CEU quiz for the August 2019 issue of *Compliance Today* magazine

To receive 1.0 non-live Compliance Certification Board (CCB)® CEU for the following quiz, at least three questions must be answered correctly. Only the first attempt at each quiz will be accepted.

Compliance Today quizzes are valid for 12 months, beginning on the first day of the month of issue.
This quiz expires July 31, 2020.

LEARNING OBJECTIVE

After reading **"Human trafficking: Compliance consideration for healthcare professionals" (page 20)** you should be able to answer the following question:

1. **What are two major challenges in combatting human trafficking?**
   A. Costs and resources associated with locating trafficked victims
   B. Identifying victims and providing necessary support services to reintegrate trafficked victims back into society
   C. Surveillance and investigating known traffickers
   D. Identifying suspected traffickers and involving law enforcement

2. **House Bill 3, known as the Human Trafficking Victims' Rights ACT (HTVRA), was passed by the Kentucky General Assembly in 2013, and provides:**
   A. Screening protocols for healthcare entities
   B. Decreased protections for adult trafficking victims
   C. Local non-profit agency support
   D. Increased protections for trafficking victims, training for law enforcement, funding to assist victims, as well as mandatory individual reporting of suspected human trafficking of minors to law enforcement

LEARNING OBJECTIVE

After reading **"The shifting federal analysis of referral relationships in healthcare" (page 38)**, you should be able to answer the following question:

3. **Application of the Federal Travel Act in the *Forrest Park* case was based on alleged violations of:**
   A. Anti-Kickback Statute
   B. State Anti-Bribery Laws
   C. Stark Law
   D. EKRA

LEARNING OBJECTIVE

After reading **"Outpatient therapy: Myths and risks" (page 64)**, you should be able to answer the following question:

4. **CMS considers a Therapy Plan of Care (POC) certification to be timely in what time period:**
   A. Within 48 hours of the initial evaluation
   B. Within 30 days of the initial evaluation
   C. Within 60 days of the initial evaluation
   D. Within 90 days of the initial evaluation

Compliance Today Continuing Education Form

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QUIZ ANSWERS: AUGUST 2019

Article: Human trafficking: Compliance consideration for healthcare professionals (page 20)

Please indicate your answer.

1. ○ A ○ B ○ C ○ D
2. ○ A ○ B ○ C ○ D

Article: The shifting federal analysis of referral relationships in healthcare (page 38)

Please indicate your answer.

3. ○ A ○ B ○ C ○ D

Article: Outpatient therapy: Myths and risks (page 64)

Please indicate your answer.

4. ○ A ○ B ○ C ○ D

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HUMAN TRAFFICKING: COMPLIANCE CONSIDERATIONS FOR HEALTHCARE PROFESSIONALS

by Meagan Parker and Jay Swacker

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Every day, healthcare professionals provide medical care to human trafficking victims—but most are unaware that their patients are victims of this crime. There has been a recent push to raise awareness and train physicians on the signs exhibited by human trafficking victims and ways to effectively help them.[1] One challenge for compliance professionals to consider when providing trauma-informed care to this population of vulnerable patients is how to protect their rights under the Health Insurance Portability and Affordability Act (HIPAA) of 1996.[2] Clinicians may be hesitant to report information related to human trafficking for fear of violating HIPAA or from confusion surrounding state reporting laws. In this article, we will examine how healthcare providers in Kentucky, in particular, have enacted protocols to comply with the state's mandatory reporting law and HIPAA.

Human trafficking in the US

Human trafficking has emerged as one of the fastest growing criminal industries in the world, but comprehensive human trafficking data in the United States is difficult to obtain. Federal law criminalizes trafficking in persons, which includes both sex and labor trafficking. The Trafficking Victims Protection Act of 2000 defines sex trafficking as the recruitment, harboring, transportation, provision, obtaining, patronizing, or soliciting of a person for the purposes of a commercial sex act, in which the commercial sex act is induced by force, fraud, coercion, or in which the person induced to perform such an act has not yet attained 18 years of age. Labor trafficking is the recruitment, harboring, transportation, provision, or obtaining of a person for labor of services, through the use of force, fraud, coercion for the purposes of subjection to involuntary servitude, peonage, debt bond, or slavery.[3]

Due to the stigma and criminalization associated with trafficking, it is empirically challenging to measure how many persons are trafficking victims. Therefore, researchers must rely on estimates.[4] These estimates reach into the hundreds of thousands for both adults and minors, and show that approximately 80% of human trafficking victims are women. Healthcare providers are often the first professionals to have contact with trafficked women and girls.[5] Because healthcare needs are common among trafficked persons, healthcare providers are in a unique position to help identify trafficked victims.

Identifying and treating human trafficking victims

Two major challenges in combatting human trafficking are identifying victims and providing the necessary support and services to reintegrate these individuals into society. Hospitals and health systems are uniquely equipped to address these challenges.

St. Elizabeth Healthcare, a health system which operates five facilities in northern Kentucky, developed a Human Trafficking Protocol and Resource Manual[6] in conjunction with the Response Initiative to Guide Human Trafficking Services (RIGHTS) campaign, which brought together community stakeholders in the Northern Kentucky area to address human trafficking issues.

The RIGHTS process was co-chaired by Theresa Vietor, Manager of Forensic Nursing at St. Elizabeth, and Professor Sharlene Boltz from Northern Kentucky University's Chase Law School.[7] We spoke with Ms. Vietor about the process for developing the manual and its utility in bringing all of the key stakeholders to the table. Ms. Vietor has worked for St. Elizabeth's Healthcare for more than 40 years, including 30 years as an emergency room (ER) nurse and nearly two decades as a forensic RN. She highlighted some tips in the manual to help emergency medical services (EMS) and other medical providers identify victims of sex trafficking:

- Any minor involved with the commercial sex trade
- The presence of an individual who answers for the victim-survivor or controls the interview
- Lack of identification documents
- Reluctance to explain tattoos
- Rectal or vaginal trauma
- Bald patches or missing hair
- Inadequately dressed for weather or inappropriately dressed
- Bruises in various stages of healing caused by physical abuse
- Scars, mutilations, or infections due to improper medical care
- Poor hygiene
- Urinary difficulties or pelvic pain
- Malnourishment or dehydration
- Dental problems
- Disorientation, confusion, or panic attacks

Additional indicators may include:

- Discrepancy in reported age and actual age
- Homelessness
- Runaway teen
- History of abuse
- Presence of an older "boyfriend"
- Limited English proficiency (but companion refuses interpretation services)
- Use of slang (such as "the game," "the life," or "dope-boy")
- Claims that the victim-survivor is just "visiting" the area and therefore is unable to provide a home address
- Victim-survivor does not know the name of the assailant or perpetrator
- Incident(s) occurred in hotel room or car
- Possession of multiple hotel room keys
- Environmental indicators (including residences locked to keep occupants inside, presence of locked refrigerators or other appliances, etc.)

