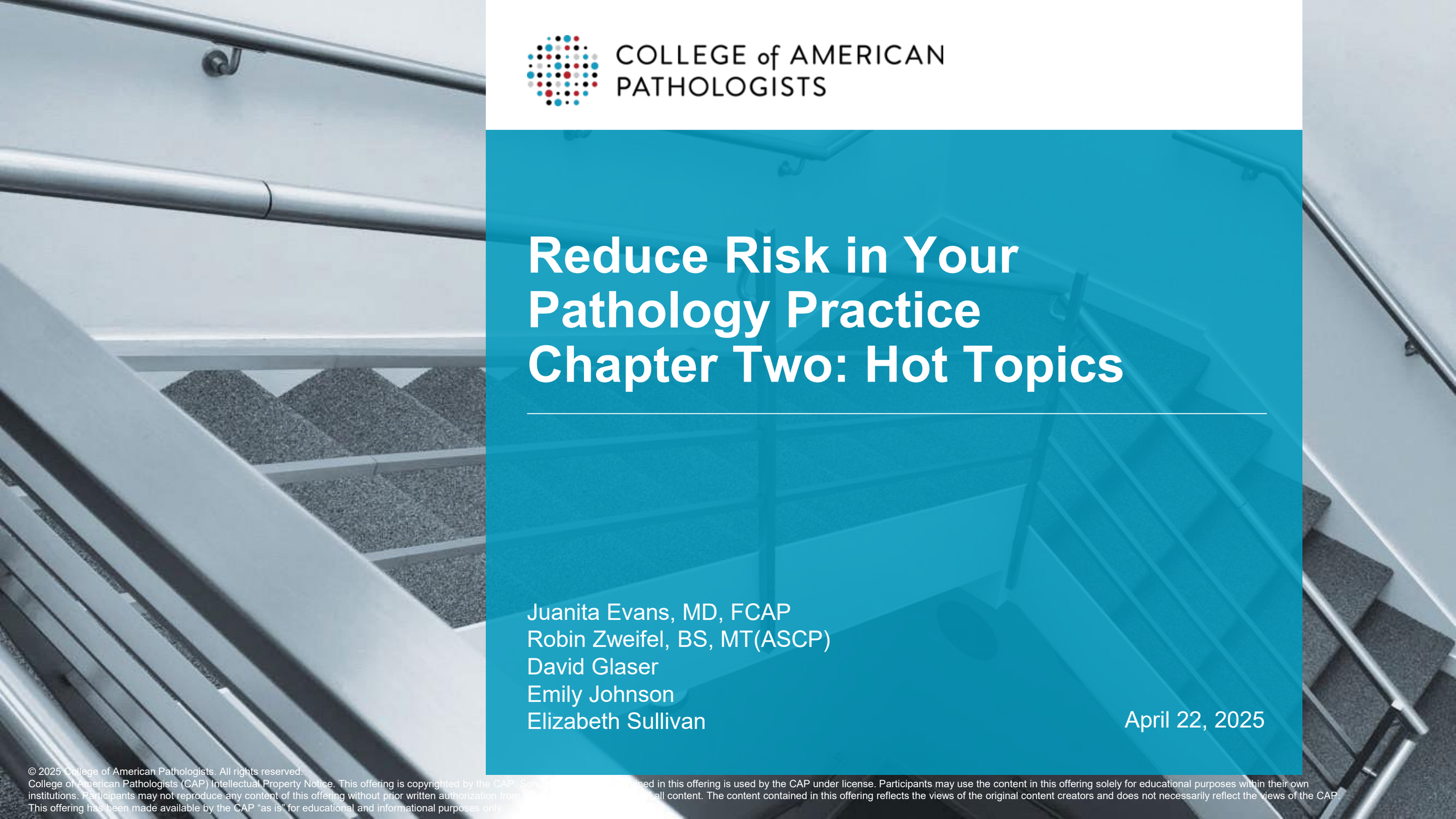

COLLEGE of AMERICAN PATHOLOGISTS

Reduce Risk in Your Pathology Practice Chapter Two: Hot Topics

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Disclaimer

The information presented today represents the opinions of the panelists and does not represent the opinion or position of the CAP.

