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The CERT Program:

What It Is and What a Practice Needs to Know

Monthly Spotlight on Fraud, Waste, and Abuse

ERISA Overview for Healthcare Providers: Part I

Overcoding: Putting a Strategic Stop to a Silent Revenue Killer

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CEO Letter

I hope your summer is going well. Where we are in Upstate South Carolina, we have had minimal summer weather with loads of rain and cooler than normal temperatures. My wife loves gardening and insists on growing (and canning/storing) our vegetables, fruits, and herbs (culinary and medicinal). The garden is hit and miss so far this season, and she is devastated but still trying diverse options to get the results of previous years. We are opting for different fertilizer to see if that helps, as well as trying "electroculture" for the first time (the copper tubing arrived yesterday so keep your fingers crossed!) in hopes that it sparks growth. Gardening is typically a source of peace for her, but the frustration at not getting anything close to previous results by this time of the year is causing her concern. If you're a gardener, you understand how tenuous the balance of a garden is and how much time it takes to grow and curate nature's bounty. I hope yours is going well!

So, to this issue. Our cover, written by Betty Hovey, is on the CERT (Comprehensive Error Rate Testing) program. She has broken it down into what to expect and what practices need to do. If you have Medicare providers, this is an important article for you to read.

We have an article written by Joanne Byron from AIHC that discusses becoming a resilient leader during trying times. We need strong and capable leaders in our workplaces right now, and someone who can adapt to provide that to their staff is beneficial on so many levels. Rachel Rose has written on the Anti-Kickback statute, so be sure to check that out as violations are expensive and ignorance is not a defense. Terry Fletcher has written on the use of AI in healthcare, and even though I understand

how this can help with tasks, etc., I am concerned with the way that we are embracing this type of technology. It's moving so fast and can be abused so badly.

ERISA is an all-important and often misunderstood topic, and we welcome Franklin J. Rooks' article for an overview for healthcare providers. Amy Wilcox from Find-A-Code has written two pieces that will help readers understand modifiers 76 and 77, as well as the identification of diagnoses for reporting and sequencing purposes. We also welcome Ritesh Ramesh with his article on over-coding, and another well-written piece from Compliance Group on HIPAA rules for medical billing. These are all must-reads for medical coders and billers.

As usual, it's a jam-packed issue full of different topics that I hope you find as interesting as I do.

Until next time.

Storm Kulhan



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Google and Mayo Clinic Partner to Infuse AI Into Healthcare

Google says its generative AI tool is HIPAA compliant.

Google Cloud launched a partnership with Mayo Clinic to implement use of its generative AI software, the tech giant announced recently. To kick things off, the collaboration aims to enhance workflows in health care with the Enterprise Search in Generative AI App Builder tool. The application is “ready to support HIPAA compliance,” Google Cloud said in a press release.

Dubbed the Gen App Builder, the tool will be used at the Mayo Clinic to assist healthcare professionals with accessing information across multiple sources in a streamlined process. That includes patient records, like lab tests, medical history, or diagnostic imaging, as well as clinical protocols and research papers. With Google-level search capabilities, it can help health organizations quickly find what they need.

Mayo Clinic’s chief information officer Cris Ross touts the technology as a way to change the healthcare system and serve patients better-and safely.

“Our prioritization of patient safety, privacy, and ethical considerations, means that generative AI can have a significant and positive impact on how we work and deliver healthcare,” Ross said. “Google Cloud’s tools have the potential to unlock sources of information that typically aren’t searchable in a conventional manner, or are difficult to access or interpret, from a patient’s complex medical history to their imaging, genomics, and labs. Accessing insights more quickly and easily could drive more cures, create more connections with patients, and transform healthcare,” he added.

Google Cloud’s Enterprise Search in Generative AI App Builder gives organizations the ability to develop custom chatbots and programs for search. AI chatbots are becoming prevalent in various industries like banking, where they’re used to provide interactive answers to customers’ questions.

Source: www.cnet.com

Telehealth Use Rose 1.8% Nationally in March

According to new data, national telehealth use increased marginally by 1.8 percent, making up 5.6 percent of medical claim lines

in March.

Following a slight decline in February, telehealth use increased slightly in March at the national level and in two United States census regions, according to the FAIR Health Monthly Telehealth Regional Tracker.

The FAIR Health Monthly Telehealth Regional Tracker is a service that describes how telehealth usage changes monthly by tracking claim lines, procedure codes, and diagnostic categories. The tracker represents a privately insured population, includes Medicare Advantage, and excludes Medicare Fee-for-Service and Medicaid beneficiaries.

Although the severity of the COVID-19 pandemic is not as high as it once was, telehealth remains widely used. The March release of the FAIR Health Monthly Telehealth Regional Tracker reflected this.

Source: mhealthintelligence.com

New Legislation on Medical Bill Transparency Has Passed. What Does This Mean?

New legislation on medical bill transparency has passed in Texas. Hospitals are now required to provide itemized receipts to patients before sending their bills to collections. This is a positive development for Americans burdened by unexpected health expenses.

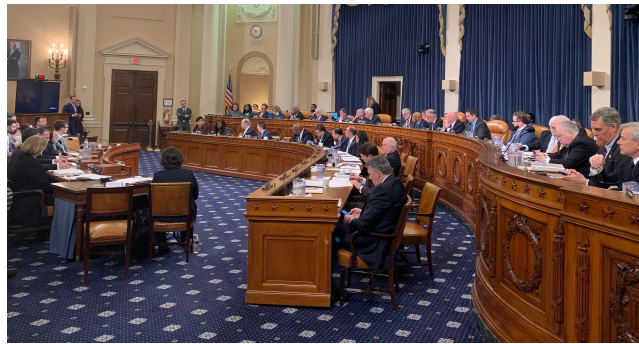
“Going door to door visiting with voters, I’d hear stories about medical bills and debt, often unexplained and over-billed charges, that burdened families,” State Rep. Caroline Harris, R-Round Rock, who worked with Sen. Bryan Hughes, (R-Mineola) to get the legislation passed, told KXAN.

According to KXAN, a Central Texas hospital recently sued hundreds of patients over unpaid medical bills, several of whom received vague invoices without itemized receipts before being served with a lawsuit. With this new law, a patient would be able to get clarity around hospital charges and contest some of them if necessary. It would also prevent patients from being taken advantage of.

Source: Newswire

Ways and Means Approves HRA, Telehealth Bills

The House Ways and Means Committee approved six health-related bills recently in the committee's first health markup of the 118th Congress, with a focus on small businesses.



Five of the bills passed with bipartisan support, and the sixth, focused on health reimbursement arrangements, passed solely on party lines.

Driving the news: The party-line vote was for the CHOICE Arrangement Act, which would codify a Trump-era 2019 health reimbursement arrangement rule.

It would allow businesses to offer their employees the option of individual coverage health reimbursement arrangements (ICHRAs), which Chairman Jason Smith rebranded as Custom Health Option and Individual Care Expense or CHOICE arrangements.

"Republicans have tried time and time again, to strike down the ACA. The bill before us today seems like another attempt to undermine the consumer protections the ACA provides," said Rep. Judy Chu.

What they're saying: Rep. Kevin Hern, the bill's sponsor, responded that a CHOICE plan would give employees options outside of an employer group plan, but the plans would still be ACA-compliant and include non-discrimination clauses.



"So employees of a business that has a CHOICE plan, has the ability now to have a flexible plan that they can be reimbursed for by the employer. That's all it does,"

said Hern.

Rep. Lloyd Doggett offered an amendment that would have ensured protections for pre-existing conditions and prevented employers from offering the arrangements to just certain types of workers, but it was voted down.

The committee also approved the Small Business Flexibility Act, which would require small businesses to be notified of the flexible health benefit options available to them, such as health reimbursement arrangements.

Meanwhile: The other bills focused on supporting telehealth and cutting paperwork.

1) The Telehealth Expansion Act would allow people with high-deductible health plans and health savings accounts to access telehealth services permanently without having to meet their minimum deductible first.

It would make permanent a telehealth flexibility that was first established in the CARES Act in March 2020, and was extended in the most recent end-of-year omnibus package, along with other telehealth extension provisions. These extensions currently expire at the end of 2024.

It was approved with some bipartisan support, with five Democrats joining all 25 Republicans in voting for it.

2) The Chronic Disease Flexible Coverage Act would allow people with high-deductible health plans used along with health savings accounts to have 14 preventive care services related to chronic disease management covered before the plan deductible is reached.

It also received bipartisan support, with 11 Democrats voting for it.

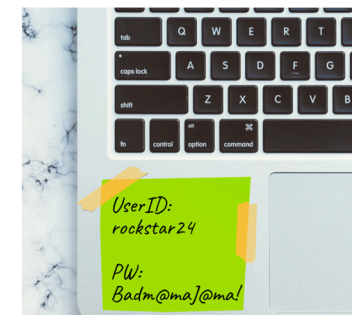
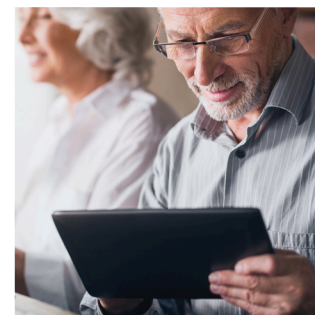
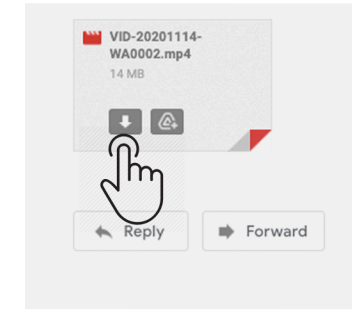
3) The Paperwork Burden Reduction Act would relieve employers from having to mail 1095-B and 1095-C forms to employees to verify health insurance coverage. Employees could instead request the forms online.

4) The Employer-Reporting Improvement Act would streamline the ACA health coverage reporting requirements for small businesses.

