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A Perfect Match or a Recipe for Disaster: Can Sleep Labs and Durable Medical Equipment Suppliers Work Together Compliantly?

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Stark and Kickback Issues in the Sleep Arena

Stark and Kickback Issues in the Sleep Arena

- The Medicare anti-kickback statute ("AKS") prohibits anyone from knowingly and willfully soliciting, receiving, offering, or paying remuneration to another person in exchange for referring or arranging for the referral of items or services that are reimbursable by federal health care programs.
- Remuneration includes anything of value including non-monetary items that is offered directly or indirectly, overtly or covertly.

Stark and Kickback Issues in the Sleep Arena

- The AKS applies to any item or service that is reimbursable by a federal health care program (e.g., Medicare, Medicare Advantage, Medicaid, Medicaid Managed Care, and TRICARE).
- Due to the broad language of the AKS, a number of safe harbors have been enacted to protect certain types of arrangements. Failure to comply with a safe harbor does not cause the arrangement to be deemed illegal. Rather, all factors of the arrangement will be evaluated for the risk of fraud and abuse.

Stark and Kickback Issues in the Sleep Arena

- The AKS is an intent-based statute. Several courts have concluded that if only one purpose of an arrangement is to induce referrals, the arrangement violates the AKS.
- Accordingly, arrangements should be structured to comply with, or substantially comply with, a safe harbor to the AKS.

Stark and Kickback Issues in the Sleep Arena

- If the arrangement cannot comply with (or substantially comply with) a safe harbor, it needs to comply with other Office of Inspector General ("OIG") guidance such as the OIG's 1989 Special Fraud Alert ("Joint Ventures") and the OIG's April 2003 Special Advisory Bulletin ("Contractual Joint Ventures").

Stark and Kickback Issues in the Sleep Arena

- The Stark physician self-referral statute states that a “physician may not make a referral to [an] entity for the furnishing of designated health services,” reimbursable by Medicare, Medicare Advantage, Medicaid, or Medicaid Managed Care (collectively referred to as “Medicare/Medicaid”) if the “physician (or an immediate family member of such physician) has a financial relationship with [such] entity,” unless a Stark exception is met.

Stark and Kickback Issues in the Sleep Arena

- "Referral" means "the request by a physician for, or ordering of … any designated health service for which payment may be made under" Medicare.
- This is a very broad definition; it is not limited to a physician's referral to a specific supplier.
- "Designated health services" ("DHS") are categorized into 10 distinct types of services including "durable medical equipment and supplies." The definition of DME includes CPAPs and supplies.

Stark and Kickback Issues in the Sleep Arena

- Stark is a strict liability statute. Unless an arrangement that implicates Stark meets a specific exception to the statute, the arrangement violates Stark even if the parties acted in good faith when they entered into the arrangement.
- Five elements are needed to implicate Stark:
  - a physician,
  - a referral,
  - DHS,
  - an entity,
  - and a financial relationship.

Stark and Kickback Issues in the Sleep Arena

- For example, Dr. Jones (“physician”) may write orders (“referral”) for Medicare/Medicaid (“DHS”) patients for CPAPs or other supplies to ABC CPAP Equipment, Inc. (“ABC”) (“entity”) in which Dr. Jones has an ownership interest (“financial relationship”).

Stark and Kickback Issues in the Sleep Arena

- Stark is implicated and, unless the arrangement can fall within an exception to Stark, the law is violated.
  - There are three exceptions that apply to ownership or investment interests:
    - publicly-traded securities;
    - mutual funds; and
    - specific providers.
  - The only potentially applicable exception would be the exception for specific providers. The specific providers exception states that an ownership interest in a rural provider is not considered a financial relationship under Stark.

Stark and Kickback Issues in the Sleep Arena

- Rural providers are defined as those that furnish at least 75% of the DHS they provide to residents of a rural area. This exception is often referred to as the rural provider exception. Whether this exception can apply depends on whether at least 75% of the patients that ABC services are located within a rural area.

Stark and Kickback Issues in the Sleep Arena

- "Rural area" is defined as "an area that is not an urban area as defined at § 412.62(f)(1)(ii) of this chapter." 42 CFR § 412.62(f)(1)(ii) states in relevant part that "the term urban area means 'A Metropolitan Statistical Area (MSA) or New England County Metropolitan Area (NECMA), as defined by the Executive Office of Management and Budget … ' "
- Therefore, any area that is not an MSA or an NECMA would be considered a rural area." So long as no less than 75% of the DME that ABC furnishes is to patients located in a rural area, the rural provider exception would apply to ABC regardless of where it is physically located.