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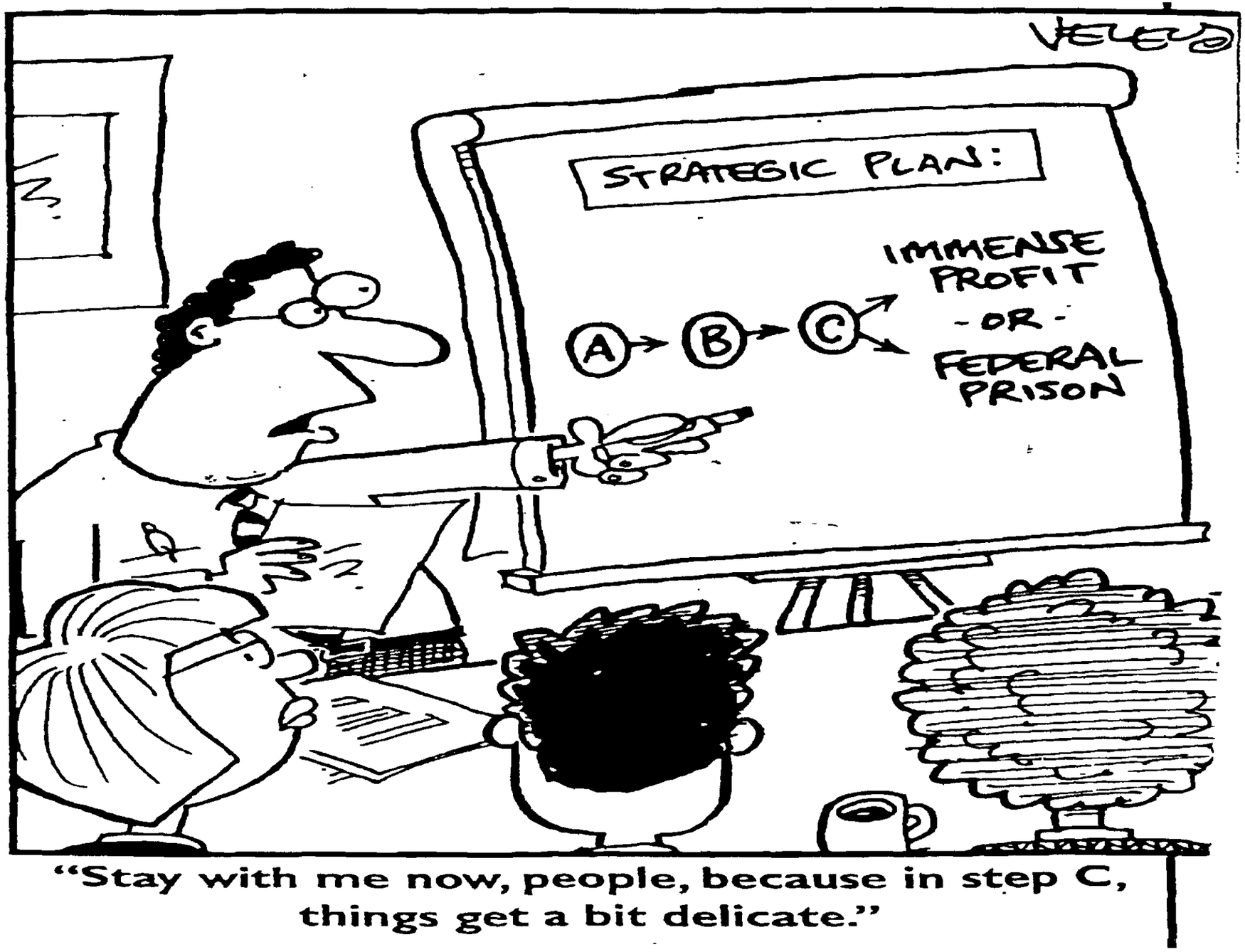
Hot Topics

- Billing Considerations
- TC/PC Arrangement Considerations
- EKRA
- Medicare 60-day Rule/ Reverse False Claims

Billing Considerations



"Stay with me now, people, because in step C, things get a bit delicate."

Can I Have Different Fee Schedules for Lab Services? Can I Charge a Referring Physician Less Than the Medicare Fee Schedule?

- Medicare U&C issues
- Compare advisory opinion 99-13 and 98-8
- 99-13 pathology concluding that discounts may implicate the antikickback statute
- 98-8 involves DME and permits discounts to reflect lower costs
- Is profit margin the proper analysis?