Both paperwork related bills were approved unanimously.

Source: AXIOS

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Everything You Need to Know About HIPAA Rules for Medical Billing

Medical billing companies must access protected health information (PHI) to perform their duties, making them HIPAA business associates. As this is the case, medical billing companies must be HIPAA compliant. So, what are HIPAA rules for medical billing?

HIPAA Security Rule and Medical Billing

The HIPAA Security Rule applies to medical billing companies concerning how they protect the PHI to which they have access. Medical billing companies must implement administrative, physical, and technical safeguards to maintain PHI's confidentiality, availability, and integrity.

The required safeguards are as follows:

- **Physical Safeguards:** Protect the physical security of your offices where PHI or ePHI may be stored or maintained. Common examples of physical safeguards include alarm systems, security systems, and locking areas where PHI or ePHI is stored.
- **Technical Safeguards:** Protect the cybersecurity of your business. Technical cybersecurity safeguards must be implemented to protect the ePHI that is maintained by your business. Examples of technical safeguards include firewalls, encryption, and data backup.
- **Administrative Safeguards:** Ensure staff members are adequately trained to execute the security measures you have in place. Administrative safeguards should include policies and procedures that document the security safeguards you have in place, and employee training on those policies and procedures to ensure they are correctly executed.

HIPAA Privacy Rule and Medical Billing

The HIPAA Privacy Rule applies to medical billing companies concerning how they are permitted to disclose PHI to other medical entities.

Medical billing companies may have access to PHI, including:

- Treatment information, including past and current medical conditions
- Fees that patients or their insurance companies paid for treatment
- The location of the treating healthcare provider

Preventing Medical Healthcare Fraud and Abuse, Administrative Simplification, and Medical Liability Reform (Title II)

Title II applies directly to medical billing companies as it dictates the proper uses and disclosures of PHI, and simplifies the processing of claims and billing. Title II also provides guidelines for keeping and sharing electronic records between healthcare entities.

Additionally, under Title II, the Office of the Inspector General (OIG) is in charge of investigating and prosecuting healthcare provider and insurance company fraud.

OIG Compliance

OIG ensures that medical billing and coding companies are not acting fraudulently.

The most common ways medical billing and coding companies commit fraud are:

1. **Upcoding:** Occurs when providers try to get more money from insurance companies for billing patients for services they did not perform.
2. **Undercoding:** Occurs when providers intentionally leave out codes for services provided, intending to

avoid an OIG investigation.

3. **Unbundling Codes:** Occurs when providers submit separate claims for services that can be submitted as one bill. This is done in an attempt to maximize payments received from insurance companies.
4. **Falsifying Medical Records:** Occurs when providers falsify patients' medical records, by altering medical histories, payment histories, or descriptions of treatment.

The Surprise Medical Bill Law

The "No Surprises Act" went into effect on January 1, 2022, but the final rules and details of the law weren't released until August 2022.

The final rules issued by the Department of Labor and the Department of Health and Human Services provide a framework for the arbitration of disputes between providers and health plans.

The rules also specify the following:

1. If a qualifying payment amount is based on a downcoded service code or modifier, a plan or issuer must provide the following information with its initial payment:
 - A statement that the service code or modifier billed by the provider, facility, or air ambulance service was downcoded
 - An explanation of why the claim was downcoded, including a description of which service codes or modifiers were altered, added, or removed, if any

- The amount that would have been the qualifying payment amount had the service code or modifier not been downcoded
2. Independent dispute resolution entities must be certified. They must consider both the qualifying payment amount and all additional permissible information submitted by each party to determine which offer best reflects the appropriate out-of-network rate. After weighing these considerations, independent dispute resolution entities should select the offer that "best represents the value of the item or service under the dispute."

3. Independent dispute resolution entities must explain their payment determinations and the underlying rationale in a written decision submitted to the parties, HHS, and the Labor Department.

A fact sheet from the Department of Labor is available on their website for a more detailed summary of the final rules. Visit: <https://www.dol.gov/sites/dolgov/files/EBSA/about-ebsa/our-activities/resource-center/faqs/requirements-related-to-surprise-billing-final-rules-2022.pdf>

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Overcoding: Putting a Strategic Stop to a Silent Revenue Killer

Overcoding is in the crosshairs as the Centers for Medicare and Medicaid Services (CMS) continues its quest to ferret out fraud and abuse and recoup improper reimbursements—a focus that returns \$8 for every \$1 spent on audits. There are no signs that they are letting up any time in the future, as the federal government has increased funding for audits and fraud investigations.

Overcoding—intentional or accidental—can bring significant fines in addition to repayment of the original claim. And the reputational damage of a fraud finding is hard to overcome. As such, provider organizations need to be vigilant with their compliance and education programs to avoid finding themselves on the losing end of a CMS or other third-party audit. Overpayments also have a negative impact on patient acquisition and experience, thereby deflating growth. The whole idea of declaring financial results to the public domain and restating the results repeatedly due to uncertain compliance risks is a nightmare for most of the financial leaders within health systems.

CMS Gets Serious

Together, CMS, the Department of Justice (DOJ), and the Department of Health and Human Services (HHS) Office of Inspector General (OIG) are investing in predictive modeling and artificial intelligence tools to scrutinize claims more closely before adjudication to reduce improper payments without adding administrative burden. At the same time, retrospective audits can claw back revenue from current and past years, putting financial pressure on providers that have long used those funds for continuing operations.

According to the MDaudit Annual Benchmark Report, 82% of all claim denials are associated with Medicare, so providers must focus their efforts on this area—even

as federal auditing efforts continue to proliferate. On the commercial side, Medicare Advantage and Medicaid managed care plans are under constant scrutiny as OIG and CMS have ongoing concerns about efforts to combat fraud, including a lack of fraud referrals.

The FY 2023 HHS budget provides \$2.5 billion in mandatory and discretionary investments for the Healthcare Fraud and Abuse Control (HCFAC) and Medicaid Integrity Programs. The budgeted \$899 million in discretionary HCFAC funding is more than \$26 million above the FY 2022 enacted level.

According to a recent NPR article, 90 audits of Medicare Advantage (MA) plans from 2011-2013 found an average yearly overbill of more than \$1,000 per patient. Extrapolated across populations, that represents \$650 million in excess payments. Further, a New York Times analysis finds that eight of the largest MA insurers, representing more than two-thirds of the market, have submitted inflated bills to the government. Additionally, four of the five largest providers have been accused of fraudulent upcoding by the government.

If you don't think the federal government is serious about overcoding, think again.

Overcoding Problem Areas

Overcoding remains an issue across the healthcare landscape. At the office-visit level, compliance teams

should pay attention to Evaluation and Management (E/M) coding and justification of different levels to maximize reimbursement. In hospital billing, bundling is a major driver of compliance issues, followed by billing and coding errors. In 2022, overcoded charges reclaimed 21% of the revenue recovered from undercoded claims.

Compliance teams should be efficient in managing external payer requests to retain at-risk revenues, with close attention paid to the below areas for overcoding, medical necessity, clinical documentation, and bundling-related issues. Getting paid on time for these high-value services can significantly impact an organization's profitability and financial health. Pay particular attention to these focus areas:

Outpatient Billing:

- Surgeries that involve multiple services performed by the same surgeon must be billed together and cannot be separately billed by different physicians
- Surgeries: orthopedic, spine, neurosurgery
- Specialty drugs and clinical justification for units administered for treatment
- Hospital observation care services
- Implants/medical devices
- Laboratory: chemistry, general classification, hematology, immunology, bacterial

Inpatient Billing:

- Short stay inpatient
- Rehabilitation facilities
- DRGs that drive higher healthcare costs
- Sepsis
- Cardiology
- Digestive system
- Kidney

Compliance teams should have a consistent playbook for auditing these claims, appealing denials to payers, and educating providers on mistakes.

Better Coding Compliance

When it comes to a proactive strategy, as tempting as it may be, undercoding claims is not the answer to overcoding to avoid an audit or potential federal penalties. Indeed, undercoding simply makes the problem worse by depriving organizations of critical income at a time when expenses are rising faster than revenues. The key is to accurately capture all aspects of a patient visit, a test, or a procedure the first time.

Education is critical to any overcoding prevention strategy, as coding changes occur frequently. Assign someone to update internal coding manuals frequently, sending out specific updates and links when warranted. Reviewing updates can become a central facet of an ongoing educational program for coders. Finally, schedule coder audits more frequently to ensure compliance with coding procedures and policies while reducing errors that can delay revenue.

Innovative and robust auditing workflows are necessary to ensure claims are accurate and reflect the particulars of the patient encounter. While undercoding may mean missing out on vital revenue to which the provider or facility is entitled, overcoding is a more significant problem that puts organizations at risk for audits that can stretch back years and jeopardize significant revenue, not to mention reputational risk and patient loyalty.

Healthcare organizations can benefit on the compliance front from a single-platform approach to coding workflows that eliminate manual processes and streamline tasks such as auditing, rebuttal, follow-up audits, and reporting. Workflows should include risk-based and retrospective audits for professional, inpatient, and outpatient charges, as well as the ability to identify new coders who may need additional guidance. The platform should enable dialog between coders and auditors, while providing full visibility into coder workloads and auditing tasks. It should also enable full reporting of end-to-end activities and outcomes.

A Proactive Compliance Strategy

CMS has made it clear that eradicating fraud, waste, and abuse is a top priority. And historically, where CMS goes, so do commercial payers. With overcoding in the crosshairs, healthcare organizations should take immediate steps to implement a proactive, tech-enabled strategy to ensure coding compliance and reduce the risk of external audits.

The right strategy can also reduce delays, thereby accelerating the revenue cycle while ensuring providers are reimbursed at the highest appropriate level for services provided.

