2024 ACR-RBMA Practice Leadership Forum

Known Unknowns: Compliance Mistakes Too Many Groups Make

Saturday, January 20 | Phoenix

American College of Radiology™
Radiology Leadership Institute

RBMA
Radiology Business Management Association

Faculty

W. Kenneth Davis, Jr.

Barbara F. Rubel, MBA, FRBMA

2024 ACR-RBMA Practice Leadership Forum

Known Unknowns: Compliance Mistakes Too Many Groups Make

Saturday, January 20 | Phoenix

American College of Radiology™
Radiology Leadership Institute

RBMA
Radiology Business Management Association

Disclosures

- Nothing to Disclose

Objectives

- Recognize & understand some of the most common compliance requirements radiology groups know about but do not necessarily know whether they are compliant with
  - Including recent & upcoming changes in compliance & regulatory requirements
- Understand how groups have met old, & are meeting new, regulatory challenges
- Determine if they have made a compliance mistake, how to fix it going forward, as well as for services furnished before the mistake was corrected
  - Evaluate if there is a 60-day repayment obligation &/or what type of self-disclosure to make

Ordering Test Rules

- According to the physician conditions of participation in 42 CFR 410.32, all diagnostic tests must be ordered by the treating physician
- Along with the office-based labs, radiologists may want to claim they are the treating physicians because they are doing drainages
- How do you define treating physicians for your interventional radiologists on an ongoing basis?
  - Remember Stark compliance implications
- If a test is electronically ordered, the order needs to say, “electronically signed by . . .,” otherwise, not a valid order
- Imaging center needs to maintain a signature log if you get unrecognizable signatures
  - Note the program integrity manual does not require this

Supervision of Diagnostic Tests

- According to 42 C.F.R. § 410.33(b):
  - (1) Each supervising physician must be limited to providing general supervision to no more than three IDTF sites. This applies to both fixed sites and mobile units where three concurrent operations are capable of performing tests
    - (1) No limitations on number of direct/personal supervision locations, and why this makes sense
  - (2) The supervising physician must evidence proficiency in the performance and interpretation of each type of diagnostic procedure performed by the IDTF
- What does "proficiency in the performance and interpretation" mean?
  - Check the Medicare Administrative Contractor ("MAC") with jurisdiction: many (all?) have issued Local Coverage Determinations ("LCDs") on the issue
  - It can vary from MAC to MAC

Supervision of Diagnostic Tests (cont'd)

- Categories of Supervision:
  - General, direct, or personal. 42 C.F.R. § 410.32(b)(3)
  - Direct requires "in the same suite"
    - What does that mean?
- Non-physician practitioners:
  - On the one hand, supervision can be provided, ". . . to the extent that they are authorized to do so under their scope of practice and applicable State law, by a nurse practitioner, clinical nurse specialist, physician assistant, certified registered nurse anesthetist, or a certified nurse-midwife ['NPPs']." 42 C.F.R. § 410.32(b)(1)
  - On the other hand, because of the proficiency requirement that is unique to IDTFs, the safest position is that NPPs cannot provide supervision in an IDTF

Supervision of Diagnostic Tests (cont'd)

- How Can Supervision be Furnished?
  - As to direct supervision: [until December 31, 2024], "the presence of the physician (or other practitioner) includes virtual presence through audio/video real-time communications technology (excluding audio-only)." 42 C.F.R. § 410.32(b)(3)(ii)
  - One could argue that, because Medicare did not explicitly revise the supervising physician provisions found in 42 C.F.R. § 410.33 (for IDTFs), then the revision to the definition of direct supervision in § 410.32 does not apply specifically to IDTFs
    - Remember that Medicare's policy behind making the revisions (when they did so during the COVID-related public health emergency) only related to allowing for social distancing
  - Note: Medicare is apparently still considering whether to make the ability to use virtual supervision permanent

Jurisdiction: Medicare Billing

- Medicare Part B requires that a service be processed & paid in the payment locality where the service was provided
  - Some states have multiple payment locality
- It is critical to know where the provider is located when the interpretation is rendered
  - So, the claim can be sent to the correct MAC that has jurisdiction over the geographic area where the service was rendered

Jurisdiction: Medicare Billing

- The site of service for jurisdiction billing purposes is where the interpreting physician is sitting when s/he provides the professional interpretation
  - Capture work-station ID
- Determine the correct MAC:
  - Must submit for same payment locality, not merely to the same MAC
  - Same zip code is same payment locality
  - Depending on the interpreting physician's site of service, true "global billing" may simply be impossible (although billing under reassignment to a different MAC would still be OK as a reimbursement matter)
- Interpreting physician & group must be credentialed with the MACs who have jurisdiction over the respective geographic areas
  - Physician must also be licensed in those states

Place of Service ("POS") Rules

- For coding purposes, usually the POS for the professional interpretation should be coded based on where the interpreting physician is sitting when s/he provides the professional interpretation
- However, Medicare has indicated that:

> "Where the face-to-face requirement isn't needed, like when a physician or other provider provides the PC interpretation of a diagnostic test from a distant site, the POS code the physician or other provider uses will be the setting in which the patient got the TC [technical component] of the service. For example, a patient gets an MRI at an outpatient hospital near their home. The hospital submits a claim that would correspond to the TC portion of the MRI. The physician supplies the PC portion of the patient's MRI from their office location. So, the physician's claim uses POS code 22 for the PC to show that the patient had the face-to-face portion of the MRI, the TC, at the outpatient hospital. IDTFs should review CR 7631 to use the correct POS code when billing for services."