Some physical indicators include:

- Evidence of sexual trauma
- Cigarette burns
- Bruises
- Brands or tattoos
- Drug abuse-related health issues (e.g., asthma, Hepatitis C, skin infections)
- Somatic complaints (e.g., headaches, back pain, stomach pain)
- Unexplained scars
- Injuries to the head or mouth
- Bladder damage, injury, or infection
- Temporal mandibular joint problems (possibly resulting from oral sex)
- Bite marks
- Stab or gunshot wounds
- Hearing loss from brain trauma
- Traumatic brain injury[8]

One of the most critical steps healthcare providers can take is building trust with the victim.

If a clinician suspects a patient is a victim of human trafficking, they are often ill-equipped to provide meaningful care and information to the patient beyond basic acute medical care. One of the most critical steps healthcare providers can take is building trust with the victim. Common tips for building trust include:

- Assure the victim that their safety and health is the main priority

- Assure the victim that their privacy/confidentiality will be maintained within the limits of the law
- Provide contact information to the victim for the national reporting hotline and any local services they may need
- Be transparent and honest—don't promise services that may not be delivered
- Be empathetic and open—practice active, judgment-free listening

In focus: Kentucky

In 2013, the Kentucky General Assembly passed House Bill 3, known as the Human Trafficking Victims Rights Act (HTVRA). The Act provides for increased protections for trafficking victims, training for law enforcement, and funding to assist victims, among other provisions.[9] The Act also includes a provision mandating individuals report suspected human trafficking of minors to law enforcement.

We spoke with Rick Lynn, a human trafficking investigator in Kentucky's Office of the Attorney General, about methods healthcare providers have developed to help human trafficking victims and assist law enforcement and social service agencies. He noted that one hospital developed special human trafficking screening tools in its ED's electronic medical records (EMR) that are triggered by a patient's responses to questions. Another hospital system developed reporting protocols in conjunction with local stakeholders.

HIPAA considerations for minors

In Kentucky, reporting requirements are clear for child victims of human trafficking. The HTVRA requires:

> [a]ny person who knows or has reasonable cause to believe that a child is a victim of human trafficking as defined in KRS 529.010 shall immediately cause an oral or written report to be made to a local law enforcement agency or the Department of Kentucky State Police; or the cabinet or its designated representative; or the Commonwealth's attorney or the county attorney; by telephone or otherwise.[10]

In such situations, healthcare professionals have a clear duty to report, but two HIPAA considerations remain: what to include in the report and which agency to contact.

The HIPAA Privacy Rule's Minimum Necessary standard "requires covered entities to evaluate their practices and enhance safeguards as needed to limit unnecessary or inappropriate access to and disclosure of protected health information."[11] In the case of mandatory reporting of human trafficking of minors in Kentucky, the law does not provide a clear definition of what should be included in the "oral or written report" provided to the law enforcement agency. The HTVRA does define the elements that must be included in a follow-up written report if requested by the law enforcement agency:

- The names and addresses of the child and his/her parents or other persons exercising custodial control or supervision;
- The child's age;
- The nature and extent of the child's alleged dependency, neglect, or abuse, including any previous charges of dependency, neglect, or abuse, to this child or his/her siblings;
- The name and address of the person allegedly responsible for the abuse or neglect; and
- Any other information that the person making the report believes may be helpful in the furtherance of the purpose of this section.[12]

These items should be considered as a basis for what constitutes the "minimum necessary" amount of information to report to law enforcement agencies in the state of Kentucky. To minimize the risk of a HIPAA Privacy Rule violation, healthcare organizations should provide training to clinicians that outlines what should be reported and whom to contact.

HIPAA considerations for adult victims of human trafficking

Kentucky does not mandate reporting by healthcare professionals for adult victims of human trafficking, and clinicians are often reluctant to report suspected trafficking and unsure how to assist these victims. In most cases, clinicians should ask for and receive the patient's consent to disclose information about suspected human trafficking. However, medical providers should be aware of two critical situations where consent does not need to be obtained:

- Law enforcement purposes
- To avert a serious threat to health or safety

The Office for Civil Rights (OCR) notes the HIPAA Privacy Rule includes a provision that covered entities "may disclose protected health information to law enforcement officials for law

enforcement purposes under the following six circumstances, and subject to specified conditions: (1) as required by law (including court orders, court-ordered warrants, subpoenas) and administrative requests; (2) to identify or locate a suspect, fugitive, material witness, or missing person; (3) in response to a law enforcement official's request for information about a victim or suspected victim of a crime; (4) to alert law enforcement of a person's death, if the covered entity suspects that criminal activity caused the death; (5) when a covered entity believes that protected health information is evidence of a crime that occurred on its premises; and (6) by a covered healthcare provider in a medical emergency not occurring on its premises, when necessary to inform law enforcement about the commission and nature of a crime, the location of the crime or crime victims, and the perpetrator of the crime."[13]

Additionally, the Privacy Rule establishes another permitted disclosure when covered entities "believe [it] is necessary to prevent or lessen a serious and imminent threat to a person or the public, when such disclosure is made to someone they believe can prevent or lessen the threat (including the target of the threat). Covered entities may also disclose to law enforcement if the information is needed to identify or apprehend an escapee or violent criminal."[14]

When developing protocols to identify and assist victims of human trafficking, compliance officials should work with clinical leaders to answer certain key questions, such as:

- How does the organization define "serious threats to health or safety?"

- Which law enforcement agency or agencies should be notified?
- Which clinical personnel should receive human trafficking awareness training? Ideally, this would include EMS, ED, OB/GYN, and primary care personnel.
- What community organizations can provide needed services to human trafficking victims, including housing, transportation, food, and counseling or mental health services?
- How will this contact information be made available to staff?

Lessons learned: St. Elizabeth's Healthcare

Ms. Vietor noted a few key lessons St. Elizabeth's learned in their implementation of the RIGHTS process:

- Inconsistencies between clinical findings and a patient's responses to human trafficking screening questions were very helpful in identifying potential victims.
- Giving nurses the ability to flag a patient as a potential human trafficking victim in the EMR and triggering forensic nursing involvement helped to provide quick, coordinated care to the patient.
- When an adult patient who is a potential human trafficking victim does not wish to disclose, it may be possible for a healthcare provider to report information learned about the suspected perpetrator, location, or business involved in the human trafficking scheme. The healthcare provider should take utmost care to not disclose any protected health information in this process or jeopardize the patient's safety. Such disclosures should be only be made after consultation with legal counsel.