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Identifying the Admitting, Principal, Primary, and Secondary Diagnoses

Knowing how to differentiate the admitting, principal, primary, and secondary diagnoses for reporting and sequencing purposes can be intimidating and confusing. The following are some commonly asked questions related to reporting diagnoses in the facility setting.

F or example:

- What is the difference between the principal diagnosis and the primary, or admitting diagnosis?
- Why is it so important to identify a principal diagnosis?
- Can the principal diagnosis and primary diagnosis be the same diagnosis?
- Do we use the same terminology for diagnoses in the office or other outpatient setting?

Sequencing diagnoses is important for every place of service and healthcare organization that wishes to ensure accurate claim processing and avoid denials. Understanding the ICD-10-CM Official Coding Guidelines for Coding and Reporting is the first step in successfully sequencing codes for reporting.

Additionally, another key factor is understanding the definitions of, and how to identify, the following types of diagnoses:

- Admitting
- Principal
- Primary

- Secondary

Let's take a look at each of these, individually, and understand how they are identified and defined.

Admitting Diagnosis

The sign/symptom, condition, injury, or disease that was the reason the patient sought medical care is considered the admitting diagnosis (even if the patient isn't actually admitted to the hospital). This is the problem that caused the patient to seek medical care, likely in the emergency department (ED).

Principal Diagnosis

As published in the ICD-10-CM Official Guidelines for Coding and Reporting, and according to the Uniform Hospital Discharge Data Set (UHDDS), the principal diagnosis is defined as, "that condition established after study to be chiefly responsible for occasioning the admission of the patient to the hospital for care."

For example, while chest pain may have brought the patient to the ED, after examination and testing,

the patient was diagnosed with an acute myocardial infarction (MI) requiring hospital admission. In this case, acute MI would be the principal diagnosis.

Primary Diagnosis

In the inpatient setting, the primary diagnosis is the diagnosis that is the most severe or resource intensive (uses the most hospital resources) during the patient's stay. In some patients, this may be the same as the principal diagnosis, but in others, it will be different.

For example, a patient presented to the ED with an acute yet severe nosebleed (epistaxis), which had become too difficult to manage at home. Upon arrival, examination, and obtaining a thorough patient history, it was noted that the patient had been discharged from a recent hospital stay on Coumadin but had not had any follow-up or testing to ensure adequate coagulation, and now her blood had become so thin, she was at risk of a nasal hemorrhage. While in the ED, she had an episode of bloody diarrhea, and additional testing revealed rupture of a prior gastric ulcer, increasing her risk of death, and requiring additional resources for testing and treatment of a high-risk condition. In this setting, the primary diagnosis would likely be the bleeding gastric ulcer, which required many more resources than the acute epistaxis.

Secondary Diagnosis

The secondary diagnosis or diagnoses can be compared to side dishes to the main course or primary diagnosis. Using the previous example, the patient who presented with an acute episode of severe epistaxis, followed by a bleeding gastric ulcer, both caused by unmonitored anticoagulant use (prescribed due to a recent deep vein thrombosis), may have an additional, secondary diagnosis, such as hypertension or type 2 diabetes unrelated to the current encounter. These additional diagnoses would be considered the "side dishes" or what some might refer to as "patient baggage."

For a secondary diagnosis to make the list of reportable diagnoses, the medical record must include documentation to support that a secondary diagnosis has been either monitored, evaluated, assessed, or treated (MEAT) in any one of the following ways, during the encounter or hospital stay:

- A medical evaluation includes evaluation of the condition.
Example: Patient admitted for altered mental status with fall but has a secondary diagnosis of leg ulcers. The provider

examines the status of the leg ulcers to ensure they haven't reopened or become infected after the fall.

- Diagnostic testing, studies, or imaging were performed, related to the secondary diagnosis.
Example: Diabetes type 2 with A1C is tested during the encounter or stay.
- Prescription or administration of a therapeutic intervention or treatment is involved.
Example: Patient's leg ulcer has re-opened and needs attention, including debridement and new dressings.
- Escalated hospital care/extended length of stay is caused by a secondary diagnosis.
Example: On top of severe epistaxis, due to unregulated Coumadin use, the patient was also noted to have dangerously high blood glucose levels, warranting a temporary change in diabetic medications and another day of admission to ensure adequate control of her diabetes (secondary condition) before discharge.
- Increased monitoring or nursing care is required.
Example: Following fusion of her cervical C4-C5, the patient was noted to have difficulty breathing when she fell asleep with the SpO2 alarm constantly going off. To ensure closer monitoring of this issue, the patient is moved to the Critical Care Unit and the provider has requested pulmonary and respiratory therapy consultations.

Conclusion

Sometimes a patient is admitted with multiple, acute conditions, and coders must determine which will be listed as the principal diagnosis, especially if either could lead to an inpatient admission. Luckily, the Official ICD-10-CM Coding Guidelines provide additional guidance for these circumstances. If, however, after a complete review of the medical record, you are still unsure which diagnosis should be listed as the principal diagnosis, it is recommended that you query the provider for the diagnosis that led to the admission.

Aimee L. Wilcox, CPMA, CCS-P, CST, MA, MT, is a medical coding, billing, and auditing consultant, author, and educator with more than 30 years of clinical and administrative experience in health-care, coding, billing, and auditing. Medicine, including coding and billing, is a constantly changing field full of challenges and learning—and she loves both. Aimee believes there are talented medical professionals who, with proper training and excellent information, can continue to practice the art of healing, while feeling secure in their billing and reimbursement for such care.

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PSQIA, PSWP, and HIPAA Compliance

This article addresses patient confidentiality and security related to patient safety evaluation systems, investigations, root cause analyses, and compliance to rules and regulations. It is a basic introduction to help understand the importance of appropriately managing this type of privileged information.

The goal of achieving quality and patient safety is to improve patient safety outcomes by creating an environment where providers can report and examine patient safety events without fear of increased liability risk. Greater reporting and analysis of patient safety events will help gain a better understanding of patient safety events and result in improvements from lessons learned.

Healthcare is like “alphabet soup” – filled with acronyms, abbreviations, and terms unique to our profession. Let’s define the three acronyms used in the title of this article and how these three rules interact from a compliance perspective.

PSQIA: The Patient Safety and Quality Improvement Act

PSQIA established a voluntary reporting system with the government’s intent to enhance the data available to assess and resolve patient safety and healthcare quality issues.

On July 29, 2005, the president signed the Patient Safety and Quality Improvement Act of 2005 (Patient Safety Act, 42 U.S.C. sections 299b-21 to 299b-26) into law. The Patient Safety Act amended Title IX of the Public Health Service Act to provide for the improvement of patient safety and to reduce the incidence of events that adversely affect patient safety by authorizing the creation of patient safety organizations (PSOs).

The Agency for Healthcare Research and Quality (AHRQ) lists patient safety organizations which work with providers to improve quality and safety through the collection and analysis of aggregated, confidential data on patient safety events.

PSQIA authorizes our government’s Health & Human Services (HHS) to impose civil money penalties (CMPs) for violations of patient safety confidentiality. The Office for Civil Rights (OCR) has been delegated the responsibility for interpretation and implementation of the confidentiality protections and enforcement provisions. When OCR is unable to achieve an informal resolution of an indicated violation through such voluntary compliance, the Secretary may impose a CMP of up to \$11,000 for each knowing and reckless disclosure of PSWP that is in violation of the confidentiality provisions.

To encourage the reporting and analysis of medical errors, PSQIA provides federal privilege and confidentiality protections for patient safety information, called patient safety work product (PSWP).

PSWP: The Patient Safety Work Product

PSWP includes patient, provider, and reporter identifying information that is collected, created, or used for patient safety activities.

The PSWP is both privileged and confidential under the PSQIA. PSWP is confidential and may only be disclosed in certain, very limited situations, where civil money penalties (CMPs) for impermissible dis-



closures of this information can be imposed.

What It Includes

PSWP is considered any data, reports, records, memoranda, analyses (such as root cause analyses), gap analysis, 8D approach, and written or oral statements that are: assembled for reporting to a Patient Safety Organization (PSO), reported to a PSO, or developed by a PSO for the conduct of patient safety activities that could result in improved patient safety, healthcare quality, or healthcare outcomes. It also applies to data used in a patient safety evaluation system (PSES).

PSWP may also include patient information that is protected health information as defined by the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (see 45 CFR 160.103).

What PSWP Is Not

PSWP differs from HIPAA as PSWP does not include a patient's medical record, billing and discharge information, or any other original patient or provider record. It does not include information that is collected, maintained, or developed separately, or exists separately, from a patient safety evaluation system.

HIPAA: The Health Insurance Portability and Accountability Act

According to the final PSQIA rule, the HIPAA Privacy Rule does not require covered providers to obtain patient authorizations to disclose patient safety work product containing protected health information to PSOs. This is because patient safety activities are considered healthcare operations, typically addressed in the Covered Entity's Notice of Privacy Practices (NOPP). PSOs are business associates and should be operating under a Business Associate Agreement or BAA to be compliant under HIPAA rules.

As a Covered Entity (CE) or Business Associate (BA) under HIPAA, regulated entities are required to implement a security management process to prevent, detect, contain, and correct security violations. This process includes conducting a risk analysis to assess potential risks and vulnerabilities to the confidentiality, integrity, and availability of ePHI and implementing security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level.

A regulated entity that has weak cybersecurity practices makes itself an attractive soft target. Hackers can penetrate a regulated entity's network and gain access to ePHI by exploiting known vulnerabilities. Malicious cyber-attacks targeting the healthcare

sector continue to increase.

Conclusion

PSQIA, PSWP, and HIPAA are government regulations working together to link healthcare quality and patient safety with privacy and security of privileged information.

All healthcare providers are expected to investigate any patient safety issues and stay HIPAA compliant while doing so. Sharing information to improve quality and safety in our healthcare environment is needed to mitigate risk and promote improved reimbursement.