- NOTE: the POS (for coding purposes) can be different than the site of service for purposes of determining MAC billing jurisdiction

PTAN

- Use the correct provider transaction access number ("PTAN"):
  - Sometimes, a non-radiologist physician owner of an imaging center will try to bill for the professional services using her/his PTAN
  - However, if a radiologist provided the service, must bill using her/his PTAN

Medicare's Anti-Markup Rule

- What the rule says, & the supporting policy
- When does its applicability come up?
- Key issue: does the interpreting physician "share a practice" with the billing physician or other supplier?
  - Site of service test
  - Substantially all test
- Under the most common of circumstances, the interpreting physician usually does NOT "share a practice," therefore, the rule applies

Medicare's Anti-Markup Rule (cont'd)

- Alternatives for billing Medicare if the rule applies:
  - Radiology group can always separately bill for the professional interpretation
  - Utilize a compensation formula derived from the Medicare Physician Fee Schedule ("MPFS") split for the PC *versus* the TC
    - Why does this work?
  - Pay the radiology group the full MPFS PC amount (with NO deductions), regardless of the amount the group is paid for non-governmental patients
    - NOTE: there is a risk with this approach
- And what if the radiology group knows or has reason to believe that the billing physician or supplier is violating the rule?

Addendums, Amendments and Corrections to Radiology Reports

- Based on guidance issued by Medicare & interpretations by various MACs (all suppliers, like radiologists, radiology groups & IDTFs, are expected to follow), it is **not** permissible to amend, correct, or add to (through an addendum) a radiology report for the purpose of claiming higher reimbursement
  - Some radiology groups have a misconception of the significance of this prohibition and the risks
- More generally, Medicare states that all medical record documentation should be completed at the time the patient is seen

Addendums, Amendments and Corrections to Radiology Reports (cont'd)

- Medicare does recognize that in limited cases a medical record might not have been properly completed, & the documentation needs to be amended, corrected, or entered after rendering the service, subject to satisfying certain requirements Medicare has specified
  - Should be infrequent & not common practice
  - Information should only be added in rare instances to provide information that may not be available at the time the patient was seen or to correct previously documented information
- How this could be encountered for interpretations?
- And is the risk of audit worth it?

Stark

- Prohibited activity:
  - “If a physician (or an immediate family member of such physician) has a financial relationship with an entity . . . then the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made” under Medicare (and to some extent Medicaid) unless an exception applies
- Most common sources of compliance problems in radiology:
  - Referrals by immediate family members
  - Sub-FMV compensation from referring physicians
  - Excessive non-monetary compensation to referring physicians

Registered Radiologist Assistant (RRA)/Radiology Practitioner Assistant (RPA)

- Effective 1.1.2019, diagnostic tests requiring personal physician supervision may be performed under direct physician supervision when furnished by:
  - RRA who is certified & registered by the American Registry of Radiologic Technologists, or
  - RPA who is certified by the Certification Board for Radiology Practitioner Assistants
- *As permitted by state law & state scope of practice regulations*

RRAs/RPAs

- RRAs & RPAs are recognized under Medicare to perform imaging services under the direct supervision of a radiologist
  - Radiology practices who employ RAs cannot bill Medicare directly for their services
    - They are not recognized as providers of care entitled to separate Part B reimbursement

RRAs/RPAs: OP & IP Hospital Setting

- Diagnostic Imaging Tests (70,000 series CPT® codes)
  - RA services are billed under the hospital's TC which is paid under HOPPS for OP services & DRGs for IP services
  - Physician bills MPFS Part B for the interpretation of the diagnostic tests
- Procedures (10,000-69,999 series CPT® codes)
  - If RA performs, e.g. thoracentesis or liver biopsy, radiologist must touch the patient in order to bill for/claim the service
  - "Incident to" rules do not apply in the hospital setting

RRAs/RPAs: Freestanding Center

- Diagnostic Imaging Tests (70,000 series CPT® codes):
  - If RA is employed by the radiologist, RA performs the test, radiologist performs the interpretation: physician may bill globally
    - EX: Barium swallow, upper GI (diagnostic tests) performed by the RA
- Procedures (10,000-69,999 series CPT® codes):
  - If RA is employed by the radiologist AND physician is “hands on” OR if incident to rules apply, then radiologist may bill
    - EX: Radiologist does a consult for a vascular procedure, an attending physician relationship has been established, & the radiologist is on the premises
      - RA can perform the procedure & the radiologist may bill

RRAs/RPAs: Challenges

- The challenge most radiologists have with the “incident to” rules:
  - Radiologists typically do not have continuing, active participation in & management of the patient’s course of treatment