Medicare U & C

- Medicare pays the lower of:
  - Actual charge
  - Fee schedule amounts
  - Usual and customary charge
- Usual and customary charge is defined as your median (50th percentile) charge. Medicare Claims Processing Manual, Ch. 23, §80.3.1

42 CFR § 405.503(b)

- This regulation defines “customary charges” as “the uniform amount which the individual physician or other person charges in the majority of cases for a specific medical procedure or service.”

Actual Charges May Vary

If the individual physician or other person varies his charges for a specific medical procedure or service, so that no one amount is charged in the majority of cases, it will be necessary for the carrier to exercise judgment in the establishment of a “customary charge” for such physician or other person. In making this judgment, an important guide, to be utilized when a sufficient volume of data on the physician's or other person's charges is available, would be the median or midpoint of his charges, excluding token and substandard charges as well as exceptional charges on the high side. A significant clustering of charges in the vicinity of the median amount might indicate that a point of such clustering should be taken as the physician's or other person's “customary” charge. Use of relative value scales will help in arriving at a decision in such instances.

Final Antimarkup Rule

… If a physician or other supplier bills for the technical component (TC) or a professional component (PC) of a diagnostic test that was ordered by the physician or other supplier (or ordered by a party related to such a position or other supplier through common ownership or control …) and the diagnostic test is performed by a physician who does not share a practice with the billing physician or other supplier, the payment to the billing physician or other supplier … for the TC or PC of the diagnostic test may not exceed the performing supplier's net charge to the billing physician or other supplier. …

Shares a Practice: 75% Option

A performing physician shares a practice with the billing physician or other supplier if he or she furnishes substantially all (which, for purposes of this section means “at least 75%”) of his or her professional services through such billing physician or other supplier. The “substantially all” requirement will be satisfied if, at the time the billing physician or other supplier submits a claim for a service furnished by the performing physician, the billing physician or other supplier has a reasonable belief that:

- For the 12 months prior to and including the month in which the service was performed, the performing physician furnished substantially all of his or her professional services through the billing physician or supplier; or
- The performing physician will furnish substantially all of his or her professional services through the billing physician or other supplier for the next 12 months (including the month in which the service is performed).

Shares a Practice: Geography

A physician will be deemed to share a practice with the billing physician or other supplier with respect to the performance of the TC or the PC of a diagnostic test if the physician is an owner, employee or independent contractor of the billing physician or other supplier AND the TC or PC is performed in the office of the billing physician or other supplier.

Shares a Practice: Geography

The “office of the billing physician or other supplier” is any medical office space, regardless of the number of locations in which the ordering physician or other ordering supplier regularly furnishes patient care, and includes space where the billing physician or other supplier furnishes diagnostic testing, if the space is located in the same building (as defined in Stark) in which the ordering physician …

or other ordering supplier regularly furnishes patient care. With respect to a billing physician or other supplier that is a physician organization (as defined in Stark), the “office of the billing physician or other supplier” is space in which the ordering physician provides substantially the full range of patient care services that the ordering physician provides generally. The performance of the TC includes both the conducting of the TC as well as the supervision of the TC.

Things to Note

It applies to both the professional and technical component.

It only applies if the physician who orders the test/read is billing for the test/read.

It only applies to physicians and suppliers, i.e., Part B.

This is only a Medicare rule.

Has CMS Overstepped its Authority?

CMS Claims Authority

"Further, we see no reason to distinguish between the TC and the PC of the diagnostic tests for purposes of the anti-markup provisions. Although the Congress did not establish an anti-markup provision in Section 1842(n)(1) of the Act or elsewhere for the PC of diagnostic tests, the omission may have been inadvertent. That is, it is not immediately clear why the Congress, if it wished to prevent overutilization of diagnostic testing, would not have desired …

an anti-markup on the PC, because without such provision, the incentive to order unnecessary tests (in profit on the PC) remains. We believe that, in order to fully effectuate Congress' intent to prevent or limit the ordering of unnecessary diagnostic tests, it is necessary to impose an anti-markup provision on the PC of diagnostic tests.

