity Enhancements: Disclosure

- Providers and Suppliers submitting Form CMS-855 application must disclose whether it (or any of its owning/managing employees or organizations) currently has (or has had in the previous 5 years) an affiliation* with a currently or formerly enrolled Medicare/Medicaid/CHIP provider with any of the following disclosable events:
  - Currently has an uncollected debt to Medicare/Medicaid/CHIP
    - *Note*: it does not matter whether this debt is being repaid, the amount of the debt or whether it is being appealed
  - Has been or is currently subject to a payment suspension under a federal health care program
  - Has been, or is excluded by the OIG, from participation in Medicare/Medicaid/CHIP (regardless of appeal status)
  - Has had Medicare/Medicaid/CHIP enrollment denied, revoked, or terminated (regardless of appeal status).

*_Affiliation_ defined on next slide

Program Integrity Enhancements: Key Terms

- Affiliation is defined as:
  - Possessing a 5% or greater ownership interest (by an individual or entity) in another organization;
  - General/limited partnership interest (regardless of percentage);
  - Possessing managerial/operational control, or directly or indirectly controlling day-to-day operations of another organization (regardless of W-2 status of the managing individual/entity);
  - Acting as a director or officer of a corporation; or
  - Any reassignment relationship under § 424.80.

Program Integrity Enhancements: CMS Authority

Expansion of CMS' Authority

- The Final Rule permits CMS to revoke/deny Medicare enrollment if:
  - A provider/supplier circumvents program rules by coming back into the program, or attempting to come back in, under a different name;
  - A provider/supplier bills for services/items from non-compliant locations;
  - A provider/supplier exhibits a pattern or practice of abusive ordering or certifying of Medicare Part A or Part B items, services or drugs; or
  - A provider/supplier has an outstanding debt to CMS from an overpayment that was referred to the Treasury Department.
- CMS may also prevent applicants from enrolling in Medicare for up to 3 years if the provider/supplier is found to have submitted false or misleading information in its initial enrollment application.
  - CMS may also block providers/suppliers that have had their Medicare privileges revoked for up to 10 years (previously 3 years was the max) or for 20 years if the provider/supplier has their privileges revoked a second time.

Program Integrity Enhancements: CMS Authority

Expansion of CMS' Authority

- CMS may also revoke/deny Medicare enrollment if the provider or supplier fails to *fully and completely* disclose affiliations with a disclosable event or if CMS determinates any disclosed affiliations pose an undue risk of fraud, waste or abuse.
- Factors for CMS making such a determination include:
  - Duration and extent of affiliation;
  - Whether the affiliation still exists or how long ago it ended;
  - Degree and extent of the affiliation;
  - Reason for termination of the affiliation;
  - The type of disclosable event, when it occurred, and whether the affiliation existed at the time;
  - For uncollected debt--amount, whether it is being repaid, and to whom it is owed;
  - For denials, revocations, terminations, exclusions or payment suspension—the reason for the action; and
  - Any other evidence that the state, in consultation with CMS, deems relevant.

See 42 C.F.R. 424.519(f)

CYBERSECURITY

Cybersecurity: Breaches

- Breaches from Jan. 1, 2005 – Jan. 31, 2020 = 11,365
  - Resulting in 1,660,423,788 records exposed.
- U.S. breaches by year:
  - 2016 – 1,093 (377 breaches in Medical/Healthcare Industry)
  - 2017 – 1,632 (384 breaches in Medical/Healthcare Industry)
  - 2018 – 1,244 (363 breaches in Medical/Healthcare Industry)
  - 2019 – 1,473 (525 breaches in Medical/Healthcare Industry)
  - 2020 – 1,108 (450+ breaches in Medical/Healthcare Industry)
- The Medical/Healthcare Industry has the highest rate of exposure/breach

Source: Identity Theft Resource Center Data Breach Reports (https://www.idtheftcenter.org/data-breaches/)

Cybersecurity: Cost of a Breach

- Breaches in the healthcare industry are the most costly of any industry, at approximately $150/record.
- Breaches cost the U.S. healthcare industry approximately $8.64 million per breach in 2020.
  - This is approximately a 10% increase from the average cost in 2019 per breach.
  - *See* 2020 Cost of a Data Breach Study by IBM and Ponemon Institute (https://www.ibm.com/security/data-breach)
- Due to the high costs, providers must be diligent in determining potential HIPAA violations and data breaches.
- Take proactive steps to ensure sufficient policies are in place to guard against cybersecurity breaches – look to HHS' Cybersecurity Guidance.

Cybersecurity: HIPAA Problem

Data Breaches implicate the HIPAA Privacy Rule

- **Privacy Rule Definition**: A Breach is an impermissible use or disclosure compromising the security and/or privacy of protected health information (PHI).
- **Exception**: Not a breach if the covered entity or business associate can demonstrate that there is a ***low probability that the PHI has been compromised (LoProCo)***.
- **Factors to Consider to Determine if a Breach is LoProCo**:
  - The nature and extent of PHI involved (including types of identifiers involved and likelihood of re-identification);
  - The unauthorized person who used the PHI or who it was disclosed to;
  - Whether the PHI was actually viewed or acquired; and
  - The extent to which risk to the PHI has been mitigated.

Cybersecurity: HHS Guidance

- HHS issued guidance regarding cybersecurity practices for the healthcare industry to adopt to address this rising trend of breaches.
  - The Guidance includes quick tips and suggested practices to minimize cybersecurity threats.
  - See https://www.phe.gov/Preparedness/planning/405d/Documents/HICP-Main-508.pdf
- The Guidance identifies 5 key cybersecurity threats:
  - Email Phishing;
  - Ransomware;
  - Loss/theft of equipment/data;
  - Insider, accidental/intentional data loss; and
  - Attacks on connected medical devices

Cybersecurity: Best Practices

HHS' 10 Cybersecurity Practices to Adopt

1. Email protection systems;
2. Endpoint protection systems;
3. Access management;
4. Data protection/loss prevention;
5. Asset management
6. Network management;
7. Vulnerability management;
8. Incident response;
9. Medical device security; and
10. Cybersecurity policies.

UPDATES TO THE MEDICARE PHYSICIAN FEE SCHEDULE (PFS)

Medicare PFS: CY 2021 Updates

E/M coding updates (effective January 1, 2021)

- Align E/M coding/payment with certain changes recommended by CPT editorial panel for office/outpatient E/M visits.
- Updates will increase reimbursement for care-related E/M services significantly, which may potentially result in payment reductions of up to 9% for radiology services.
  - Could result in payment reductions to radiologists as high as $450M in a single year or more than $5.6B in as little as a decade.
  - This loss would be due to budget-neutrality requirements (*i.e.*, changes in policy do not impact the budget). As such, an increase in E/M payments will result in losses elsewhere

Medicare PFS: CY 2021 Updates

Expansion of Telehealth

- The CY 2021 PFS Final Rule has permanently added a number of the telehealth services to the Medicare telehealth list on a Category 1 basis.
  - CMS also adopted a new category of telehealth services – Category 3 – to serve as a temporary category for adding services to the Medicare list of telehealth services.

Supervision of Diagnostic Tests by NPPs

- CMS finalized its proposal to permit the following nonphysician practitioners ("**NPPs**") to supervise the performance of diagnostic tests in certain scenarios if the tests are within their scope of practice and permissible under state law:
  - Nurse Practitioners ("**NPs**"), Clinical Nurse Specialists ("**CNSs**"), Physician Assistants ("**PAs**"), Certified Nurse-Midwives ("**CNMs**"), and Certified Registered Nurse Anesthetists ("**CRNAs**")

THANK YOU!

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