RRAs/RPAs: Challenges

- The following must be met before an RA may bill under "incident to" provisions:
  - RA must be an employee (either W1 or leased) of the physician
  - The initial visit (for that condition) must be performed by the physician
    - There must be a direct, personal, professional service furnished by the physician to initiate the course of treatment for which the services being performed by the RA are an incidental part
    - The patient does NOT need to see the physician on each occasion of an incidental service performed by an RA

RRAs/RPAs: Challenges

- The physician must be physically present & immediately available to render assistance if necessary
- The physician must have an active part in the patient's ongoing care
  - Subsequent services by the physician must be of a frequency that reflects his/her continuing active participation in & management of the course of the treatment

Credentialing Issues

- Reporting corporate ownership changes
  - Retirement, leaving to practice elsewhere, death
  - Not updating practice ownership timely with Medicare will cause the group to be disenrolled from the Medicare program
  - Payments will start to deny immediately
    - CMS will go back to the date the physician left the practice
    - We had a Client who did not report a change for 7 years & CMS recouped over $4M

Credentialing Issues

- You have 60 days in which to report the change . . . the sooner the better!
- There is a “trickle down” effect
  - CMS reports the disenrollment to RR Medicare, Medicare HMOs

Credentialing Issues

- Fee-for-time (locums) rules
  - Most critical issue: reporting where the physician is sitting when the interpretation is rendered
  - Workstation IDs are imperative
    - These come through the PACS
    - Must be maintained ongoing
  - Must be proactive about ensuring this information is correct

CY 2024 MPFS Final Rule

- Issued on 11.2.2023
- 2024 conversion factor: $32.74 finalized
- 3.4% (or $1.15) decrease from 2023 ($33.89)
  - CF x RVU = allowed amount
- Adjusting for inflation, Medicare physician payments have decreased 26% from 2001-2023 (before 2024 cuts)
- Strengthening Medicare for Patients and Providers Act (proposed legislation)
  - Would provide a permanent annual inflationary physician payment update that is tied to the Medicare Economic Index (MEI)
  - 4.14.2023: Referred to Subcommittee on Health by Committee on Energy & Commerce

CY 2024 MPFS Final Rule Impact (Table 118)

Specialty	Impact of wRVU Changes	Impact of PE RVU Changes	Impact of MP RVU Changes	Combined Impact
Interventional Radiology	-1%	-3%	0%	-4%
Radiology	-1%	-2%	0%	-3%
Radiation Oncology & Radiation Therapy Centers	0%	-2%	0%	-2%
Interventional Pain Management	0%	0%	0%	0%

- CMS acknowledges anesthesiology, interventional radiology, radiology, nuclear medicine, vascular & thoracic surgery, physical/occupational therapy & audiology have payment decreases
- Due to redistribution of payments to other specialties

CY 2024 MPFS Final Rule

Topic	Description	Comments
AUC Program	Implementation is paused	Includes ending educational & operations testing period
E/M*	Payment for O/O E/M code G2211 (complexity add-on payment)	National reimbursement: $16.04
	Recognizes costs associated with E/M visits for primary & longitudinal care	Goal is to increase patient compliance by building clinician-patient relationship
Virtual Supervision	For direct (level 2) supervision	Extended through 12.31.2024

2024 Quality Payment Program

- MIPS payment adjustments
  - 79% of MIPS ECs will receive a positive payment adjustment for CY 2024
  - 2024 maximum est. payment adjustment 100 pts = 2.985%
  - 2023 estimated to be 6%
  - 2024 maximum penalty still -9%
- Performance threshold: 75 points (82 was proposed)
- Data completeness: 75%

Quality Measures Deleted

Measure #	Measure Description	Reason
147	Correlation with existing imaging studies for all patients undergoing bone scintigraphy	Topped out
324	Cardiac stress imaging not meeting appropriate use criteria: testing in asymptomatic, low-risk patients	Topped out
112	Breast cancer screening	Replaced with more robust composite measure (#497)
113	Colorectal cancer screening	Replaced with more robust composite measure (#497)
128	Body mass index (BMI) screening & follow-up plan	Replaced with more robust composite measure (#497)

Other measures removed include: 14, 93, 107, 110, 111, 138, 283, 391, 402

Quality Measure Not Deleted

- **Measure 436:** Radiation Consideration for Adult CT: Utilization of Dose Lowering Techniques
  - Lives to see another day!
  - 2024 is the last year
- Giving the industry one more year to prepare for the outcome measure that is set to replace 436
  - **#494** (out of EHR) Excessive Radiation Dose or Inadequate Image Quality for Diagnostic Computed Tomography (CT) in Adults (Clinician Level)
  - Requires the use of additional software to access primary data elements stored within radiology EHR records