72 FR 66315

The Antimarkup Statute 1842(n)

If a physician's bill or a request for payment for services billed by a physician includes a charge for a diagnostic test described in section 1861(s)(3) (other than a clinical diagnostic laboratory test) for which the bill or request for payment does not indicate that the billing physician personally performed or supervised the performance of the test or that another physician with whom the physician who shares a practice personally performed or supervised the performance of the test, the amount payable with respect to the test shall be determined as follows:

Interpretations Are NOT Diagnostic Tests under 1861(s)(3)

Medical and Other Health Services

- (s) The term “medical and other health services” means any of the following items or services:
  - (1) physicians' services;
  - (2)(A) services and supplies (including drugs and biologicals which are not usually self-administered by the patient) furnished as an incident to a physician's professional service…;

Interpretations Are NOT Diagnostic Tests under 1861(s)(3), (cont'd)

Medical and Other Health Services

- (3) diagnostic X-ray tests (including tests under the supervision of a physician, furnished in a place of residence used as the patient's home, if the performance of such tests meets such conditions relating to health and safety as the Secretary may find necessary and including diagnostic mammography if conducted by a facility that has a certificate (or provisional certificate) issued under section 354 of the Public Health Service Act[407]), diagnostic laboratory tests, and other diagnostic tests;

The Antimarkup Statute 1842(n)

If a physician's bill or a request for payment for services billed by a physician includes a charge for a diagnostic test described in section 1861(s)(3) (other than a clinical diagnostic laboratory test) for which the bill or request for payment does not indicate that the billing physician personally performed or supervised the performance of the test or that another physician with whom the physician who shares a practice personally performed or supervised the performance of the test, the amount payable with respect to the test shall be determined as follows:

Supervision of Diagnostic Tests

Medicare has three levels of supervision:

- Personal
- Direct
- General

Each year the fee schedule lists the required level of supervision.

Supervision of Diagnostic Tests

Personal supervision means a physician must be in attendance in the room during the performance of the procedure.

Direct supervision in the office setting means the physician must be present in the office suite and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician must be present in the room when the procedure is performed. Through December 31, 2025, the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only).

Supervision of Diagnostic Tests

General supervision means the procedure is furnished under the physician's overall direction and control, but the physician's presence is not required during the performance of the procedure. Under general supervision, the training of the non-physician personnel who actually perform the diagnostic procedure and the maintenance of the necessary equipment and supplies are the continuing responsibility of the physician.
42 CFR §410.32

What Does It Mean to Provide “General” Supervision?

- Who would the tech ask?
- When multiple groups are involved, beware
- Leased techs merit extra attention

TC/PC Arrangements

TC/PC Arrangements - Background

- Referring physician practices (for example, urologists, gastroenterologists, dermatologists, hematologists, oncologists) interested in establishing an in-house AP lab
- The laboratory may be a technical component laboratory and/or professional pathology services moved in-house
- Referring practices typically need the assistance of pathology groups in order to perform such services

TC/PC Arrangements – Stark Exceptions

- Physicians in a referring practice are permitted to refer DHS internally if exception applies. Most relevant exceptions:
  - Group Practice
  - In-Office Ancillary Services (IOAS)
  - Personal Services
  - Employee

- Exceptions are highly technical, and all elements must be met

- Pathology groups cannot separately confirm a referring group's compliance, but pathology groups should make reasonable inquiry into a referring group's compliance

TC/PC Arrangements – Stark Exceptions

- Failure to comply with Stark law can result in:
  - Repayment payment for all services performed pursuant to the arrangement
  - Additional monetary penalties
  - Exclusion of the group and the individual physicians from the Medicare and Medicaid programs
  - False Claims Act liability
  - In addition, violations of Stark may also give rise to AKS violations or violations of state law

TC/PC Arrangements – Group Practice Exception

- Two or more physicians that are members of the group
- Each member furnishes substantially the full range of services through joint use of space/equipment/personnel
- No physician member's compensation is based on the volume or value of referrals (except as permitted – productivity bonus)
- Members of the group conduct at least 75% of the patient encounters

TC/PC Arrangements – IOAS Exception

- Referring group must meet the definition of a “group practice”
- Services furnished by referring physician, physician considered to be member of the group, individual appropriately supervised by the group
- Furnished either in the “same building” as, or a “centralized building” of, the referring group
- Billed by performing/supervising physician or group