Conclusion

Healthcare providers are increasingly aware of the threats human trafficking poses to their most vulnerable patients. As healthcare organizations develop procedures and protocols to assist these individuals and coordinate with other stakeholders, they must be mindful of the restrictions HIPAA and state privacy laws place on disclosures of protected health information. The cases discussed here illustrate innovative means Kentucky healthcare providers have found to help human trafficking victims, while balancing the sometimes competing requirements of HIPAA, state privacy laws, and state mandatory reporting laws. CT

Endnotes

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Takeaways

- Compliance officers should familiarize themselves with their state's human trafficking reporting laws.
- Health systems should work with local law enforcement and nonprofit partners to establish lines of communication and referral for victim needs.
- Developing screening questionnaires within electronic medical records can create valuable information which law enforcement can subpoena later.
- Human trafficking victims likely require a broad spectrum medical and health services.
- If a victim declines to report human trafficking activity, healthcare workers should, without pressuring the victim, provide them with contact information and resources.

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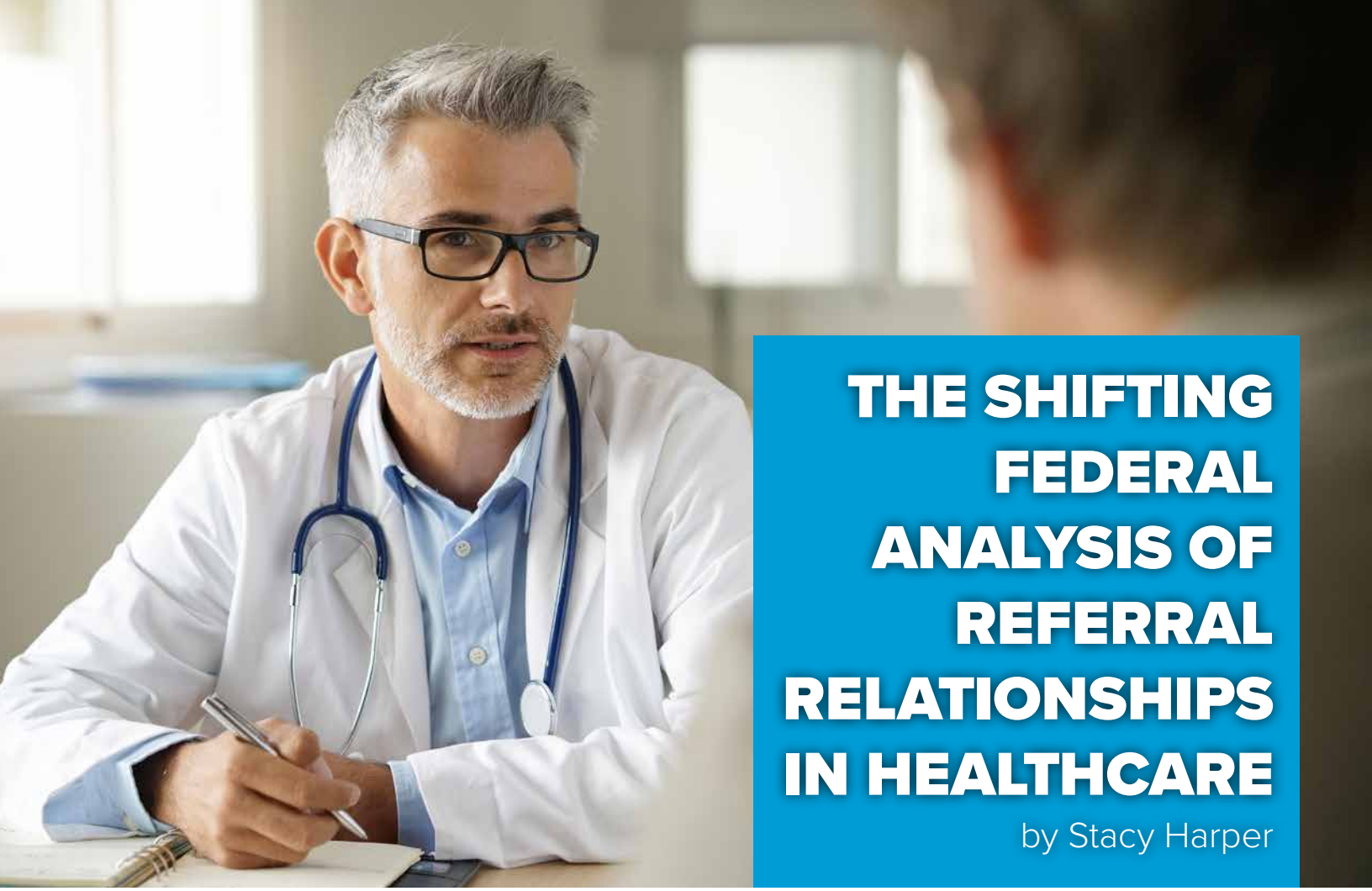

THE SHIFTING FEDERAL ANALYSIS OF REFERRAL RELATIONSHIPS IN HEALTHCARE

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The compliance analysis necessary to structure financial arrangements between potential healthcare referral sources and referral recipients has been complex for decades. Unlike other industries, healthcare organizations face a myriad of overlapping state and federal laws that restrict the financial relationships and associated referrals, each with their own definitions, triggers, intent, and exceptions or safe harbors.

At the federal level, these compliance obligations have typically applied only to financial relationships in which the referral source is referring patients where care will be reimbursed by a federal healthcare program. However, the implementation of the Eliminating Kickbacks in Recovery Act of 2018 (EKRA) and recent enforcement activity by the Department of Justice in the Forest Park Medical Center bribery case[1] are shifting the scope of the federal compliance obligations to include additional layers of federal and state laws, each applicable in the absence of reimbursement by federal healthcare programs.

As such, if a relationship with physicians or other referral sources has been structured to carve out federal healthcare program beneficiaries to avoid triggering federal law requirements, it is time to review its compliance.

The historic federal analysis

The primary enforcement against financial arrangements between referral sources and referral recipients at the federal level has historically arisen under either the Stark Law or the Anti-Kickback Statute (AKS).

Stark Law

Section 1877 of the Social Security Act, also known as Stark Law or the physician self-referral law, prohibits a physician from referring a Medicare or Medicaid patient for designated

health services (DHS)[2] to an entity with which the physician or his immediate family member has a financial relationship, unless an exception is met.[3] "Physician," for purposes of the Stark Law, is defined as doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor. DHS include clinical laboratory services; physical therapy, occupational therapy, and outpatient speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; durable medical equipment and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.