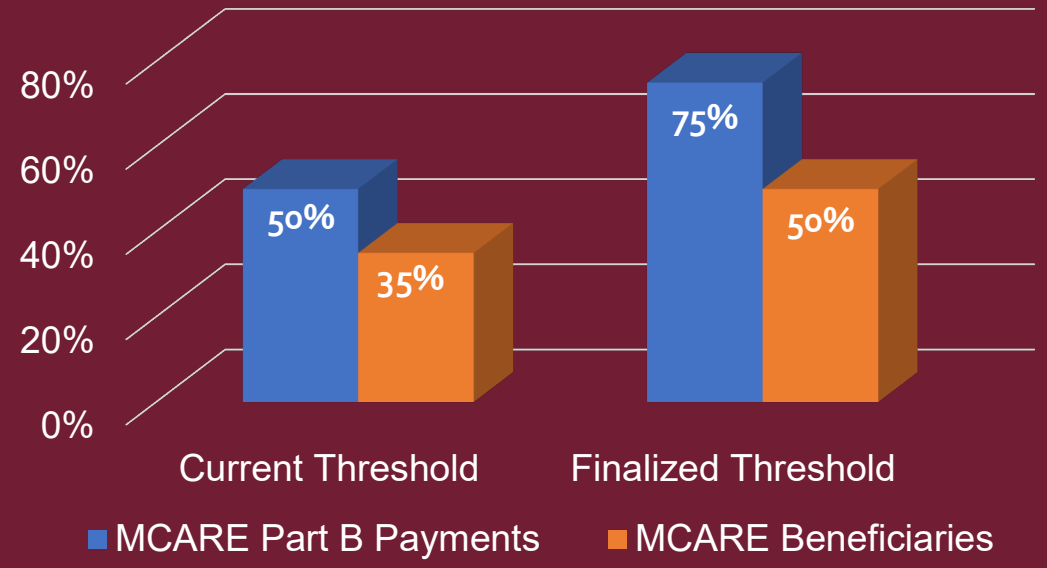
Episode-Based Cost Measures

- 5 new episode-based cost measures finalized beginning with CY 2024 PY
  - Depression
  - Emergency medicine
  - Heart failure
  - **Low back pain**
  - Psychoses & related conditions
- 20-episode case minimum for each new measure

Measure Name	Description	Case Minimum	Episode Window
Low back pain	Chronic condition; for OP treatment & ongoing management of low back pain	20-case minimum	At least 2 E/M services are billed with low back pain diagnosis in a 60-day global period (ASC/Office/HOPD)

Major AAPM Change: QP Determination

- NOT passed: proposal to make QP determinations at the NPI-level rather than at the APM-Level
- Passed: increase to QP thresholds
  - Means hospital-based providers would rarely qualify as QPs



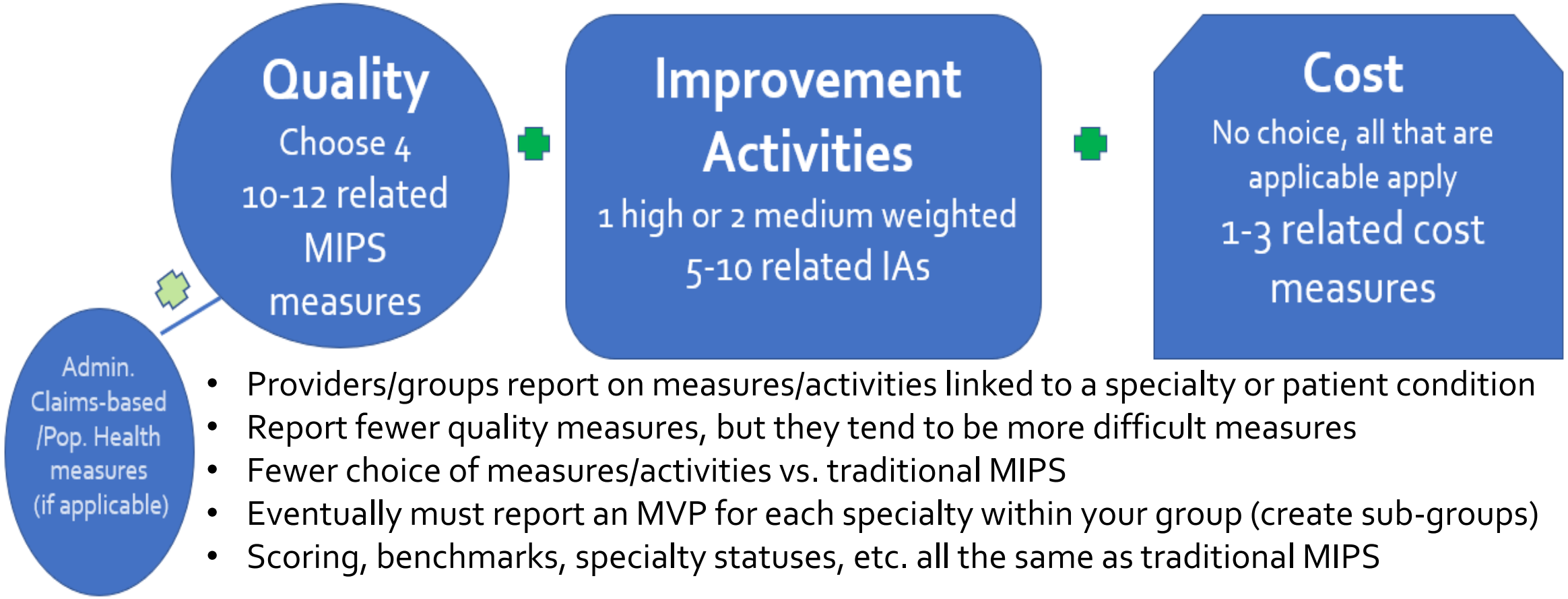
Major AAPM Change: QP Determination

- In 2024+ if you are a QP you are exempt from MIPS AND there is no bonus
    - Since bonus is gone, there is no benefit to QP status
    - Only opportunity under the quality portion is if your ACO wants to share money with you
- If you are not a QP you receive the higher of your ACO score or your MIPS score