Stark and Kickback Issues in the Sleep Arena

- The current list of MSAs can be found on the U.S. Census Bureau website. Note that a town might fall within a Micropolitan Statistical Area, which is defined as an urban cluster of at least 10,000 but less than 50,000 people.
- In regard to whether a Micropolitan Statistical Area could be considered a rural area under the definition of Stark, the Stark II, Phase III implementation final rule states "**Micropolitan Statistical Areas are not within MSAs; thus**, for purposes of the physician self-referral rules, **Micropolitan Statistical Areas are not considered urban and are, therefore, rural areas**."

Stark and Kickback Issues in the Sleep Arena

- Based on the above, Stark would be implicated by the referral of Medicare/Medicaid patients by Dr. Jones to ABC. However, the rural provider exception may offer protection if ABC falls within the definition of a rural provider. Specifically, no less than 75% of the DHS (i.e., CPAPs and supplies) that ABC furnishes must be provided to residents of a rural area. It is important to, again, emphasize that Stark is a strict liability statute, meaning that all of the elements of the rural provider exception must be met, or the law is violated. There is no wiggle room for that percentage.

Stark and Kickback Issues in the Sleep Arena

- ABC may dispense CPAPs/supplies to Medicare/Medicaid patients if Dr. Jones is not the physician who issues the order for the CPAPs/supplies. If Dr. Jones does not provide the referral directly to ABC, it is possible that his involvement with the patient's care, coupled with a pre-printed order form (prominently listing ABC) provided by XYZ Sleep Lab could give rise to concerns under both Stark and the AKS.

- As discussed above, Stark is a concern if 5 elements are present. Let's focus on the referral element.
- A referral is more than just an order written by a physician and sent to a DME supplier or pharmacy.

Stark and Kickback Issues in the Sleep Arena

- "Referral" is defined as "the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service."
- If Dr. Jones does not write the order to ABC for the CPAPs/supplies, Dr. Jones may conduct the interpretation of the sleep test that determines whether the patient should be prescribed such DME.
- Dr. Jones, as the interpreting physician, could be characterized as "certifying the need for" DHS (e.g., CPAPs/supplies).

Stark and Kickback Issues in the Sleep Arena

- Assume that XYZ will send the patient's physician a pre-printed order form that lists ABC at the top of the list of available suppliers, giving the patient's physician the opportunity to select a supplier but strategically placing ABC first. It is arguable that this scenario gives rise to a referral as defined under Stark which would complete the 5 elements required to implicate the law. Absent an applicable exception, Stark would likely be violated by this arrangement. The specific providers exception, discussed above, may apply here if the requirements are met.

Stark and Kickback Issues in the Sleep Arena

- Both a Medical Director Agreement and a Sleep Test Interpretation Agreement can be scrutinized from two perspectives.
  - First, whether the compensation provided under either agreement is actually compensation for referrals that Dr. Jones generates for XYZ.
  - Second, whether the compensation provided under either agreement can be viewed as compensation to XYZ from Dr. Jones in exchange for referrals.

Stark and Kickback Issues in the Sleep Arena

- Medical directorships have seen increased scrutiny by the federal government in recent years. For example, on June 9, 2015, the OIG issued a Fraud Alert warning physicians about suspect compensation arrangements that can give rise to liability. Specifically, the Fraud Alert addressed 12 recent OIG settlements with physicians who entered into questionable medical directorship and staff arrangements with entities. The OIG alleged that these arrangements violated the AKS for a number of reasons including that the physicians were paid in a manner that did not reflect fair market value for the services, the physicians did not actually render the services outlined in the agreements, and an affiliated entity paid the salaries of the physicians' staff in exchange for providing referrals to the entities.

Stark and Kickback Issues in the Sleep Arena

- The role that a medical director plays for an entity can vary. However, the OIG notes that successful medical directors should:
  - "Actively oversee clinical care in the facility;"
  - "Lead the medical staff to meet the standard of care;"
  - "Ensure proper training, education, and oversight for physicians, nurses, and other staff members; and"
  - "Identify and address quality problems."
- Furthermore, it is crucial that the medical director actually perform whatever responsibilities s/he agrees to assume and that his/her compensation for such responsibilities is commensurate with fair market value.

Stark and Kickback Issues in the Sleep Arena

- A notable fraud and abuse judgment was against Tuomey Healthcare System (“Tuomey”). Tuomey is a South Carolina-based hospital system that entered into suspect arrangements with physicians wherein the physicians would provide services to Tuomey’s outpatient facilities but required such physicians to refer patients to Tuomey in exchange for above fair market value compensation.

Stark and Kickback Issues in the Sleep Arena

- A jury determined that these arrangements violated Stark and the court entered judgement against Tuomey for more than $237 million. Principal Deputy Assistant Attorney General Benjamin Mizer said of the case, “This case demonstrates the United States’ commitment to ensuring that the doctors who refer Medicare beneficiaries to hospitals for procedures, tests, and other health services do so only because they believe the service is in the patient’s best interest, and not because the physician stands to gain financially from the referral.”