TC/PC Arrangements – Physician Services Exception

- Set out in writing, signed by the parties, and specifies the services covered by the arrangement
- Covers all of the services to be furnished by the physician (or an immediate family member of the physician) to the entity
- Aggregate services contracted for do not exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement
- The term of each arrangement is for at least one year
- Compensation to be paid over the term of each arrangement is set in advance, does not exceed fair market value, and is not determined in a manner that takes into account the volume or value of any referrals or other business generated between the parties
- Services to be furnished under each arrangement do not involve the counseling or promotion of a business arrangement or other activity that violates any State or Federal law

TC/PC Arrangements – Member of the Group versus Physician in the Group

- *Members of the Group*
  - Owners
  - Employees

- *Physician in the Group Practice*
  - Any member
  - Independent contractors during the time the physician is furnishing patient care under a contract and in the facility

TC/PC Arrangements – Additional Considerations

- Pathologists must be credentialed under the group's payor contracts, Medicare, and Medicaid group numbers
- Individual pathologists must sign the services agreement for Stark purposes
- Certain state laws require the pathologist to be employed by billing group (state direct bill laws)
- Malpractice coverage should be borne by the referring group
- Cost of equipment/overhead should be borne by the referring group

TC/PC Arrangements – Consulting Services for Lab

- Providing assistance to a referring group to set up or managing its lab or path services and/or serving as CLIA Laboratory Director
- Consulting services by a pathologist to the referring group:
  - Services should be compensated
  - Comply with the Stark personal services exception or the Stark exception for fair market value (FMV) compensation;
  - Comply with the safe harbor under AKS for personal services contracts; and
  - The referring practice must be responsible for its supervision obligations under IOAS

TC/PC Arrangements – Purchased Testing

- On September 25, 2023, the Office of Inspector General (OIG) issued Advisory Opinion No. 23-06 (AO 23-06)
- AO 23-06 evaluates a proposed arrangement between laboratories for the purchase of the technical component (TC) of anatomic pathology (AP)
- A full-service AP laboratory was approached by its clients to purchase TC services from such clients' laboratories in instances in which the client was having difficulty obtaining reimbursement
- The OIG arrived at an unfavorable determination, finding that the arrangement could generate prohibited remuneration under the federal Anti-Kickback Statute and could create grounds for the imposition of sanctions
- In the discussion of the arrangement, the OIG noted that these types of arrangements offer value to the client laboratories that are in a position to direct both commercial and federal work to the AP laboratory because the arrangement offers the client laboratories an opportunity to monetize the TC when such laboratories would otherwise be unable to do so pursuant to its own payor agreements
- As support for its ultimate conclusion, the OIG highlighted the fact that the proposed arrangement would allow the AP laboratory to give the client laboratories the opportunity to bill and receive payment for TC services they otherwise would not be able to bill for as in-network providers
- Purchased service arrangements have been scrutinized for years, even though purchased service arrangements continue to exist
- AO 23-06 is a call to re-evaluate existing purchased service arrangements to determine if and how such arrangements can be distinguished from the contemplated arrangements described in AO 23-06

TC/PC Arrangements - Additional Considerations

- Is the lab/pathology group allowing outstanding A/R to pile up?
  - This could implicate Stark, AKS, etc.
- Groups approaching pathology groups to access the pathology group's payor agreements
- Is a group permitted to bill for purchased services under its payor agreements?

Where to find more info?

CMS Resources (Stark)

- General Stark Info Page – https://www.cms.gov/medicare/regulations-guidance/physician-self-referral
- Advisory Opinions - https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/advisory_opinions.html
- FAQs - https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/FAQs.html

OIG Resources (AKS, CMP, FCA, Exclusion, Stark)

- Advisory Opinions - https://oig.hhs.gov/compliance/advisory-opinions/index.asp
- Physician Education – https://oig.hhs.gov/compliance/physician-education/intro.asp
- Special Fraud Alerts, Bulletins, Other Guidance - https://oig.hhs.gov/compliance/alerts/index.asp

Don't forget your state laws and the state where arrangement would take place

EKRA

EKRA

- *Eliminating Kickbacks in Recovery Act of 2018 (EKRA)*
  - Effective October 24, 2018
  - Passed as a part of the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act)
  - Intended to address America's opioid epidemic
  - Applies to recovery homes, clinical treatment facilities, and laboratories
  - Prohibits solicitation, receipt, payment, or offer of remuneration to induce patient referrals
  - Extends to services covered by both government and private payors
  - Essentially expands prohibited conduct that would be an AKS violation if a government payor were involved to services paid for by ANY payor