MIPS Value Pathways (MVPs)

- MVPs are the future
  - Being implemented so clinicians can report on measures that are directly relevant to their clinical practice
- Rather than selecting individual measures & activities from a large inventory that are reported under "siloed" MIPS performance categories . . .
- 5 new MVPs approved for 2024 (16 in total)
  - None apply to radiology

MIPS Value Pathways (MVPs): Think of a Bundle



- Providers/groups report on measures/activities linked to a specialty or patient condition
- Report fewer quality measures, but they tend to be more difficult measures
- Fewer choice of measures/activities vs. traditional MIPS
- Eventually must report an MVP for each specialty within your group (create sub-groups)
- Scoring, benchmarks, specialty statuses, etc. all the same as traditional MIPS

16 MVPs Available in 2024

MVP Description	Year Implemented
Advancing Rheumatology Patient Care	2023
Coordinating Stroke Care to Promote Prevention and Cultivate Positive Outcomes	2023
Advancing Care for Heart Disease	2023
Adopting Best Practices and Promoting Patient Safety within Emergency Medicine	2023
Improving Care for Lower Extremity Joint Repair	2023
Support of Positive Experiences with Anesthesia	2023
Advancing Cancer Care	2023
Optimal Care for Kidney Health	2023
Optimal Care for Patients with Episodic Neurological Conditions	2023
Supportive Care for Neurodegenerative Conditions	2023
Value in Primary Care	2023
Focusing on Women's Health	2024
Quality Care for the Treatment of Ear, Nose, and Throat Disorders	2024
Prevention and Treatment of Infectious Disorders Including Hepatitis C and HIV	2024
Quality Care in Mental Health and Substance Use Disorders	2024
Rehabilitative Support for Musculoskeletal Care	2024

Cybersecurity

- ProPublica investigative report in September 2019:
  - Millions of medical images & health data, generated from PACS, existed on unprotected internet servers that were easily accessible by anyone with basic computer expertise
- Cyber Security compliance is critical
  - Not only system access but also user utilization, especially for remote users

Cybersecurity

- NY AG Letitia James fines US Radiology Specialists $450,000 (Nov 10, 2023)
  - Failing to update its IT systems
  - A move that could have prevented a 2021 ransomware attack

Attorney General James Secures $450,000 from Medical Company Providing Services in Western New York for Failing to Protect Patient Data

Cybersecurity

- Windsong Radiology Group cited
  - USRS did not prioritize upgrading its hardware
  - Personal information of 92,000 NY citizens exposed to hackers
    - 198,260 across the US (NC, AZ, TX)
  - Patient & provider names, dates of birth, SSNs, driver's license, passport #s, patient IDs, types of radiology exams, diagnoses, health insurance information compromised

US Radiology Specialists will pay $450K for failing to upgrade hardware to prevent ransomware attack (radiologybusiness.com)