Online Training Options

CEs and BAs are encouraged to have C-Suite and management teams trained in HIPAA privacy. AIHC offers an online HIPAA Privacy course worth 12 AHIMA/AIHC CEUs.

Learn more about the basics of Quality, Root Cause Analysis and the 8 Disciplines – Register for the online training Quality, Root Cause Analysis (RCA) & the 8D Approach – Short Course.

Quality and Patient Safety Resources

For tips on preventing medical errors and promoting patient safety, measuring healthcare quality, consumer assessment of health plans, evaluation software, report tools, and case studies, visit the Agency for Healthcare Research and Quality (AHRQ) website and sign up for email updates.

The National Advisory Council (NAC) for Healthcare Research and Quality provides advice and recommendations to AHRQ's director and to the Secretary of the Department of Health and Human Services (HHS) on priorities for a national health services research agenda.

AIHC Volunteer Education Committee with Joanne Byron as the contributing editor. American Institute of Healthcare Compliance

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As CMS Focuses on Quality, There Are Monumental Changes to Reimbursement for Quality on the Horizon!

The Centers for Medicare and Medicaid Services (CMS) utilizes risk adjustment factors to estimate the cost of Medicare Advantage (MA) beneficiaries and those associated costs of providing care. Risk adjustment factor scores govern the amount paid by the health plan during the year for the beneficiary's care.



The risk adjustment scores factor in demographic and specific life and health information, such as the beneficiary's:

- Age
- Biological sex
- Geographical location
- Dual coverage eligibility
- Acquired health status
- Active medications
- The presence and active nature of multiple chronic conditions whose level of severity are much greater, and the estimated cost to treat the beneficiary are estimated at higher benchmarks.

CMS released the "Advanced Notice of Methodological Changes for CY 2024" on May 1, 2023. The change will affect MA capitation rates, along with Part C and Part D payment policies. The Advanced Notice describes the drastic changes to the MA risk adjustment model, from Version 24 to Version 28.

CMS noted that the change from Version 24 to Version 28 was initiated to better align with Medicare Fee-for-Service (FFS) to clinically identify those conditions which may have a coding variation. In the latter portion of CY 2022, CMS released numerous audit findings, noting the Risk Adjustment Model included ICD-10-CM diagnosis categories that could include variations leading to inappropriate assignment by providers. CMS also cited that the diagnosis

codes did not provide a clear picture of future cost predictors. This, along with the Hierarchical Condition Categories (HCC) payment models becoming insignificant, including diagnoses that were rarely seen, did not meet coding specificity criteria.

The CMS-HCC model was initiated in 2004 and is becoming increasingly prevalent as the environment shifts to value-based payment models.

The HCC coding relies on ICD-10-CM coding assignments to translate to risk scores for patients. An HCC is mapped to a specific ICD-10-CM code. The current HCC model has been used with minor updates year after year but has remained standard since 2015. However, with the initiation of Version 28, there will be a significant change to that model. This will affect the way we do business across MA plans.

Once the new Version 28 (V28) is released, provider documentation will be even more critical to assign the best and most proper code to capture the most accurate HCC assignment. This is because the volume of ICD-10-CM codes are going to be reduced and may affect the scores of a large percentage of beneficiaries who may have scores higher than they would after the V28 change.

One of the largest changes to the RA model for CY2024 is the expansion of HCC categories from 86 to 115. However, with the deletion of 2,194 diagnosis codes that currently risk adjust, the same conditions will no longer lead to additional payment. For

example, in V28, diabetes will limit the coefficient categories that also currently carry the same HCC weight, because CMS adjusted all the relative factor weights for diabetes codes and reclassified them into four levels instead of three. Additionally, the risk adjustment model is going to drop solid organ transplants, and instead will classify under the specific body system.

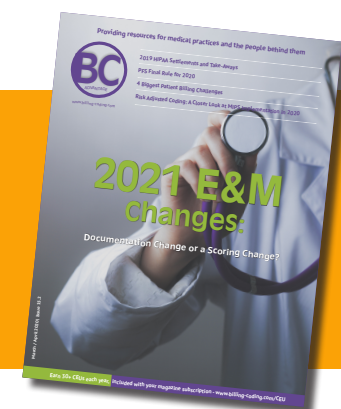
In another example, diabetes with peripheral vascular disease carried a risk adjustment weight of 0.302 in V24 with the addition of the disease coefficient of 0.288 for peripheral vascular disease. However, in the V28 model, diabetes has been recalculated to a lower risk adjustment score of 0.166 and no longer contains the disease coefficient interaction for peripheral vascular disease. This change, which is a common condition in member populations that currently risk adjust results in V28 lowering the risk adjustment score by 0.424 for its reimbursement calculation.

It will be imperative to capture disease interactions, such as type II diabetes with congestive heart failure, to receive the coefficient amounts, where in V24, underlying complications of diabetes also calculated to a coefficient.

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The CERT Program:

What It Is and What a Practice Needs to Know

The Comprehensive Error Rate Testing (CERT) program is a crucial component of the Medicare program that helps ensure the government is paying only for the services and care that beneficiaries actually receive. The program is designed to identify improper payments made to healthcare providers and suppliers under Medicare Part A and B and Durable Medical equipment MACs (DMACs). This article will explore what the CERT program is, how it works, what a practice should do if a CERT request for records arrives, and how the CERT report can be used to help a practice stay compliant.

What Is the CERT Program?

In 1996, the measurement of the Medicare FFS improper payment rate commenced. The estimation of the national Medicare FFS improper payment rate from 1996 through 2002 was the responsibility of the Office of Inspector General (OIG) under the Department of Health and Human Services (HHS). The OIG's sampling method was designed to only determine a national Medicare FFS paid claims improper payment rate. However, due to the small sample size of approximately 6,000 claims, the OIG was unable to produce valid breakdowns of improper payment rates by contractor, contractor type, service type, or provider type. The OIG recommended an increase in sample size, which

was implemented by CMS when they began producing the Medicare FFS improper payment rate in 2003 with the CERT program. It has been updated periodically to reflect changes in Medicare policies and regulations. The program is overseen by CMS and is carried out by a contractor that is responsible for collecting and analyzing the data.

The goal of the CERT program is to quantify the rate of improper payments made by the Medicare program and to identify the root causes of these errors. The program collects data on a sample of claims that have been paid by Medicare and then reviews those claims to determine if they were paid

correctly. The program then calculates an error rate based on the number of claims that were paid incorrectly.

According to the Centers for Medicare & Medicaid Services (CMS), the CERT program is designed to provide a national estimate of the Medicare fee-for-service (FFS) improper payment rate. The program is also used to identify areas of vulnerability in the Medicare program and to develop strategies to reduce improper payments.

How Does the CERT Program Work?

The CERT program uses a statistically valid stratified random sampling process to select about 50,000 claims that will be reviewed. The sample is drawn from claims that have been paid by Medicare Parts A and B during a given year. The sample is stratified by provider type and by the amount of the claim. An independent medical review contractor then reviews each claim to determine if it was paid correctly. If a claim is found to be paid incorrectly, the contractor will calculate the amount of the overpayment or underpayment.

The CERT review auditors look for five specific types of billing and medical necessity errors that cause improper payments:

- Duplicate payments
- Payments for incorrect amounts
- Payments for ineligible services
- Payments for services not rendered
- Payments to ineligible recipients

Billing errors occur when a healthcare provider or supplier bills Medicare for services or items that were not provided or were provided at a different level of care than what was billed. Medical necessity errors occur when a service or item is not medically necessary or is not supported by the medical record.

The results of the CERT program are published annually in a report that is available to the public. The report includes the error rate for the year, the types of errors identified, and the root causes of those errors. The

report also includes recommendations for improving the Medicare program and reducing improper payments.

The most recent report (2022) found that the Medicare FFS improper payment rate was 7.46%, or \$31.46 billion, in improper payments.

The report also broke the error rate down by the top reasons for improper payments:

- **Insufficient documentation:** This error indicates that the provider's documentation is insufficient to determine whether the claim is payable. Examples are inadequate documentation or documentation that is missing elements that are required as a condition of payment. This accounted for 63.6% of the errors in the 2022 report.
- **Incorrect coding:** This error may indicate things like the incorrect code was reported for the services provided, the services were performed by someone other than the billing provider, and the services reported were unbundled.
- **No documentation:** This error indicates that the provider does not supply the records requested.
- **Lack of medical necessity:** This error indicates that the services billed were not medically necessary based upon Medicare coverage and payment policies.
- **Other:** This error is used for any error that does not fit in any of the above error reasons.

The report recommended several strategies for reducing improper payments, such as increasing education and outreach to healthcare providers, improving claims processing systems, and enhancing the use of data analytics.

The CERT program has been successful in identifying improper payments and reducing the rate of errors in the Medicare program. Since the program was implemented, the overall error rate has decreased from 14.2% in 1996 to 7.25% in 2020. The program has also helped to identify areas of vulnerability in the Medicare program and to develop strategies for reducing improper payments.



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- Utilize the revised 2023 Medical Decision Making (MDM) Table in CPT to review E/M services.
- Demonstrate to physicians and other providers proper documentation that supports the level of services reported.

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Betty A. Hovey is a seasoned healthcare professional with over three decades of experience in the field. She has extensive experience conducting audits for medical practices and payors. She specializes in educating various groups including coding professionals, auditors, doctors, APPs, payors, and others on coding, billing and related topics. Betty is a highly sought-after speaker and has co-authored manuals on ICD-10-CM, ICD-10-PCS, E/M, and various CPT specialty areas.



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Why Is the CERT Program Important?

In addition to its primary function of identifying improper payments, the CERT program also provides valuable data to researchers and policymakers. The data collected by the program can be used to identify trends and patterns in Medicare claims and to develop policies and regulations that improve the quality and efficiency of healthcare delivery.