A financial relationship includes direct or indirect investment or ownership interest or direct or indirect compensation arrangements. The Stark Law is a strict liability statute, requiring no proof of ill intent by the parties to the relationship. As such, each financial relationship must satisfy all elements of an exception to the Stark Law for the DHS entity to be permitted to accept a referral from the physician for the provision of DHS to a Medicare or Medicaid beneficiary.

When analyzing a financial relationship under the Stark Law, the analysis typically follows this simplified set of steps:

1. Is there a physician involved?
2. Does the physician order or refer DHS?
3. Are the DHS billed to Medicare?
4. Does the physician have a financial relationship with the entity providing the DHS?

If the answers to all four questions are yes, then a Stark Law exception must be satisfied to allow the DHS claims to Medicare.

Anti-Kickback Statute

Section 1128B of the Social Security Act, commonly referred to as the Anti-Kickback Statute, prohibits the solicitation, receipt, offer, or payment of remuneration in exchange for the referral of a service or item reimbursed by a federal health care program.[4] The AKS is violated where one purpose of the remuneration is to pay for the referral.[5] "Remuneration" includes a kickback, bribe, or rebate.[6]

Thus, the simplified analysis of a financial relationship under the AKS is:

1. Is there a payment or transfer of value from a person or entity providing healthcare services or supplies to an individual?
2. Is there a referral from the individual to the provider of healthcare services or supplies?
3. Are the services or supplies billed to a federal healthcare program?

If the answer to all three questions is yes, then the AKS is implicated and compliance then turns on the fourth question: Is a purpose of the arrangement to induce or reward the referral of federal healthcare program beneficiaries? If the financial arrangement is structured to comply with an AKS safe harbor, then the answer to the fourth question is deemed to be no, and the arrangement complies with the AKS. If all elements of a safe harbor cannot be satisfied, then the arrangement may be subject to federal scrutiny and compliance will turn on the intent of the parties.

Thus, a complete absence of claims to federal healthcare programs may avoid triggering compliance obligations under the Stark Law and AKS.

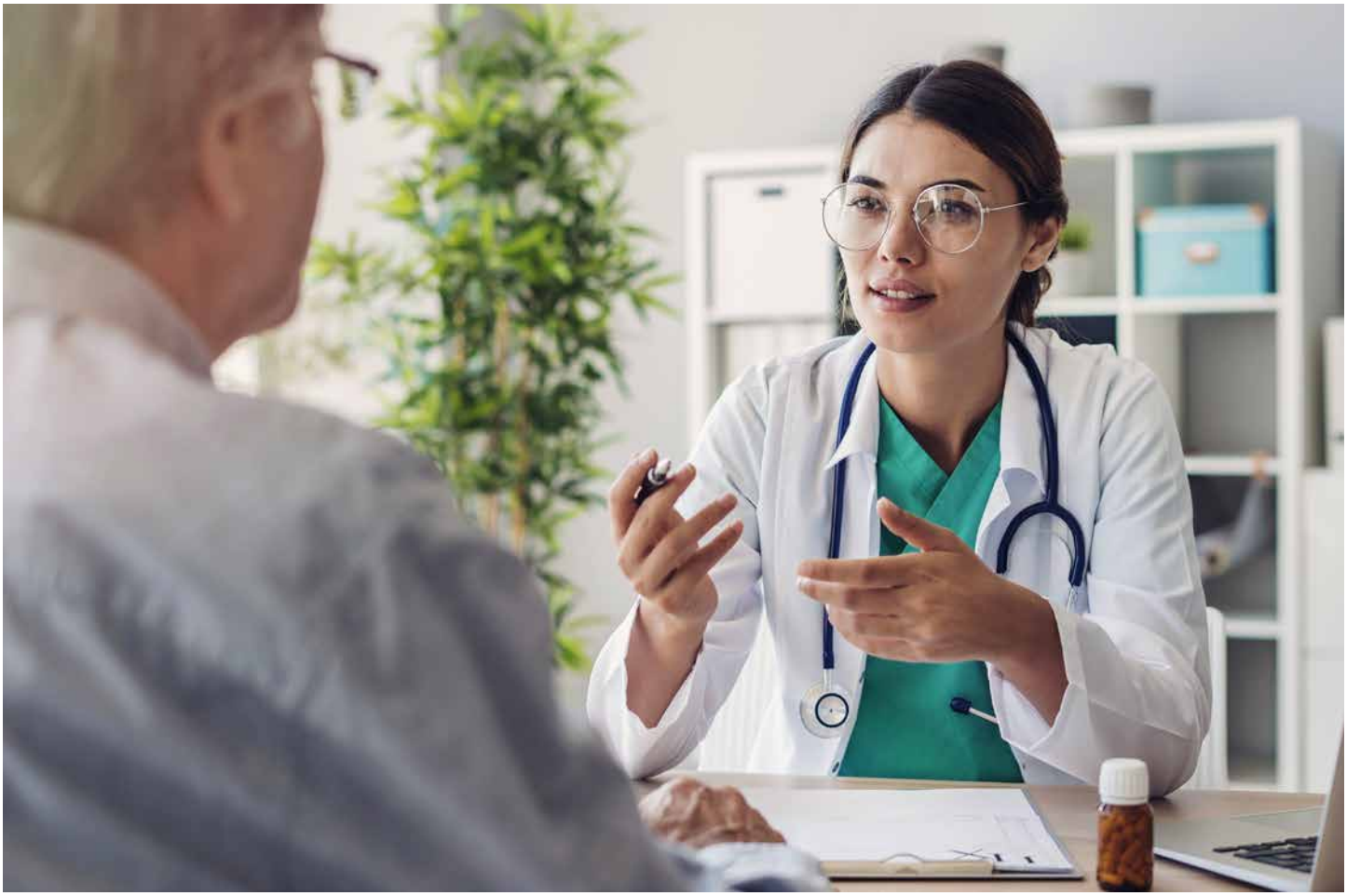
Structuring compliance through a "carve out" of federal healthcare programs can be a risky option, because the billing of a single claim to a federal healthcare program could trigger the obligations and the administrative processes to ensure no claims are submitted can be burdensome. However, the exclusion of federal healthcare programs is not an entirely uncommon strategy for addressing possible Stark Law and AKS compliance.

If all elements of a safe harbor cannot be satisfied, then the arrangement may be subject to federal scrutiny and compliance will turn on the intent of the parties.

State law considerations

Outside Stark Law and AKS obligations, the compliance requirements for arrangements between healthcare organizations have significantly varied under state law.

Some states focus their restrictions on financial relationships between referral sources and referral recipients on the involvement of Medicaid claims. Other states have



laws that restrict relationships between referral sources and referral recipients related to only specific types of services (frequently laboratory or physical therapy services), and still other states have laws that mirror the Stark Law or AKS but apply to all payment sources.