Cybersecurity: HHS Alert

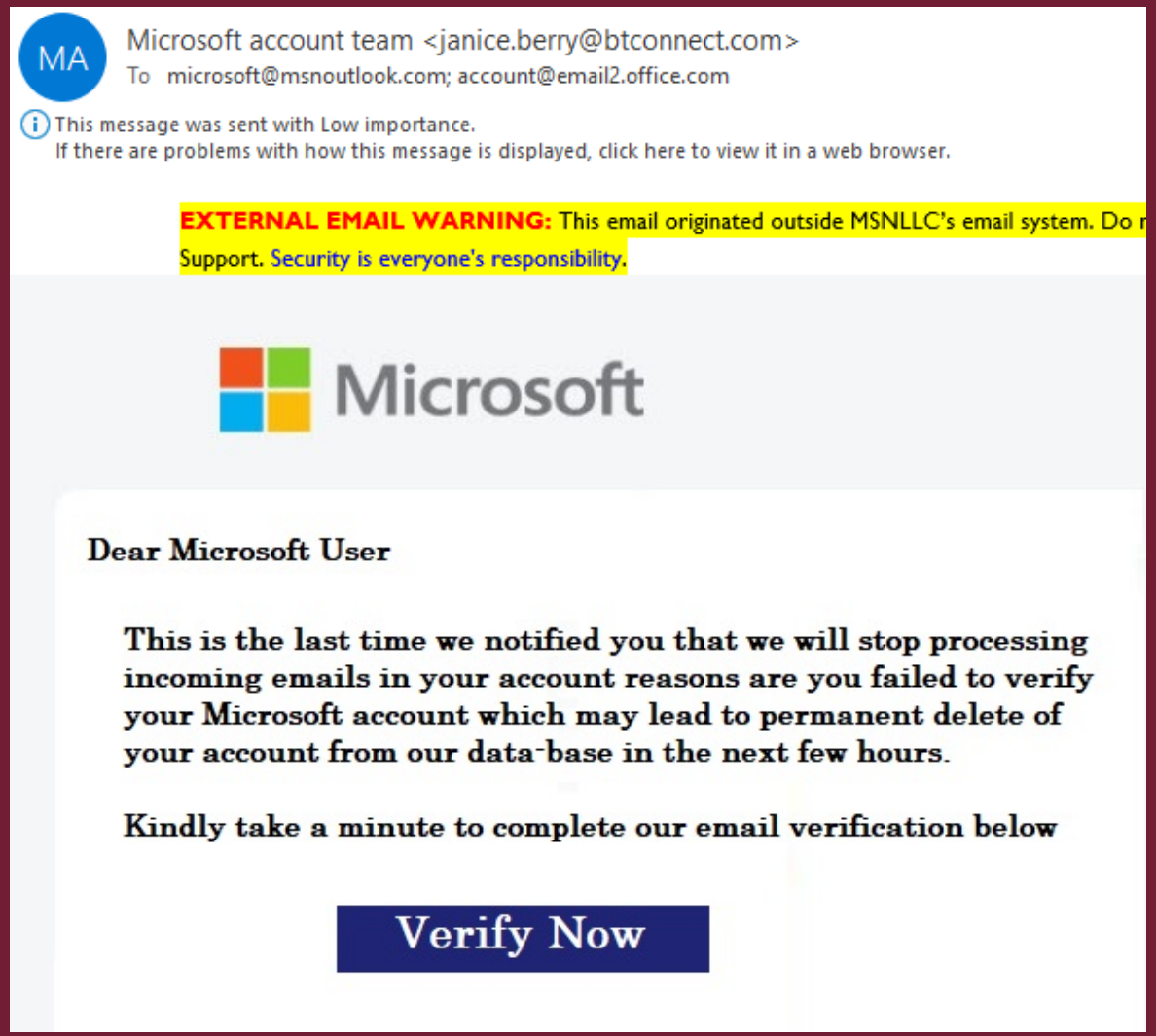
- HHS issued alert on new ransomware group discovered in May 2023
  - BlackSuit claimed radiology 1st US healthcare victim in October 2023
    - Files are encrypted & locked until ransom is paid
    - Data is leaked
    - “Double-extortion” method
  - Group serves almost 1,000 hospitals & health systems in 48 states - has not been identified

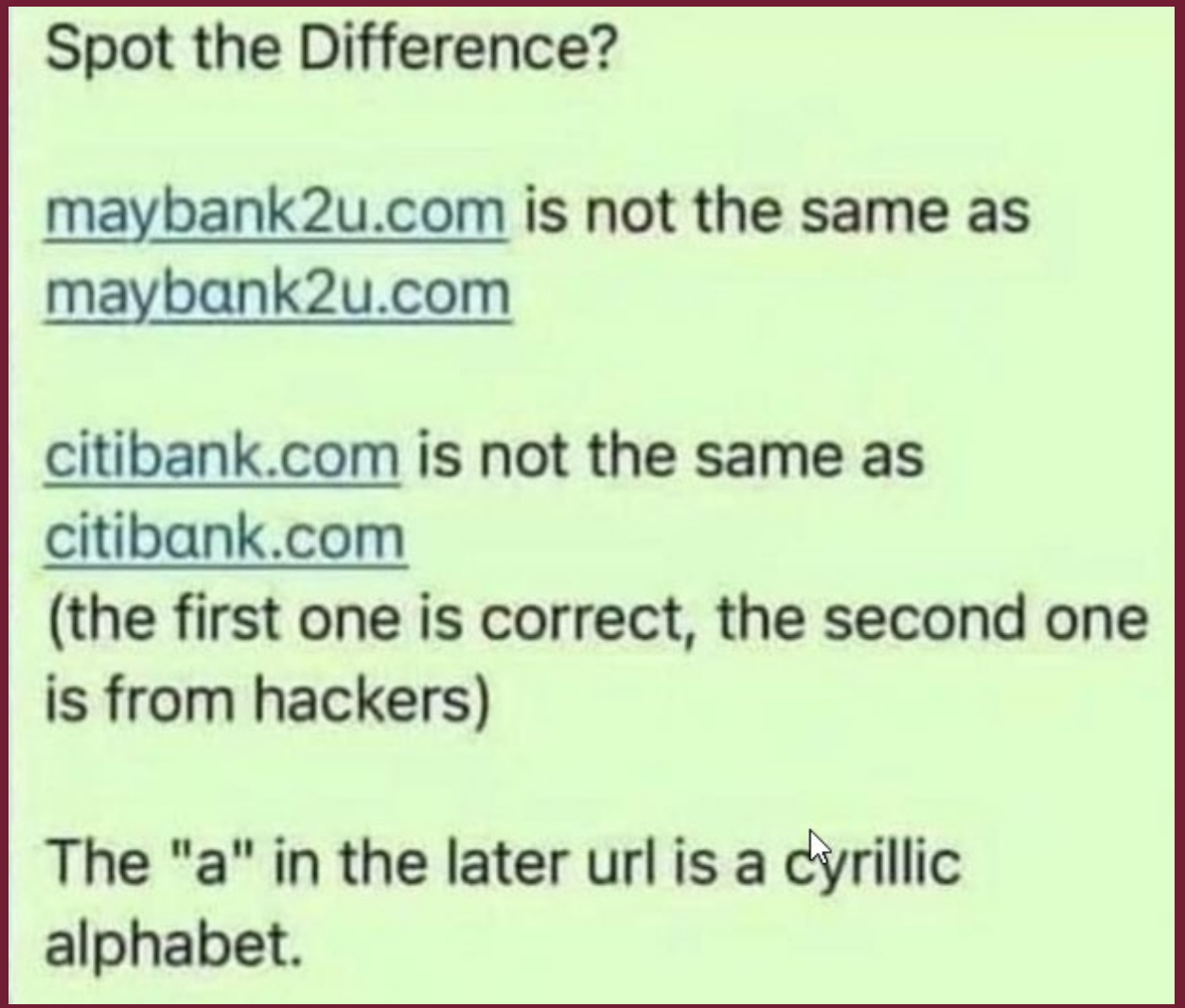
HHS issues alert on new ransomware group that claimed radiology provider as 1st US healthcare victim (radiologybusiness.com)
202311061700_BlackSuit Ransomware Analyst Note_TLPCLEAR (hhs.gov)