EKRA, (cont'd)

- Eliminating Kickbacks in Recovery Act of 2018 (EKRA)
  - Applies to recovery homes, clinical treatment facilities, and laboratories
  - Prohibits solicitation, receipt, payment, or offer of remuneration to induce patient referrals
  - Extends to services covered by both government and private payors
  - EKRA uses the CLIA definition of "laboratories", so it applies to all laboratories, not just those performing toxicology services, and enforcement actions have included COVID testing

Penalties

Under EKRA

- Fined not more than $200k/offense; and/or
- Imprisoned not more than 10 years

Other possible implications:

- Loss of payor contracts
- Potential exclusion

Preemption

- EKRA does not apply to conduct:
  - prohibited under AKS
  - prohibited by state laws on the same subject matter
- Unclear how to reconcile conduct that meets an AKS safe-harbor, but does not meet an EKRA exception
- No legislative history because added to SUPPORT Act so late

EKRA Updates

Updates

- No clarifying regulations as of today
- Current industry trends
- ***S&G Labs Hawaii, LLC v Graves***
  - Federal court case
  - Interesting case/data point
  - Continue to hope that this will spur the government to provide clarification

EKRA Updates (cont'd)

U.S. v. Mark Schena (N.D. Cal.)

- Criminal case, unlike S&G Labs, which was a civil contract dispute
- Department of Justice (DOJ) enforcement action
- Owner of Arrayit, a lab company offering allergy testing
  - Charged with health care fraud, wire fraud, and EKRA
  - Indictment includes EKRA violations based on payment for referral in April 2020
  - During the case, Schena's team filed a motion to dismiss EKRA based on S&G Labs case (Hawaii case)
  - The DOJ disagreed and pushed back arguing that the reasoning of the S&G Labs case was incorrect
  - Schena attempted to argue that EKRA did not apply because the marketers worked with physicians and not patients directly.
  - Court did not agree with this proposition, instead finding that the act of marketing is an inducement to refer an individual and can violate EKRA when such marketers are paid on a per specimen, per person, or percentage of reimbursement

Future

- Professional associations and stakeholders are advocating for clarification
- Unclear whether the government will address
- Affected providers should continue to monitor

60 Day Rule

The 60 Day Rule

- Providers have an obligation to refund any reimbursements received from federal healthcare programs to which they are not entitled
- Failing to return an overpayment can be a False Claims Act violation (“Reverse False Claim”)
- 42 C.F.R. § 401.305 sets out the requirements for the timeline for investigation and repayment of an overpayment

The 60 Day Rule

- Credible information of a potential overpayment –
  - MAC or contractor determination of an overpayment
  - Billing company identifying overpayment
  - Regular internal compliance monitoring and auditing
  - Reconciliation of billed claims
- No minimum threshold; preamble states: “After finding a single overpaid claim, we believe it is appropriate to inquire further to determine whether there are more overpayments on the same issue before reporting and returning the single overpaid claim.”
- 180 days to allow for investigation of the potential overpayment
- 60 days from identification of an overpayment

The 60 Day Rule - Responding

- Involve counsel early to establish attorney-client privilege and maintain confidentiality as long as possible
- Engage third party independent experts to provide opinion regarding investigation, billing/coding practices, statistical extrapolations (if applicable)
- Document, document, document!
  - The entire process should be documented, from investigation, to corrective action, to future monitoring for compliance

The 60 Day Rule, (cont'd)

Refund processes:

- MAC voluntary refund process
- Claims adjustments
- Credit balances
- Voluntary offset
- OIG Self Disclosure Protocol
- CMS Self-Referral Disclosure Protocol

Additional Resources

Practice Management Webpage

- https://www.cap.org/member-resources/practice-management

Previous and Upcoming Roundtables/Webinars

- https://www.cap.org/calendar/webinars/listing/practice-management-webinar

Articles Authored by Members of the CAP Practice Management Committee

- https://www.cap.org/member-resources/articles/category/practice-management

Practice Management Networking Community

- https://www.cap.org/member-resources/practice-management/practice-management-networking-community-application

Practice Management Frequently Asked Questions

- https://www.cap.org/member-resources/practice-management/frequently-asked-questions

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