Because of the variance at the state law level, the impact of the new federal compliance considerations will have more significant affects in certain states.

If a healthcare organization is located in a state that has a state law version of the Stark Law or AKS applicable to all payers, the healthcare organization is less likely to have structured an arrangement based on exclusion of federal payers, because the arrangement would have raised compliance problems at the state level. In states where there is no all-payer limitation or where there has been an absence of enforcement, healthcare organizations are more likely to have carve out relationships that need re-assessment.

The new layers

In the last year, a new statute and new case law has added additional layers to the compliance analysis for financial relationships between healthcare organizations.

EKRA

Effective in October 2018, EKRA imposed new federal requirements on healthcare organizations that provide recovery home, clinical treatment facility, or laboratory services.[7] EKRA prohibits the knowing and willful solicitation, receipt, offer, or payment of any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory.[8]

Like the AKS, EKRA is an intent-based statute that provides several safe harbors to guarantee compliance, although the safe harbors under EKRA do not align entirely with the safe harbors under the AKS. For example, the AKS provides a safe harbor for all payments made to a bona fide employee.[9]

However, employee safe harbor under EKRA only protects arrangements where the employee's payment is not determined by or does not vary by the number of individuals referred, the number of

tests or procedures performed, or the amount billed to or received for the services provided.[10] Further, unlike the Stark Law and AKS, EKRA is not limited to any particular payer and applies to arrangements that do not include federal healthcare programs.

Forest Park

In 2016, the Department of Justice indicted 21 individuals associated with Dallas-based Forest Park Medical Center for kickback violations. The indictment included alleged violations of the AKS based on claims to Tricare and federal employee benefit plans, but the alleged damages were significantly broader than the Tricare and federal employee benefit claims, based on the additional claim for violations of the Federal Travel Act, which forbids engaging in certain criminal acts involving the use of the U.S. mail or interstate or foreign travel.[11]

The *Forest Park* case is the second time the Department of Justice has used the Federal Travel Act to exercise jurisdiction in a healthcare-related indictment. The Travel Act was also used in 2016 to indict Bernard Greenspan, D.O. for an alleged laboratory bribery scheme. The indictment of Dr. Greenspan involved claims to Medicare, and he was convicted in 2017 of violations of both the Travel Act and AKS.[12]

Forest Park Medical Center was a group of physician-owned hospitals that filed for bankruptcy in 2015 and 2016. Because the hospitals were physician-owned, the Stark Law prevented the hospitals from enrolling in Medicare or Medicaid, and the hospitals primarily provided out-of-network services to patients insured through other healthcare programs.

The conduct giving rise to the kickback indictment included a complex structure of various companies, consulting agreements, marketing arrangements, waiver of out-of-network copayments, and other arrangements that would likely be subject to scrutiny under the Stark Law and AKS if Medicare and Medicaid claims were involved. Because Forest Park Medical Center did not provide services to Medicare or Medicaid beneficiaries, it argued that the Stark Law and AKS did not apply.

At trial, several of the defendants asserted that they obtained legal opinions as to the compliance of the arrangements based on the absence of Medicare and Medicaid patients.

Following the initial indictment, ten of the defendants pleaded guilty and only nine defendants continued to trial. In April, the jury found seven of the nine defendants guilty on at least some counts, primarily related to conspiracy, bribery, and paying kickbacks. One of the physician defendants was acquitted and a mistrial was declared for one defendant. Although only one defendant was affirmatively convicted at trial under the Travel Act, the law is seen as having had a significant impact on the case.

The Travel Act is a federal racketeering statute implemented in 1961 that prohibits the use of interstate commerce in the commission of an "unlawful activity," including bribery in violation of the laws of the state where committed. The Travel Act is not limited to healthcare and does not require any payment from or claim to the federal government.

In the *Forest Park* case, the Travel Act's application was based on alleged violations of the Texas commercial bribery statute that prohibits the: (1) intentional or knowing (2) offering, conferring, solicitation or acceptance of a benefit (3) to or by a fiduciary, (4) without the consent of the fiduciary's beneficiary (5) where acceptance of such benefit will influence the conduct of the fiduciary in relation to the affairs of his or her beneficiary.[13] A "fiduciary" under the statute includes, among others, "a lawyer, physician, accountant, appraiser or other professional advisor."[14]

...unlike the Stark Law and AKS, EKRA is not limited to any particular payer and applies to arrangements that do not include federal healthcare programs.

The majority of states have some form of commercial bribery statute that, like Texas, focuses on the acceptance of value in exchange for violating a fiduciary relationship owed to an individual. Many of these statutes specifically include a physician or other professional advisor as a fiduciary. Many of these statutes are drafted in a manner that requires only proof of the intentional offer, payment, solicitation or acceptance of a value, without approval of the beneficiary, that will impact the fiduciary relationship. In many states, there is little-to-no case law interpreting the statutes, and many do not appear to require that the intent be to actually influence the decisions of the fiduciary.

Further, unlike the Stark Law, AKS, and EKRA, the Travel Act does not provide any exceptions or safe harbors to guarantee an arrangement free from scrutiny.

The new analysis

Both EKRA and the Travel Act are intent-based statutes. As such, they do not automatically make every relationship that has carved out federal healthcare programs improper. They instead add layers to the analysis that must be conducted.

Although the involvement of federal healthcare programs continues to be a relevant question for determining Stark Law and AKS application, the absence of these claims to these programs no longer ends the analysis. Consideration of state law requirements—not only within the healthcare-specific laws, but also general laws relating to financial relationships such as a commercial bribery statute—has increased importance.

For physicians and other healthcare organizations desiring to structure collaborative arrangements, consideration should continue to be given to the Stark Law and AKS. The parties should now also consider EKRA, the applicable state laws, and the extent to which the relationship may influence the physician or other provider's fiduciary obligations to the patient.

...unlike the Stark Law, AKS, and EKRA, the Travel Act does not provide any exceptions or safe harbors to guarantee an arrangement free from scrutiny.