Cybersecurity: HHS Alert

- Akumin experienced a significant ransomware attack in October
  - Forcing it to temporarily postpone most clinical & diagnostic operations
  - Company website says it serves about 1,000 hospitals & health systems across 48 states
  - No response from Akumin to messages seeking confirmation

Cybersecurity: Humans Are The Weakest Link





Medicare “Wet Reads” *versus* “Final Reads”

- Historical context
- Generally accepted rule
- Previous guidance from Medicare.
- Be aware: a potential theory is evolving for attacking the billing of a final read after a wet read was earlier performed
  - The theory is, at least in part, contrary to previous guidance
- What the Supreme Court has said
- For planning purposes, remember that previous guidance can be changed and replaced with new guidance and/or with new regulatory focus

Medicare “Wet Reads” *versus* “Final Reads” (cont’d)

- Note that final reads rendered outside the United States cannot be billed to Medicare
- Billing final reads to non-governmental payors will depend upon each payor’s agreements and policies

Affordable Care Act “60 Day Rule”

- The so-called “60 Day Rule” requires providers to report & refund overpayments within 60 days of “identification”
  - “Overpayment” is defined in Section 6402 of the Affordable Care Act as any funds a person receives or retains under Medicare or Medicaid to which the person, “after applicable reconciliation,” is not entitled

Affordable Care Act "60 Day Rule" (cont'd)

- An overpayment is "identified" when a person has or should have, through the exercise of reasonable diligence, determined that an overpayment was received
  - "Reasonable diligence" is demonstrated by timely, good faith investigation, which CMS indicates is at most six (6) months from the receipt of credible information regarding a potential overpayment absent extraordinary circumstances (but see below)
  - An overpayment is not "identified" until it is quantified (unless a provider fails to exercise reasonable diligence) (but see below)
  - Overpayments identified by a probe sample need not be returned until the full overpayment amount is identified

Affordable Care Act "60 Day Rule" (cont'd)

- Failure to exercise reasonable diligence to investigate credible information regarding a potential overpayment will result in a violation of the 60 Day Rule under the "should have known" standard if an overpayment was received
- CMS advises providers to maintain records of their reasonable diligence efforts
- ***BE AWARE OF THE IMPLICATIONS FOR FAILURE TO COMPLY WITH THE 60 DAY RULE:***
  - Any overpayment retained past the deadline is an "obligation" under the reverse false claims provision of the False Claims Act ("FCA")
  - FCA penalties are not less than $5,500 nor more than $11,000 per claim plus treble damages

Affordable Care Act "60 Day Rule" (cont'd)

- Why mention the 60 Day Rule?
- Mostly because even today, over 12 years after passage of the Affordable Care Act:
  - Too many people in health care (especially among physician groups) still aren't aware of the 60 Day Rule, and . . .
  - They don't seem to realize that sweeping the past overpayments under the rug, even if steps are taken to assure the overpayment never happens in the future, is no longer an option

Affordable Care Act "60 Day Rule" (cont'd)

- On December 27, 2022, CMS published proposed changes to the 60-Day Rule that would eliminate the "reasonable diligence" standard & adopt the False Claims Act definition of "knowing" and "knowingly" as set forth in 31 USC §3729(b)(1)(A)
- Under this change, the Medicare organization, sponsor, provider, or supplier has identified an overpayment if it has actual knowledge of the overpayment or acts in reckless disregard or deliberate ignorance of the overpayment
- There's some concern that under these proposed rule changes, the day an enrollee knows or should know of an overpayment, it has exactly 60 days to report and refund that payment to Medicare
  - No 6 months
  - No link to quantification
- The changes are still only proposed

Self-Disclosure Options

- Updated OIG Self-Disclosure Protocol (“SDP”)
- CMS Self-Referral (Stark) Disclosure Protocol (“SRDP”)
- Department of Justice/U.S. Attorneys Office
- Routine Report and Refund Channels
- State Provider Self-Disclosure Protocols