The CERT program is an essential component of the Medicare program. The program provides critical information about the state of the Medicare program and helps to ensure that taxpayer dollars are being used in the most efficient and effective manner possible.

Once the CERT report is given to the Medicare Administrative Contractors (MACs), they must remit any underpayments to providers and recoup any overpayments. Besides that, they can also require prepayment reviews of all a provider's future Medicare claims, suspend the provider from the program, or refer a provider to a law enforcement agency for further review. So, any CERT request for records must be acted upon.

What to Do if a Records Request Arrives at a Practice

A practice may want to contact a healthcare attorney should they receive a request for records notifying them they are under a CERT audit. This can be especially helpful if the practice has never undergone a CERT audit. The request will specify that it is a request for records for a CERT audit. The practice needs to be aware of the deadline for submission of records, which is within 45 calendar days of the request. If the practice needs more time, an extension can be requested to comply with the record request. If the practice is notified that errors were found and overpayments are requested to be paid back, the practice can appeal the decision to their MAC. The process will follow the normal Medicare appeals process: redetermination, reconsideration, administrative law judge (ALJ), appeals court, and finally to a federal district court.

A practice should have protocols set for requests of

CERT records. This will help ensure that the practice does not miss the deadline for submission of the records. The practice should have an employee that is responsible for overseeing the records submission. This will help to ensure that everyone knows who is responsible for overseeing the records submission and who the backup person is in case the main person is out of the office.

Here are steps to take if a records request is received:

- **Verify the request:** Make sure that the request is legitimate. CERT requests are typically sent by mail and include a unique control number. If you have any doubts about the authenticity of the request, contact the CERT contractor to confirm.
- **Review the request:** Carefully read the request and identify the specific information that is being requested. This may include medical records, billing information, and other documentation related to the patient's care.
- **Gather the information:** Collect all the information requested in the request. Make sure that the information is accurate and complete.
- **Organize the information:** Organize the information in a clear and logical manner. Use tabs or dividers to separate different types of documents.
- **Make copies:** Make copies of all the documents being submitted. Keep a copy of everything sent together for reference.
- **Submit the information:** Send the requested information to the address specified in the request. Make sure that the information is sent within the specified time frame.
- **Follow up:** After submitting the information, follow up with the CERT contractor to confirm that they have received it. Keep a record of all communications with the contractor.

Receiving a CERT records request can be a daunting experience for a medical practice. A consultant can assist in organizing the requested records and ensuring that they are complete and accurate. They can also provide guidance on how to respond to the request, including timelines and any necessary documentation.

A healthcare attorney can provide legal advice and representation throughout the audit process. They can help to identify any potential legal issues or liabilities and provide guidance on how to address them. Additionally, they can help to negotiate any settlements or appeals that may arise from the audit.

It is important to note that failing to comply with a CERT records request can result in serious consequences, including fines, penalties, and even exclusion from Medicare and Medicaid programs. As such, seeking the guidance of a consultant and healthcare attorney can help to mitigate these risks and ensure that the medical practice is in compliance with all relevant regulations and laws.

How the CERT Report Can Be Used to Keep a Practice Compliant

The yearly CERT report can be a valuable resource for a medical practice to stay compliant with Medicare regulations. The report provides information on the improper payment rates for Medicare claims, including the types of errors that were made and the reasons for those errors.

By reviewing the CERT report, a medical practice can identify any areas where they may be at risk for non-compliance and take steps to address those issues. For example, if the report shows a high rate of errors related to coding or documentation, the practice may need to provide additional training to staff members on these topics.

Additionally, the CERT report can be used to monitor the effectiveness of any compliance measures that have been implemented. By comparing the results of the report from one year to the next, a practice can determine whether their efforts to improve compliance have been successful or if further action is needed.

Overall, the yearly CERT report can serve as a valuable tool for a medical practice to maintain compliance with Medicare regulations and ensure they are providing high-quality care to their patients.

In Conclusion

The CERT program has been around since 1996 and is used to estimate the national Medicare FFS improper payment rate. A practice needs to have a plan on how to respond if they receive a CERT records request. Since the CERT contractor may refer a practice for further review from other agencies, it is important to follow the request and respond within the given time frame. External assistance from a healthcare consultant and healthcare attorney may be warranted.

Betty Hovey, CCS-P, CDIP, CPC, COC, CPMA, CPCD, CPB, CPC-I, is the Senior Consultant/Owner of Compliant Health Care Solutions, a medical consulting firm that provides compliant solutions to issues for all types of healthcare entities.

Compliant Health Care Solutions (CHCS) was founded by Betty A Hovey, BSHAM, CCS-P, CDIP, CPC, COC, CPMA, CPCD, CPB, CPC-I. Coders, Auditors, Physicians, Other Providers, Clinics, and Facilities need assistance in navigating today's healthcare environment, especially when it comes to coding and compliance. CHCS' philosophy is to offer every single client extraordinary service that is customized to their situation. No cookie-cutter answers here. Each person, practice, and situation is unique; so is our response. We are honored to partner with every client we serve and will continue to show it for the long haul.

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Sources:

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Becoming a Resilient Leader During Trying Times

Resilience is the ability to confidently face challenges, embrace change, recover from setbacks, and bounce back from adversities. This can be extremely difficult for leaders in today's healthcare environment. Increasing your resilience is easier said than done, especially post-COVID. This article provides insight to managers on how to succeed in a competitive, challenging industry.



Are You a Leader or Manager—or Both?

Leadership, as defined by the Oxford Dictionary, states that leadership is “the action of leading a group of people or an organization.”

The terms leadership and management tend to be used interchangeably, and while healthcare leaders must have strong management skills, the terms are not the same. Both leaders and managers must seek accomplishment with resources at their disposal, but true leadership requires more. Leadership requires traits that extend beyond management duties, such as creative problem-solving (CPS) and “thinking outside the box,” which is a metaphor that means to think differently, unconventionally, or from a new per-

spective. The phrase also often refers to novel or creative thinking.

Becoming a resilient leader is about taking risks and challenging the status quo. It means you can motivate others to achieve something new and better and reinvent pathways for those you are leading to succeed, even during these challenging times. This can lead to increased trust and respect in the top-down approach (filtering down from the top of the organizational structure).

It is necessary to address near-misses, incidents, audit failures, and other reportable situations. But sometimes focus-

ing only on the negative only attracts more negative.

The human brain has a natural tendency to give weight and to remember negative experiences or interactions more than positive ones. Why? They stand out more.

Psychologists refer to this as *negativity bias*. “Our brains are wired to scout for the bad stuff” and fixate on the threat, says psychologist and author Rick Hanson. As a leader, we need to find a way to break the negative bias “cycle” and maintain a more positive attitude, especially during trying times.

From my personal experience, keeping a positive attitude (although extremely difficult at times) is best achieved by leading with strength, wisdom, and kindness. These are traits we want to see in our healthcare providers, nursing staff, and other direct care workforce members. But how can we expect these traits if the work environment lacks encouragement and doesn't reward behavior required to provide compassionate care and support a culture of compliance?

Begin by acknowledging success at all levels. Each success builds better relationships and promotes a culture of compliance in the organization. The management of a small project can be delegated and used as a teaching or mentoring moment to encourage that person to be more, do more, and contribute more.

Resilient Leaders Build Workforce Resilience

Traits demonstrating resilience will be recognized by your workforce, and by C-suite executives. People believe what they see, and a true leader is seen as an optimist—even during the most stressful of times. Winston Churchill said it best: “A pessimist sees the difficulty in every opportunity; an optimist sees the opportunity in every difficulty.”

If your tendency is to be a perfectionist and likely a pessimist, the first step is to recognize this trait and work to see the good that can come out of a difficult situation. You first need to transform yourself before transforming your workforce.

If you are uncomfortable in leading people, try the mentoring

approach first.

When I first transitioned from nursing to coding and reimbursement, I had to develop a different skillset when working with our clinic's providers. I started night classes at a local college, taking business communication and leadership courses, which helped. But excelling is credited to my mentors. My most influential mentor was Vice President (VP) of the healthcare organization where I worked for 10 years. He took me under his wing as he coached and encouraged me after a promotion into management.

I learned so much just by watching how he was never late for a meeting out of respect for another's time (which gained respect back), and how he listened carefully to what others had to say. He taught me how to not jump to conclusions, to be more observant during high-power meetings, and to believe in myself. Another mentor, the Chief Financial Officer (CFO), took the time to teach me how to navigate the Medicare & Medicaid rules and regulations which I, in turn, used to win huge appeals for my organization. He was my tactical mentor and also guided me through the politics of a large healthcare organization.

Staying competent is only part of what is needed to be resilient in any profession. I needed confidence, which is huge when working with physicians. How can providers have confidence in you if you don't have confidence in yourself? Without confidence, competence, and strength, the providers would resist change, and my workforce would fail. I asked for direction and guidance from my primary mentor and learned about strengthening my leadership skills so I could become more effective with my interactions with the physicians. I must have achieved this, because it was noticed, and additional advancement came.

When you are mentored, it makes it easier to realize what it takes to mentor others. Mentoring others helped increase my resilience, even during a major takeover of our clinic by a large hospital system.

An important aspect of mentoring others is to foster psychological safety, which is the belief that the work environment is safe for interpersonal risk taking. It leads to authentic conversations,

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which promote problem solving, innovation, connection, and growth. This practice is built into the culture over time and requires leaders to respond to staff challenges by modeling authenticity, accountability, and compassion, and by creating space for sharing and listening.

If you can't change the organizational culture, at least improve the culture within your own department. Other leaders in your organization will notice and you might become a trendsetter!

The Challenge in Leading Remote Workers

Build meaningful connections with your remote workforce. A study conducted by the O.C. Tanner Institute in the 2022 Global Culture Report states that 45% of employees say the number of individuals they regularly interact with at work has decreased significantly over the past year, and one in three employees feel disconnected from their supervisor. They also report that an organization is 12 times more likely to thrive when employees feel connected.