Where arrangements have been previously structured to comply with the AKS and Stark Law by avoiding federal healthcare programs, these arrangements should be re-evaluated for compliance with EKRA and the Travel Act. CT

Endnotes

1. Department of Justice press release, Northern Disctrict of Texas. "Seven Guilty in Forest Park Healthcare Fraud Trial" April 10, 2019. https://bit.ly/2WZU1kv
2. 42 C.F.R. 411.351 - Definitions
3. 42 U.S.C. 1395nn(a)(1) - Limitation on certain physician referrals
4. 42 U.S.C. 1320a-7b(b) - Illegal remunerations
5. See U.S. v. McClatchey, 217 F.3d 823 (2000).
6. Ibid, Ref #5
7. 18 U.S.C. 220 Illegal remunerations for referrals to recovery homes, clinical treatment facilities, and laboratories
8. 18 U.S.C. 220(a).
9. 42 C.F.R. 1001.952(i) - Exceptions
10. 18 U.S.C. 220(b)(2).
11. 18 U.S.C. § 1952. Interstate and foreign travel or transportation in aid of racketeering enterprises.
12. 2017 WL 894809. The Travel Act
13. Texas Penal Code 32.43 Commercial Bribery
14. Texas Penal Code 32.43(a)(2), definition of "fiduciary"

Takeaways

- Relationships between physicians and/or referral sources should be reviewed to ensure compliance in wake of the *Forest Park* verdicts.
- Structuring compliance through a "carve out" can be a risky option because the billing of a single claim to a federal healthcare program could trigger obligations and administrative processes.
- Outside of federal regulations, the compliance requirements for arrangements between healthcare organizations significantly varies under state law.
- In the last year, a new statute and new case law have added additional layers to the compliance analysis for financial relationships between healthcare organizations.
- Intent-based statutes do not automatically make every relationship that has carved out federal healthcare programs improper, but EKRA and the Travel Act add layers to necessary compliance efforts.

OUTPATIENT THERAPY: MYTHS AND RISKS

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Outpatient therapy, particularly physical therapy, continues to be an area of concern for providers, regulators, investigators, adjudicators, and legislators. With Centers for Medicare & Medicaid Services (CMS) having entered an enlightened era of reducing provider burden, outpatient therapy providers are not necessarily "feeling the love," save the elimination of functional limitation reporting (FLR) for dates after 1/1/2019. Physical therapy has continually been a topic on the OIG's Work Plan; therapy over the $2,040 annual therapy threshold is subject to CMS medical necessity review; data analytics are driving CMS therapy reviews under the Targeted Probe and Educate (TPE) program; and the Health and Human Services Office of Inspector General (OIG) and the Department of Justice, including various United States Attorney's offices, seem to keep therapy on the top of their radar.

With all the reviews, reports, and whistleblower activity, it seems therapy providers would revisit and update a compliance risk assessment, incorporate these case studies in compliance education and training, or at the very least, take to late night reading and studying the transparently available CMS rules and policy. Providers often look to social media groups to find answers to questions on key areas of therapy risk. More often than not, providers accept answers that are incorrect, out-of-date, or not applicable for one reason or another. Providers that have compliance programs and hotlines report that clinicians ask questions about basic therapy documentation coding and billing requirements, often identifying therapy CEU courses and social media groups as the source of inaccurate and misleading information.

This article identifies a few of the top therapy myths and inaccurate

information that gains a life of its own in social media groups. Each of these identified areas of concern also may pose an area of risk to be addressed in the provider's compliance program and risk assessment.

Referrals/orders for therapy

A physician order is always required for therapy services, even if the therapist is operating under direct access laws in their state of practice. Myth or risk?

It is a myth that a referral or an order is required for outpatient therapy services. A referral or order is not required if the physical or occupational therapist is complying with direct access rules in their state of practice. The practice of speech-language pathology is autonomous; therefore, a physician referral is not required for practice. Direct access allows for a therapist to evaluate a patient in the absence of an order, but may have the number of treatment visits limited following the evaluation until a physician referral is obtained.

A referral/order may be required by CMS if evaluation was the only service performed. If the evaluation concludes that no further therapy is needed, the evaluation charge will be paid if there is a referral or if the evaluation is sent for certification. An evaluation serves as the plan of care (POC) if it contains a diagnosis; further, CMS assumes that the amount, frequency, and duration of therapy are incorporated into the evaluation by the very nature of the one-time visit for an evaluation. When a beneficiary receives a therapy evaluation without a referral or order and does not require treatment, a physician referral/order or certification of the evaluation is required for payment of the evaluation. CMS further instructs that a delayed referral/order that is dated after the evaluation shall be interpreted as certification of the plan to evaluate the patient.

Given that most therapy evaluations also include some therapy intervention, such as instruction in a home exercise program or modalities for pain relief, there are limited examples when the evaluation is the only service. For example, a surgeon may request a physical therapy evaluation to determine if the patient would benefit from therapy and limits the referral to "evaluation" only, rather than "evaluate and treat." If therapy was complete on the date of the evaluation, then the POC must be certified, because services were provided.[1] Comprehensive Outpatient Rehabilitation Facility (CORF) providers should review the applicable rules and policies on referrals and certification that are unique to CORFs.[2,3]

Providers should also look to their local coverage determination (LCD) or other Medicare Administrative Contractor (MAC) educational resources for additional guidance. Novitas, the MAC for Jurisdictions JH and JL, states in LCD L35036 that:

> Outpatient therapy *must* be under the care of a Physician/Non-physician provider (NPP). An order (sometimes called a referral) for therapy services, documented in the medical record, provides evidence of both the need for care and that the patient is under the care of a physician. Payment is dependent on the certification of the plan of care rather than the order, but the use of an order is prudent to determine that a physician is involved in care and available to certify the plan.[4]

Therapy providers that are subject to CMS review, for example under the TPE program, are routinely asked to provide a copy of the physician order as part of the documentation requested for review. Myth or risk?

Providers responding to a TPE that do not have the requested therapy order should identify in a TPE cover letter that CMS does not require an order if the POC is certified. The cover letter should also appropriately cite the CMS reference and applicable LCD reference. As noted above from Novitas, "the use of an order is prudent." Having an order for therapy, even when not required, may likely save a denial and resultant appeal for the purpose of pointing out CMS requirements that the reviewer may have overlooked.

Certification

If the Medicare POC is not certified on a timely basis, the MAC will deny services as not medically necessary. Myth or risk?

This is both a myth and a risk. Following a therapy evaluation, a POC is developed and sent to the referring physician/NPP for certification. A certification requires a dated signature on the POC within 30 days to be considered a timely certification. Therapy prescribed under the POC can take place while the certification is pending, but therapy providers often fail to have *effective* certification procedures in place to ensure timely certification when repeated faxed attempts and/or phone calls to the physician's office go unanswered with respect to the certification.

CMS also suggests that when certification is delayed for long periods of time, the provider is advised to submit other documentation in support of a long-delayed certification.

A certification may also be verbal; however, it must be followed by a valid signature within a 14-day period in order to be timely. Providers should notate in the record all phone and fax requests for certification, and document the receipt of verbal orders, paying close attention to the requirement for the 14-day requirement to obtain the written certification. Evidence of a provider's efforts in communication of the plan to the physician "may" be considered by the Medicare contractor during review in the event of a delayed certification. Being aware of this consideration by the MAC will help a provider pre-emptively communicate with the MAC during an audit, such as a TPE.