OIG Self-Disclosure Protocol
Potential Benefits of SDP

- Presumption against corporate integrity agreements
- Lower damages multiplier
- Suspends 60-day rule
- Mitigates FCA exposure
- Nearly always releases parties from permissive exclusion

OIG Self-Disclosure Protocol
Background

- Conduct that may violate federal criminal, civil or administrative laws for which civil monetary penalties ("CMPs") are authorized
  - Does not include matters exclusively involving overpayment or errors
  - Does not include "Stark only" disclosures
  - Requires additional disclosures
  - Internal investigation & corrective action must be completed within 90 days of submission (subject to extension)
  - Requires disclosing party to screen all current employees and contractors against the List of Excluded Individuals and Entities ("LEIE") before making "excluded persons" disclosures

OIG Self-Disclosure Protocol
Baseline Disclosure Requirements

- Information regarding disclosing party
- Concise statement of conduct disclosed, including conduct giving rise to the matter, time period, and the names of implicated parties, including an explanation of their roles in the matter
- Statement of the federal criminal, civil or administrative laws that are potentially violated by the disclosed conduct
- Federal health care programs affected by the disclosed conduct
- Damages estimate

OIG Self-Disclosure Protocol
Baseline Disclosure Requirements (cont'd)

- Description of corrective action taken upon discovery of the conduct
- Whether the disclosing party has knowledge that the matter is under current inquiry by a Government agency or contractor
- Name of individual authorized to enter into a settlement agreement on behalf of the disclosing party
- Certification statement

OIG Self-Disclosure Protocol
Additional Disclosure Requirements

- New requirements for false billing disclosures, including a minimum sampling requirement of 100 items
- Excluded persons disclosures
- Greater detail regarding why disclosed conduct potentially violated the Anti-Kickback Statute ("AKS") and Stark Act, if applicable (*e.g.*, why arrangement was not commercially reasonable)
  - Also requires estimate of amount paid by federal health care programs for services associated with and total remuneration paid under unlawful arrangement

OIG Self-Disclosure Protocol
Settlement Parameters

- $10K floor for non-AKS disclosures/$50K floor for AKS disclosures
- 1.5 times multiplier presumed
- Damages in false billing disclosures based on all affected claims or random sample, without “netting” of underpayments
- AKS/Stark settlements typically based on multiplier of remuneration conferred by referral recipient to referral source

OIG Self-Disclosure Protocol
Settlement Parameters

- Previously refunded amounts will be credited
- Presumption against corporate integrity agreements
- Criminal matters referred to Department of Justice for resolution
- Financial inability to pay must be documented with assessment of how much can be paid

CMS Self-Referral (Stark)
Disclosure Protocol Resolution

- CMS has the authority to accept a reduced overpayment (*i.e.*, less than 100%)
- CMS is clear to point out that it is under no obligation to accept the disclosing party's calculation of its financial liability or to compromise the overpayment at all
- There are no limits on the reduction that CMS may make
  - Theoretically, CMS may reduce the overpayment to $0
- Refund does not have to accompany the initial submission made under the SRDP

CMS Self-Referral (Stark)
Disclosure Protocol Limitations

- Parties have no guarantee of acceptance into the SRDP
- CMS will not waive the “refund to individuals” requirement in section 1877 of the Social Security Act which requires refund of any amounts collected that were billed in violation of the Stark law
- Does not prohibit intervention by law enforcement

CMS Self-Referral (Stark)
Disclosure Protocol Requirements

- Thorough description of the parties, financial relationship, time period of non-compliance, designated health services ("DHS") at issue, and roles of the individuals involved in the matter
- Analysis of the application of the Stark law to the conduct at issue, including which elements of the relevant exception were met and not met
- Complete financial analysis identifying the 100% overpayment amount:
  - Can include alternate theories of the overpayment amount
  - CMS FAQ has clarified that the financial analysis should be based on the applicable reopening period
- Description of compliance efforts prior to and since the discovery of the Stark violation
- Agreement to forfeit appeal rights

Other Options for Self-Disclosure

- Department of Justice/U.S. Attorneys Office
- Routine Report and Refund Channels

Tips For Handling Self-Disclosures

- Adopt and implement policies to ensure satisfaction of the 60-day rule
- Define “identification” of overpayments to occur following investigation and validation that overpayment was received and determination of the amount of the overpayment
- Develop timely investigation & audit plan that avoids need to report and refund on a rolling basis to satisfy the 60-day rule when possible
- Investigate “root cause” of overpayments to determine if they arose from intentional misconduct or reckless disregard of applicable law (ideally before quantifying damages)
- Limit investigation/audit scope to arrangements/claims where there is reason to believe that violations may have occurred
- Ensure that disclosures satisfy all requirements and anticipate Government concerns
- Consider pros/cons of reporting under a protocol *instead of* to local U.S. Attorneys Office or through routine channels
- Evaluate benefits of any state provider self-disclosure protocols

Thank You!

W. Kenneth Davis, Jr.
ken.davis@katten.com
(312) 902-5573

Barbara F. Rubel, MBA, FRBMA
brubel@msnllc.com
(770) 823-3597