Find creative ways to connect, such as through more frequent information sharing or education sessions, etc. Encourage your staff to share their thoughts. Consider creating a policy that if someone brings a problem to the table (or virtual table), only bring it if they can suggest at least one solution. This type of policy stops complaining and creates a more constructive conversation, whether it is in a virtual group session or one-on-one.

Another policy that is recommended: Don't have meaningless and time-consuming meetings—remote or in person. Be prepared, expect everyone to be on time, and have an agenda published in advance. It is easy to check off topics and create worklists, but first, have discussion and listen to ideas to gain insight on perhaps doing things not only different but better than before.

Apply the Pareto Principle (also known as the 80/20 rule) correctly; avoid 80% of the time used in a meeting to cover 20% of the “meat” in your remote or in-person meetings!

Consistent practices, such as frequent check-ins; supporting peer mentorship; normalizing discussions around

change; and finding shared purposes all build meaningful connections, even in our virtual and hybrid settings.

Conclusion

Join other organizational leaders, managers, and human service experts to explore concepts and strategies that are foundational to building a workforce that can stay well and healthy, even amid constantly changing environments.

As a leader, encourage a positive organizational culture, which is critical for supporting staff as they partner authentically with patients, families, and communities, who often experience complex challenges, systemic inequities, and personal trauma.

This means avoiding toxic stress, mitigating its impact, and building healthy and realistic expectations. It is tempting to hire a consultant to “reinvent” the organizational structure. From my experience, it typically ends by solving some problems but creating more in another area, resulting in a negative gain overall. Resist trends which cost a bundle, upend the organization, and can result in distrust with your workforce. Be transparent, be a compassionate and good listener, and display traits that you want to see in your own workforce.

Investing in your workforce can improve productivity, encourage confidence, and maintain a high-performance culture, which is more likely to engage employees. In healthcare, the return on this investment can be measured in reduced turnover, in a heightened ability to deliver improved quality care, and in drawing higher-quality people to apply for open positions—because your organization has become the place to work.

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ERISA

Overview for Healthcare Providers: Part I

In the United States, approximately 88% of the employees who are enrolled in employer-sponsored health insurance benefits have plans that are subject to ERISA regulations.

ERISA is the acronym for the Employee Retirement Income Security Act, which is a federal law that was enacted in 1974 to protect employees who participate in employer-sponsored benefit plans. Among the employer-sponsored plans that are covered under ERISA are health insurance plans, retirement plans, disability plans, and life insurance plans. It is important to note that not all employers that offer employee benefits are subject to ERISA. Employer sponsored plans that are offered by religious organizations, government entities, and small employers with fewer with 100 participants are not subject to ERISA. The employer-sponsored health benefit plans subject to ERISA's provisions include those that are intended to provide "medical, surgical, or hospital care or benefits, or benefits in the event of sickness, accident, disability, death..."

ERISA protects employees in several ways. ERISA imposes fiduciary duties on plan administrators and trustees who are responsible for managing and overseeing employee benefit plans. Regarding retirement plans, ERISA establishes minimum vesting standards, which determine when employees have a non-forfeitable right to their accrued benefits. This ensures that employees who have contributed to a retirement plan or earned benefits over time are entitled to receive those benefits, even if they leave their job before retirement. With respect to ERISA-covered health insurance plans, these fiduciary duties require plan administrators to act in the best interest of plan participants and beneficiaries. Whether it is an ERISA-covered retirement plan or a health insurance plan, employers are required to provide plan participants with important information about their benefit plans. ERISA-covered employers that offer health insurance benefits to their employees must furnish them with a summary plan description (SPD). The SPD describes the health insurance benefits provided and how the plan works. Specifically, the SPD is a "written instrument which describes the terms of the plan, identifies the plan under which it is established, provides information as to the sources of contributions to the plan, advises the participants and beneficiaries of their rights and obligations under the plan, explains the procedures to be followed in presenting a claim for benefits under the plan,

and sets forth the provisions for review of denied claims." ERISA also provides a legal framework for plan participants and beneficiaries to bring lawsuits to enforce their legal rights.

ERISA plan participants are generally entitled to the benefits that are provided by their employee benefit plans, under the terms and conditions outlined in the plan documents. But, benefits can be denied under ERISA if the plan administrator determines that the benefits sought do not meet the eligibility requirements, are not covered under the plan, or do not meet the plan's criteria or standards. ERISA uses the term, "adverse benefit determination" for denied benefits. The term "adverse benefit determination" means a "denial, reduction, or termination of, or a failure to provide or make payment (in whole or in part) for, a benefit resulting from the application of any utilization review, as well as a failure to cover an item or service for which benefits are otherwise provided because it is determined to be experimental or investigational or not medically necessary or appropriate." When a claim for benefits is denied, ERISA requires the employer's health benefit plan to provide the plan participant or beneficiary with written notice which identifies the specific reasons for the denial. The written notice must be "in a manner calculated to be understood by the participant." In addition to identifying the specific reason(s) for the adverse benefit determination, the

notification must make a reference to the specific plan provision(s) upon which the adverse determination is based, describe the additional information that is necessary for the beneficiary to perfect the claim for benefits, and provide an explanation of why such information is necessary.

ERISA permits the medical provider to act as the beneficiary's authorized representative when appealing adverse benefit determinations. ERISA requires the health insurance benefit plan to provide a framework to appeal adverse benefit determinations. The appeal process must offer a full and fair review of the health insurance claim and the adverse benefit determination. The appeal must be initiated within 180 days of the beneficiary's notification of the adverse benefit determination. The insurance company or plan administrator generally has 60 days to respond to the appeal. The entire appeal process typically involves several levels of review, including an initial review, an appeal, and a final review by an independent reviewer or arbitration.

In appealing the insurance claim denial, medical providers can take the following steps:

- Obtain a copy of the patient's insurance policy and the plan documents (SPD) to gain an understanding of the terms and conditions of the policy and the reason for the denial.
- Ensure that the services or treatments sought are covered under the plan and determine if any specific exclusions or limitations apply.
- Review the denial letter provided by the insurance carrier or plan administrator; this should provide a written explanation for the claim denial. Note that an explanation of benefits (EOB) alone likely will not satisfy ERISA's notification requirements.
- Scrutinize the rationale provided in the denial notice and assess whether the plan administrator or health insurer has adequately explained their decision and provided sufficient evidence or documentation to support their determination. Identify potential errors in their reasoning.
- If the denial notice is unclear or lacks specific information, contact the plan administrator or insurer for clarification. Request additional documentation to obtain clarity to the explanation offered as the reason behind the adverse benefit determination.
- Gather relevant medical records and documentation that support the medical necessity of the services that were provided.
- File a written appeal within the timeframe specified in the denial letter. The written appeal should be comprehensive and well-documented. It should outline the reasons why the adverse benefit determination should be overturned.

Clearly identify errors or omissions in the initial decision and provide robust evidence in support of your position.

- The appeal should include a detailed explanation of why the claim should be approved. Include the supporting documentation and a copy of the denial letter.
- Calendar the date for which the insurance company or plan administrator is obligated to provide a response to the appeal.

To the extent possible, the healthcare provider should take all necessary steps to avoid denials in the first place by controlling what they can on their end.

Healthcare providers who provide care to patients with health insurance plans falling under ERISA should ensure that their billing department takes the following steps:

- Verify the patient's coverage and understand the terms and provisions of the specific plan to determine the benefits available, coverage limitations, and requirements for obtaining those benefits.
- Obtain a valid assignment of benefits for the right to seek payment directly from the health insurance plan on behalf of the patient. A valid and enforceable assignment of benefits must be in place to pursue claims on behalf of the patient.
- Comply with the plan's claims submission requirements and deadlines to ensure timely reimbursement.
- Establish communication channels with the plan administrator or the designated claims administrator for the plan to clarify coverage, understand the claim submission processes, and to address questions or concerns regarding reimbursement.
- Be aware of the process for appealing denied claims and the timeframes for which an appeal process must be initiated.
- Request a copy of the SPD or other relevant plan documents from patients to better understand the plan's provisions.

When a medical provider requests the SPD from an employer, the employer must respond within 30 days of the request. If the employer fails to respond or provides incomplete or inaccurate information, the medical provider may file a complaint with the Department of Labor's Employee Benefits Security Administration (EBSA). The EBSA is responsible for enforcing ERISA regulations and can provide assistance in obtaining plan documents. If an employer fails to comply with a request for the SPD within the required timeframe, it may be subject to penalties and enforcement action by the EBSA. Penalties for failing to provide the SPD can include fines of up to \$110.00 per day per participant

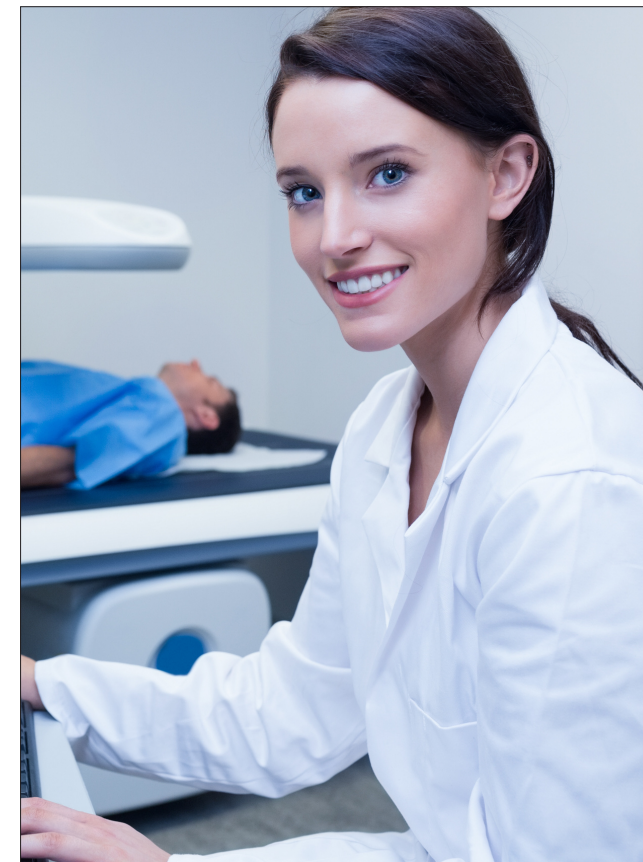
or beneficiary who is denied a copy of the SPD. In addition, the EBSA may seek an order requiring the employer to provide the SPD and may take other enforcement action as necessary.