CMS allows for delayed certification and recertification when the late certification is accompanied by a reason for the delay. Per CMS, "Delayed certifications should include any evidence the provider or supplier considers necessary to justify the delay." CMS sites several plausible reasons as a reason for delayed certification, including lack of physician signature or the POC was "lost" or overlooked at the physician office. CMS also suggests that when certification is delayed for long periods of time, the provider is advised to submit other documentation in support of a long-delayed certification. This could include the physician referral/order, notes in the record documenting therapist's communication with the referring/certifying physician, or alternatively, an attestation statement from the physician indicating that the patient was under their care during the time period of therapy treatment.

CMS has made it clear that that the beneficiary's therapy may not be put on hold and instructs the contractors to accept the delayed certification unless there is reason to believe there was no physician involvement (as required), or the certification was not properly obtained or signed. Certification is a Condition of Payment (CoP), so CMS advises that providers should seek certification as soon as possible.

Providers should review all relevant policy on therapy certification, including timely certification, recertification, and delayed certification in Chapter 15 of the *Medicare Benefits Policy Manual*. Therapy electronic medical records (EMR) systems generally signal when a certification is due as well as provide automated faxes to the physician office; however, the EMRs have not yet advanced to the point that they can mitigate issues of non-certification on behalf of the provider on this essential, required element for payment. This is an area of provider burden for both therapy and referring physicians; however, until CMS considers an opportunity to reduce or eliminate the burden, compliance with certification is an important compliance element to address in an annual risk assessment and monitoring and auditing plan.

Therapy caps

The therapy caps are still in place and limit the amount of therapy that the beneficiary can receive. Myth or risk?

This is a myth. The therapy caps (in place since the Balanced Budget Act of 1997) were permanently eliminated effective January 1, 2018. Section 50202 of the Bipartisan Budget Act (BBA) of 2018 repealed the Medicare outpatient therapy caps, as well as the therapy caps exceptions process. This legislation, in addition to eliminating the therapy caps, added two threshold limits to ensure appropriate therapy.

The BBA preserved what was *previously* the amount of the therapy cap as a "threshold" above which claims must include the KX modifier. Use of the KX modifier attests that therapy services above the threshold amount are medically necessary and attests that the therapy record maintains documentation in support of the medical necessity of therapy over the threshold. There is a threshold amount of $2,040 that includes both physical therapy and speech—language pathology combined in 2019 and a separate threshold amount of $2,040 for occupational therapy in 2019. The $2,040 represents the amount of what would have been the therapy cap, had it not been repealed.

CMS has posted an update on the application of these changes to highlight the resultant medical reviews that providers may anticipate:

> Along with this KX modifier threshold, the

> new law retains the targeted medical review (MR) process (first established through Section 202 of the Medicare Access and CHIP Reauthorization Act of 2015 [MACRA]), but at a lower threshold amount of $3,000. For CY 2018 (and each calendar year until 2028 at which time it's indexed annually by the MEI), the MR threshold is $3,000 for physical therapy (PT) and speech—language pathology (SLP) services and $3,000 for outpatient therapy (OT) services. The targeted MR process means that not all claims exceeding the MR threshold amount are subject to review as they once were.[5]

An area where many providers remain uncertain is related to beneficiary vs. provider liability for therapy over the $2,040 threshold that is not medically necessary. CMS has provided guidance via an updated FAQ document specific to the use of the Advance Beneficiary Notice (ABN) for therapy providers. Prior to offering a beneficiary an ABN, providers should be aware that routine ABNs for therapy services should not be offered to transfer liability to the beneficiary.[6] All medically necessary therapy should be provided, and a mandatory version of the ABN appropriately coded to the claim to transfer liability to the beneficiary. As a note of caution, ABNs are generally among the requested documents for medical review.

CMS has also provided updated information to beneficiaries regarding the limitation on

therapy services as a result of the therapy cap. The new guidance removed reference to the therapy cap by stating "Medicare law no longer limits how much it pays for your medically necessary outpatient therapy services in one calendar year."[7]

Group therapy or not

If a Medicare beneficiary is seen at the same time as another patient, the group code is billed for the Medicare patient. Myth or risk?

The use of group therapy, perhaps more so than any other therapy code, is a topic of misinformation. Some misinformation stems from the fact that "group" in a skilled nursing facility (SNF) or an inpatient rehabilitation facility (IRF) each have different definitions and rules. In outpatient therapy, the use of group therapy is based upon the code definition for CPT® 97150.

Other misinformation stems from urban legends, which run the gamut from "Always bill group therapy when more than one patient is seen at the same time" to "Bill the group code to the Medicare patient, and the 1:1 code to the other patient(s)." This is an area of myth as well as substantial risk. Providers should consider if the interventions for patients seen in the same period of time should apportion the one-to-one minutes for each patient or should establish that the interventions for those patients should be conducted in a group fashion. CMS provides guidance in the long established "11 Part B Billing Scenarios for PTs and OTs—Individual vs. Group Treatment."[8]

The MACs provide guidance, not only on the use of the group therapy code, but also on the documentation that should be in the record to support the use of the code. Novitas indicates that:

> [I]n the case of group therapy, Medicare expects that skilled, medically necessary services will be provided as appropriate to each patient's plan of care. Therefore, group therapy sessions (two or

> more patients) should be of sufficient length to address the needs of each of the patients in the group. Although group therapy services are included with the therapeutic procedures that require one-on-one patient contact, these services involve constant attendance of the qualified health care professional, but by definition do not require one-on-one patient contact by the same health care professional...

Documentation must identify the specific treatment technique(s) used in the group, how the treatment technique will restore function, the frequency and duration of the particular group setting, and the treatment goal in the individualized (patient-specific) plan. The number of persons in the group must also be documented. These records must be made available to Medicare upon request."[9]

First Coast Service Options, Inc. (FCSO, providing coverage for Florida, Puerto Rico, and the U.S. Virgin Islands) policy on documentation for group therapy reads:

> Documentation must be maintained in the patient's medical record identifying the specific treatment technique(s) used in the group, how the treatment technique will restore function, the frequency and duration of the particular group setting, and the treatment goal in the individualized plan. The number of persons in the group must also be furnished."[10]

National Government Services, Inc. (NGS, Part B coverage in New York) policy requires that:

> If group therapy is billed on a given day, it must be listed in the Treatment Note. The minutes of this untimed code must be added to the Total Treatment Time for that day. Further documentation describing the skilled nature of the group session documented in the progress report or the treatment note may assist in supporting the medical necessity of the service.[Documentation per NGS should include] the purpose of the group and the number of participants in the group, Description of the skilled activity provided in the group setting, such as instruction in proper form, or upgrading the difficulty of the activity for an individual.[11]

Table 1 provides a listing of pertinent LCDs for each contractor. All LCDs can be accessed via the CMS Coverage Database.

MAC	Jurisdictions	LCD #	Title
CGS	J15	L34049	Outpatient Physical and Occupational Therapy Services
FCSO	JN	L33413	Therapy and Rehabilitation Services
NGS	JK, J6	L33631	Outpatient Physical and Occupational Therapy Services
Noridian	JE, JF	N/A	Retired
Novitas	JH, JL	L35036	Therapy and Rehabilitation Services (PT, OT)
Palmetto	JJ, JM	L34428 L34427	Outpatient Physical Therapy Outpatient Occupational Therapy
WPS	J5, J8	N/A	Retired

Table Note: Medical policies pertinent to speech-language pathology may be identified in separate LCDs; verify with the appropriate MAC. Therapy providers that are also enrolled as DME suppliers should reference the appropriate DME Jurisdiction's supplier policies and procedures for documentation, coding, and billing.

There is risk associated with not using the group code when more than one patient is seen in the same time period and billing all as if therapy was provided one-to-one. There is also an emerging risk of the incorrect use of the group code. For example, only the Medicare beneficiary is billed group ("group of one"), and patients with non-Medicare coverage are billed using one-to-one codes.

Audits and investigations

Therapy providers that are audited or investigated by CMS, the OIG, and other contractors must be doing something wrong to merit audits or investigations. Myth or risk?

It is a myth that only "bad actors" are subject to audits and investigations. In an era where "data is king," contractors rely on data analytics to review patterns to determine if there is a potential problem and may conduct further review in the form of an audit or may request for records prior to payment.

If a therapy clinic has a pool, it would be expected that coding for aquatic therapy at that clinic would be at a higher volume than coding for a clinic that does not have a pool, or occasionally uses a community pool to conduct aquatic therapy. Alternatively, a hand therapist appropriately using the whirlpool code for fluidotherapy is identified for review because comparative data indicates a significantly higher utilization of this code by the hand therapist. In both examples the data suggests patterns that may trigger a therapy provider for review. Knowing in advance those areas of a practice that are a higher risk for review because of utilization patterns and comparative statistics is essential in assessing an auditing program.

To continue with the aquatic therapy example, a provider that offers aquatic therapy as part of a POC should identify the coding and documentation requirements, develop a training program to educate providers on the requirements for the use of the code as well as the documentation requirements, and should routinely audit the use of this code against the documentation and coding requirements. Audit questions to consider should include, but not be limited to:

- Was aquatic therapy included in the plan of care?
- Was aquatic therapy designed as a transition to land-based exercises, and does the documentation address the patient progression?
- Was aquatic therapy done one-to-one with the patient, or was it done in a group setting and appropriately billed as group for all the patients in the group? Review the schedule for the therapist/clinic to answer this question and to determine if there was sufficient time on the schedule to support the codes that were documented and billed.
- Did the recorded therapy time/minutes take into account the non-billable time where the patient took a rest break, including changing clothes if land-based therapy interventions preceded or followed aquatic therapy? (Not many therapy patients step out of the pool and into the clinic without changing to street clothes!)

As part of their monitoring and auditing program, therapy providers should establish a systematic process of identifying and assessing national, regional, and local trends that affect therapy, including available reports and data, and use the available data to benchmark themselves to determine risk.

...therapy providers should establish a systematic process of identifying and assessing national, regional, and local trends that affect therapy...

In additional to sources available at the MAC's website, other sources of information include:

- **OIG audit reports that have been published to OIG.HHS.gov.** A number of reports on physical therapy that were conducted under the OIG Work Plan provide excellent sources of errors and findings.
- **OIG settlements published to OIG.HHS.gov.** A recent settlement by the OIG included a self-disclosure related to billing for therapy services to TRICARE.
- **Enforcement actions and other reports published to OIG.HHS.gov from various offices of United States' Attorneys.** Recent settlements arriving out of a qui tam complaint detail therapy billed as one-to-one when it was provided in a group setting.

Summary

This article highlighted several areas of therapy documentation, coding, and billing where there is a lack of understanding of regulations and CMS policy. Providers are encouraged to review their contractor's LCDs, CMS National Coverage Determinations (NCD), and the relevant state practice acts for each discipline. Additionally, providers should consider variances by type of CMS enrollment for private practice supplier vs. facility provider, relevant CoP, or accreditation authority. Providers that have specific questions regarding the applicability of regulations and CMS policy as it relates to billing policies and procedures of the practice that may require a refund or a self-disclosure should seek the advice of competent legal counsel. CT

Endnotes

1. Centers for Medicare & Medicaid Services (CMS), Publication IOM-02, Ch.15 (Rev. 256, 02-01-19). https://go.cms.gov/2usS8eb.
2. CMS, Publication IOM-02, Ch.12 (Rev. 255, 01-25-19). https://go.cms.gov/2w89aRw
3. Ibid, Ref #1
4. CMS, Medicare Coverage Database, LCD: Therapy and Rehabilitation Services (PT, OT) L35036, (04-18-2019). https://go.cms.gov/2Wf8uZc
5. CMS, CY 2019 Therapy Services Udates. https://go.cms.gov/2HsL8XZ
6. CMS, Outpatient Therapy Services and Advance Beneficiary Notice of Noncoverage (ABN), Form CMS-R-131, August 2018. https://go.cms.gov/2VOtQxm
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8. CMS, 11 Part B Billing Scenarios for PTs ad OTs (Individual vs. Group Treatment). https://go.cms.gov/2XDgZej
9. Ibid, Ref #4
10. CMS, Medicare Coverage Database, LCD Therapy and Rehabilitation Services, L33413 (01-01-2019). https://go.cms.gov/2YHzzBX
11. CCMS, Medicare Coverage Database, LCD Outpatient Physical and Occupational Therapy Services, L33631 (01-01-2019). https://go.cms.gov/2JyPwHd

Takeaways

- A referral (order) from a physician is not always required by Medicare for outpatient physical therapy, occupational therapy, and speech-language pathology services.
- A timely certification of the therapy plan of care by a physician or NPP who is enrolled in Medicare is required within 30 days; however, a delayed certification may be obtained after the 30 days, and even after 60 days if certain requirements are met.
- The physical therapy cap (including speech-language pathology) and the occupational therapy cap were permanently eliminated effective January 1, 2018. Medicare beneficiaries continue to be entitled to receive all medically necessary therapy services.
- If a Medicare beneficiary is seen in the same time slot as another patient and the therapist chooses to use the group therapy code, certain requirements must be documented to the record to support the use of the code.
- CMS, the OIG, and other regulators and enforcers are using data to profile providers, identify aberrant patterns of billing and utilization, and target providers for audits and investigations.