If a healthcare provider exhausts all of the administrative appeals processes, legal action can be a consideration. Healthcare providers can file suit against the health insurer if there is a valid assignment of benefits from the plan beneficiary. ERISA provides a private right of action to file suit against the health insurer to recover the value of the benefits that are provided under the plan. Healthcare providers do not have direct statutory authority under ERISA to sue for benefits. The healthcare provider's ability to file suit against the health insurance plan is derived from an assignment of the plan beneficiary's rights. However, before any suit can be initiated, the beneficiary must first exhaust the plan's internal appeals process. In addition to seeking damages for the wrongfully denied benefits, ERISA permits the prevailing party to recover reasonable attorney's fees and litigation costs. Of course, filing suit is a last resort.

As stated earlier, not all health insurance plans are ERISA plans. While approximately 88% of the employees who receive employer-sponsored health insurance benefits have ERISA-covered

plans, 12% of employees with employer-sponsored health insurance have plans that are governed under state law, not ERISA. With respect to state laws that govern health insurance benefits, those laws are preempted when the plan falls under ERISA, if those laws "relate to any employee benefit plan." A state law pertaining to insurance is "preempted" and therefore unenforceable when it is inconsistent with ERISA's regulatory scheme. Stay tuned for Part II.

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If Conduct Appears to Buck the Legal Norm, Chances Are That It Does

It's akin to wearing Doc Martens to a professional cocktail party reception or Uggs to court. In other words, the wardrobe choice jumps out as not being appropriate for the situation. Likewise, certain conduct that violates the Anti-Kickback Statute (AKS) and the False Claims Act (FCA) unequivocally jumps out as being unlawful under the facts and circumstances, yet persons engage in the inappropriate behavior.

Analysis
Codified at 42 U.S.C. § 1320a-7b(b), the AKS has been around since 1972. The AKS was “enacted to ensure that clinical decisions and medical services are provided to patients based on their medical needs and not on the improper financial considerations of providers.” Unless a “safe harbor” (42 U.S.C. §1001.952) is met, then liability is highly probable. According to the U.S. Department of Health and Human Services - Office of the Inspector General (HHS-OIG), a safe harbor is to “describe various payment and business practices that, although they potentially implicate the Federal anti-kickback statute, are not treated as offenses under the statute.”

The FCA is the federal government's primary tool in fighting fraud. As the U.S. Department of Justice (DOJ) explained in its annual press release relaying the results for the previous fiscal year (FY 2022), the FCA “imposes treble damages and penalties on those who knowingly and falsely claim money from the United States or knowingly fail to pay money owed to the United States. The False Claims Act thus serves to safeguard government programs and operations that provide access to medical care, support our military and first responders,

protect American businesses and workers, help build and repair infrastructure, offer disaster and other emergency relief, and provide many other critical services and benefits.”

In this same FY2022 Report, the DOJ emphasized the impact that the AKS has on FCA cases. Before delving into specific examples, it is important to note material changes that occurred as a result of the Affordable Care Act, which was signed into law on March 23, 2010. ACA changed the language of the AKS to expressly include claims submitted in violation of the AKS that automatically constitute false claims for purposes of the FCA. Specifically, the language provides that “a claim that includes items or services resulting from a violation of [the Anti-Kickback Statute] constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31 [the False Claims Act]” (42 U.S.C. § 1320a-7b[g]). Additionally, Congress added a new provision that eliminates the requirement that a person have actual knowledge of the law or specific intent to commit a violation of the statute. See 42 U.S.C. § 1320a-7b(h).

This brings us to some key FCA settlements, which were premised on AKS violations and were expressly mentioned by the DOJ. Specifically:

- The department intervened and pursued claims under the False Claims Act in several qui tam actions alleging kickback violations. For example, the department filed a complaint against two laboratory CEOs, a hospital CEO, six physicians, and other individuals and entities, alleging False Claims Act violations based on patient referrals in violation of the Anti-Kickback Statute (AKS) and the Stark Law, as well as alleging that defendants caused claims to be improperly billed to federal healthcare programs for medically unnecessary laboratory testing.
- The department also filed suit against a chiropractor, 15 office-based labs primarily owned by the chiropractor, and five affiliated companies owned by the chiropractor, alleging that the defendants offered physicians the opportunity to invest in the labs to induce them to refer their Medicare and TRICARE patients to the labs for the treatment of peripheral arterial disease.
- Fiscal year 2022 also saw the resolution of numerous matters involving kickback violations. In a case pursued by a whistleblower, the pharmaceutical company Biogen Inc. paid \$843.8 million to resolve allegations that the company offered and paid kickbacks, including in the form of speaker honoraria, speaker training fees, consulting fees, and meals, to physicians who spoke at or attended Biogen programs in connection with Biogen's multiple sclerosis drugs Avonex, Tysabri, and Tecfidera. The relator alleged that this conduct occurred between 2009 and 2014.
- Durable medical equipment manufacturer Philips RS North America, LLC, formerly Respironics, Inc., paid \$24.75 million to resolve allegations that it knowingly provided unlawful kickbacks to DME suppliers to induce them to select Respironics' respiratory equipment. The inducements allegedly came in the form of physician prescribing data that Respironics provided free of charge yet knew was valuable in assisting DME suppliers' marketing efforts to physicians.
- Flower Mound Hospital Partners LLC, a partially physician-owned hospital, paid \$18.2 million to resolve allegations that it knowingly submitted claims to federal healthcare programs that arose from violations of the Stark Law and the AKS. The government alleged that the hospital repurchased shares from physician-owners aged 63 or older and then resold those shares to younger physicians, impermissibly taking into account the volume or

value of physician referrals when selecting the physicians to whom the shares would be resold and determining the number of shares each physician would receive.

- Kaléo Inc. paid the United States \$12.7 million for alleged false claims for the drug Evzio, used to reverse opioid overdoses, for providing illegal remuneration to prescribing physicians and their office staff, and for directing physicians to send Evzio prescriptions to certain preferred pharmacies that, in turn, submitted false prior authorization requests to insurers. In addition, the United States obtained a \$1.3 million settlement from pharmacy Solera Specialty for submitting false and misleading prior authorizations for the drug.

This is not the first time that the DOJ or OIG has pursued this type of conduct—it has been doing it for years. It begs the question: Why would entities engage in conduct that is glaring and runs afoul of any comprehensive and substantive compliance program? Stated another way, why would one wear shoes that are not considered appropriate for a legal professional environment?

Conclusion

While I don't have the answer to one's choice of footwear or ignorance of the law when it comes to kickbacks, what I do know is that other people notice. In relation to AKS violations, either OIG or a whistleblower will hone in on the glaring choice. In turn, an FCA case will be filed and consequences for the perpetrator will ensue. Some whistleblowers attempt to raise these concerns and are met with resistance and retaliation, while others simply collect evidence and go to an attorney to file an FCA case. Either way, it's as glaring as wearing Uggs into federal court. A caveat for whistleblowers, make sure that a safe harbor does not apply.

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The Use of “AI” in Healthcare: Proceed With Caution

Unless you have been climbing Mount Everest alone with no cell or Wi-Fi services for the past few months, I am certain you have heard of ChatGPT and its use as a form of artificial intelligence (AI). The reality is that AI, or certainly the concept, has been around for a very long time. Until recently, it’s been much less actual intelligence and more number crunching in that it goes through every variation and combination of responses until it finds one that fits—as opposed to what many conventionally thought AI was: “true intelligence and reasoning.” Well, let’s use some common sense here. AI is “machine learning.” AI has also now leaped into popular and mainstream culture and how we look at innovation and our world going forward.

And, fortunately or unfortunately, healthcare is one industry where this has been an ongoing discussion and raging debate, on both the pros and cons sides of the discussion.

AI has the potential to bring enormous benefits to healthcare by improving diagnosis and treatment, predictive analytics, drug discovery and development, virtual assistants and chatbots, and streamlining administrative tasks. However, to fully realize these benefits, significant challenges such as data privacy and security (HIPAA), bias in the data, lack of transparency, regulation, and governance, AI “hallucinations”—meaning creating its own forethought without foundation—and lack of understanding need to be overcome. It is crucial that healthcare organizations, regulators, and researchers work together to ensure that the technology is used in an ethical, actionable, and meaningful manner.

The pros or the positives first. Again, AI in healthcare has the opportunity to transform the way we diagnose, treat, and prevent diseases. The technology could help improve patient outcomes, reduce costs, and increase efficiency in the healthcare system.

Pros

1. **Diagnosis and Treatment Planning:** AI can be used to analyze imaging, such as X-rays and MRIs, to help doctors identify diseases and plan treatment. For example, AI-powered algorithms can detect signs of cancer in mammograms with a high degree of accuracy, which can help doctors make a diagnosis and plan treatment more quickly (see Fierce Healthcare’s “Google AI Can Outdo the Experts in Finding Breast Cancer”).
2. **Predictive Analytics:** Electronic health records and other patient data can be analyzed by AI to predict which patients are at risk of developing certain conditions. This may help doctors intervene early before a condition becomes more serious and can also help healthcare organizations allocate resources more effectively.
3. **Virtual Assistants and Chatbots:** AI-powered virtual assistants and chatbots can help patients access healthcare information and services in a simpler

and possibly easier fashion. However, this is where improvement needs to be made. For example, a chatbot could potentially answer patients’ questions about their symptoms or help them schedule an appointment with a doctor, but not all rare conditions may be known to the AI bot.

4. **Streamlining Administrative Tasks:** AI can also be used to automate routine administrative tasks, such as scheduling appointments and processing insurance claims. This can help reduce costs and increase efficiency in the healthcare system.

While the potential benefits of AI in healthcare are clear, there are also significant challenges that must be overcome. Here are five that I find the most important:

Cons

1. **Data Privacy and Security:** The use of AI in healthcare requires large amounts of patient data, which raises concerns about data privacy and security. It is important to ensure that patient data is protected from unauthorized access and that patients have control over how their data is used. Companies that engage in the creation of AI platforms will need specific BAAs, HIPAA, and privacy agreements in place, or this could turn into a big marketplace to tag consumers with ads to purchase their products based on shared medical data that should not be shared. Additionally, proper security measures must be put into place in order to protect sensitive patient data from being exploited for malicious purposes.
2. **Bias in the Data:** AI systems can be biased if the data they are trained on is not representative of the population they will be used to serve. This may lead to inaccurate or unfair results, particularly for marginalized communities. I have already experienced this when using the Beta testing ChatBot, and the biases just in mainstream information are severe. This would not serve well in the healthcare field.
3. **Lack of Transparency:** Many AI systems are considered “black boxes or black holes” because it is difficult to understand how they arrived at a particular decision. This lack of transparency can make it difficult for doctors and other healthcare professionals to trust the

- results of an AI system. Who will be monitoring and fact-checking the information?
4. Regulation and Governance: There is currently a lack of clear regulations and guidelines for the use of AI in healthcare. This can make it difficult for healthcare organizations to know how to use the technology responsibly and can also make it difficult for patients to know what to expect when they interact with an AI system. (For more information, read "Why is AI Adoption in Health Care Lagging?" on brookings.edu.)
 5. Lack of Understanding: Many healthcare professionals and patients may not have a good understanding of how AI works and what it can and cannot do. This can lead to unrealistic expectations and mistrust of the technology.

As healthcare organizations increasingly invest in the use of artificial intelligence in healthcare for a range of tasks, the challenges facing this technology must be addressed, as there are many ethical and regulatory issues that may not apply elsewhere.

Some of the most pressing challenges in addition to the above concerns: patient safety and accuracy, training algo-

gorithms to recognize patterns in medical data, integrating AI with existing IT systems, gaining physician acceptance and trust, and ensuring compliance with federal regulations. Currently, there is a lack of federal oversight.

Finally, gaining acceptance and trust from medical providers is critical for successful adoption of AI in healthcare. Physicians need to feel confident that the AI system is providing reliable advice and will not lead them astray. This means that transparency is essential; physicians should have insight into how the AI system is making decisions so they can be sure it is using valid, up-to-date medical research. Let's hope with the rapid rollouts of these platforms, the federal government has a plan to protect consumers before it completely comes to market, or we could have a mess on our hands instead of innovation.

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Monthly Spotlight on Fraud, Waste, and Abuse

The following cases highlight fraud, waste, and abuse (FWA) and serve as a reminder to uphold high ethical standards when providing patient care and services.



A Former Louisiana Hospice Care Owner Convicted of Defrauding Medicare

A federal jury returned a guilty verdict against a former hospice care owner for one count of conspiracy to commit healthcare fraud and three counts of healthcare fraud following a trial that lasted almost one month.

She was the owner of a hospice care corporation that was purported to provide hospice services to patients who were terminally ill.

Through evidence presented at trial, jurors learned that

from approximately 2009 through 2017, over 24 patients were placed on hospice by this hospice care corporation without meeting the criteria required by Medicare.

During the time that the patients were on hospice and under the care and supervision of this hospice entity, none of them had been diagnosed with a terminal illness.

In fact, many of the patients themselves, who are still alive and thriving many years later, as well as family members of other patients, testified that they never knew that they had been placed on hospice.

The testimony revealed that, while on hospice care, many of

the patients were living normal lives, and although most of them did have medical conditions, none had been diagnosed as being terminally ill.

The fraudulent claims submitted to Medicare and reimbursed to the hospice corporation resulted in a loss of approximately \$1.5 million.

As the owner of the hospice care corporation, this woman faces a sentence of up to 20 years in prison on the conspiracy to commit healthcare fraud charge, up to 10 years in prison on the healthcare fraud charges, 3 years of supervised release, and a fine of up to \$250,000.

Read the specifics of this case at www.justice.gov

A South Florida Man Sentenced with Prison Time After Buying and Selling 2.6 Million Medicare Beneficiary Identification Numbers

A man was sentenced in federal court to 41 months in prison following his earlier guilty plea to buying and selling more than 2.6 million Medicare beneficiary identification numbers, along with other personal identifiers.

In one of the first prosecutions brought under The Medicare Access and CHIP Reauthorization Act of 2015 (MACRA), this man was sentenced to 41 months imprisonment following his guilty plea to one count of conspiracy to violate MACRA by buying and selling beneficiary identification numbers.

Among other things, MACRA makes it illegal to buy, sell, or distribute without lawful authority Medicare or Medicaid beneficiary numbers (Title 42, United States Code, Section 1320a-7b[b][4]).

As part of his plea, he admitted that he and his co-conspirators used “data mining” and “social engineering techniques” to collect Medicare beneficiary information, which he then advertised and sold online.

The trafficked information included beneficiary names, addresses, dates of birth, social security numbers, and Medicare beneficiary identification numbers.

According to the indictment, some of the illicit transactions involved foreign actors, including sellers in the Philippines and

buyers in Egypt.

Read more about this case at www.justice.gov

An Adult and Pediatrics Healthcare Practice Has Agreed to Pay \$3 Million to Settle FCA Allegations

A Virginia adult and pediatrics practice has agreed to pay \$3,000,000 to resolve allegations that it violated the False Claims Act by engaging in fraudulent billing activities between January 2017 and May 2021 with regards to pediatric in-home health, personal care, and related services.

From 2017 and continuing through May 2021, this pediatrics healthcare practice allegedly billed its state Medicaid for reimbursements for in-home healthcare services for pediatric patients who were actually hospitalized at the time the in-home services were billed.

They allegedly routinely billed the state Medicaid for home health services that were not actually provided.

The civil settlement includes the resolution of claims brought under the qui tam or whistleblower provisions of the False Claims Act against the adult and pediatrics practice.

The state’s Attorney General said, “Those who take advantage of Virginians during some of their most vulnerable times must be held accountable. Thanks to the excellent work done by my office and our federal partners, this organization will have to answer for its illegitimate billing methods that exploited hospitalized pediatric patients.”

The claims resolved by the settlement are allegations only and there has been no determination of liability.

Read additional details of this case at www.justice.gov

Sonal Patel, BA, CPMA, CPC, CMC, ICDCM, is the CEO and Principal Strategist for SP Collaborative, serving as a partner to healthcare organizations, medical practices, physicians, healthcare providers, vendors, consultants, medical codes, auditors, and compliance professionals to elevate coding compliance education for the business of medicine. <https://spcollaborative.net>

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Our team of auditor/educators spend so much time educating providers, it's appropriate to put that knowledge and skill to work and create a manual specifically for physician, nurse practitioners, and physician assistants!

The goal of our training events are not to convert providers into coders-and the same is true for this resource manual. The manual is created for the provider, and with the provider in mind. The focus is on documentation skills to ensure documentation outcomes are supporting appropriate level of service. The structure of coding, the history of coding, scoring principles, nor the order of E&M code selection are fundamental references in this resource guide.

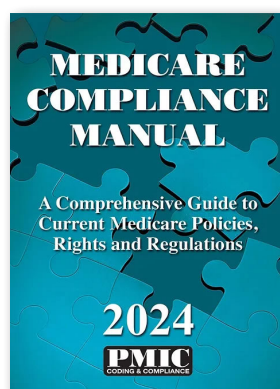
Rather, providers can find resources on how to effectively use SMART documentation tools in their EMR, proper use of addendums, medical necessity in the E&M encounter, documentation guidelines, and even review of clinical vignettes, all using resources and training that is relatable, efficient, and a straightforward approach.



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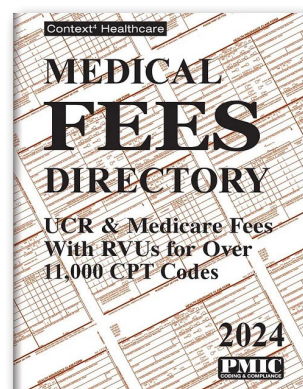
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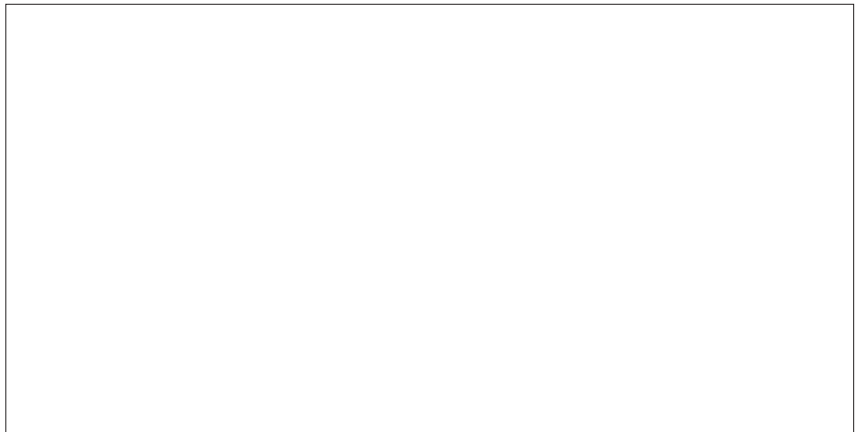
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