Stark and Kickback Issues in the Sleep Arena

- Again, a “referral” under Stark does not only mean an order for an item or test but can also include “the request by a physician for, or ordering of, or the certifying or recertifying of the need for, any designated health service.”

Stark and Kickback Issues in the Sleep Arena

- In our example, if Dr. Jones is both the Medical Director and an interpreting physician, he is in a unique position to direct referrals to XYZ. Thus, it would be in the parties' interest to ensure that the arrangement complies with an applicable exception to Stark. The personal services arrangements exception requires:
  - The arrangement to be in writing, signed by the parties, and specifies the services that are covered by the arrangement;
  - The arrangement covers all services that are furnished by the physician to the entity;

Stark and Kickback Issues in the Sleep Arena

- The personal services arrangements exception requires (cont'd):
  - The services provided are reasonable and necessary for a legitimate business purpose;
  - The agreement is for a term of at least 1 year.
  - Compensation is set in advance and does not exceed fair market value, and does not take into account the volume or value of referrals generated between the parties.
- Similarly, the AKS could be implicated, as XYZ would be providing remuneration (compensation) in exchange for referrals. However, the Personal Services and Management Contracts Safe Harbor could offer protection from the AKS.

Stark and Kickback Issues in the Sleep Arena

- Assume that XYZ is providing referrals for CPAPs/supplies to ABC, an entity in which Dr. Jones has ownership and in whose success Dr. Jones will directly benefit. In other words, XYZ is providing referrals to/generating business for Dr. Jones. In turn, Dr. Jones is providing services to XYZ in the form of his medical directorship and sleep test interpretation services. Such services, if not compensated at fair market value, could be viewed as remuneration to XYZ by Dr. Jones in exchange for the business being generated for ABC, implicating the AKS. In other words, it is possible that the government could take the position that Dr. Jones is providing XYZ with discounted services (i.e., remuneration) in exchange for the business that XYZ generates for ABC (i.e., referrals). In that case, the arrangement between Dr. Jones and XYZ would have to substantially comply with a safe harbor to the AKS.

Stark and Kickback Issues in the Sleep Arena

- The Personal Services and Management Contracts Safe Harbor provides protection for such arrangements. Specifically, the Safe Harbor excludes from the definition of remuneration any payment made as compensation for services to the entity so long as certain standards are met. In other words, if the relationship between Dr. Jones and XYZ can fall within the Safe Harbor, such relationship would not be considered remuneration and would be protected from the AKS.

Stark and Kickback Issues in the Sleep Arena

- The Personal Services and Management Contracts Safe Harbor requires that:
  - The agreement between the parties is set out in writing and signed.
  - The agreement includes all services that Dr. Jones is to provide for the term of the agreement.
  - If the services are to be provided on a part-time or periodic basis, the agreement outlines the specific schedule for the intervals of service.
  - The agreement is set out for a term of at least one year.

Stark and Kickback Issues in the Sleep Arena

- The Personal Services and Management Contracts Safe Harbor requires that (cont'd):
  - The aggregate compensation paid to Dr. Jones is set out in advance, reflects fair market value, and does not take into account the volume or value of referrals or business generated between the parties.
  - The services to be furnished do not involve activities that violate Federal or state law.
  - The services are reasonable and necessary to accomplish the business purpose of the services.

Stark and Kickback Issues in the Sleep Arena

- In analyzing the arrangement under the AKS, questions that are important to this analysis include:
  - Does Dr. Jones actually perform all of the services outlined in the Agreement?
  - Is Dr. Jones' compensation commensurate with fair market value for such services?
  - Although not obligated to full-time employment, how much time does Dr. Jones devote to such responsibilities?
  - How often is Dr. Jones actually paid under this agreement?

Professional Reading Agreement

- Similar to a Medical Director Agreement, a Professional Reading Agreement (“PRA”) should comply with the applicable exception to Stark and applicable Safe Harbor to the AKS. The PRA should be examined to ensure that the compensation is fair market value for the services that are rendered. It is possible that the government could take the position that in exchange for referrals to ABC, XYZ receives remuneration from Dr. Jones in the form of discounted services. Therefore, it is imperative that the arrangement fit as closely as possible within the Personal Services and Management Contracts Safe Harbor to the AKS and that the parties are able to support the fee as fair market value for Dr. Jones’ interpretation services.

Professional Reading Agreement

- Assume that the PRA states that Dr. Jones will receive a flat $___ per Fully Interpreted Test. The fee should be consistent with fair market value for the services rendered. Also, although the fee is flat, the compensation will take into account the volume of the business that is generated by XYZ (i.e., the more interpretations that Dr. Jones performs, the higher his compensation). The OIG has stated that this "per-click" type of fee is "inherently reflective of the volume or value of services." However, per-click fees are not automatically considered a violation of the AKS. In our example, Dr. Jones's fee does not appear to take into account any referrals that Dr. Jones may provide to XYZ; however, this general red flag should be noted.

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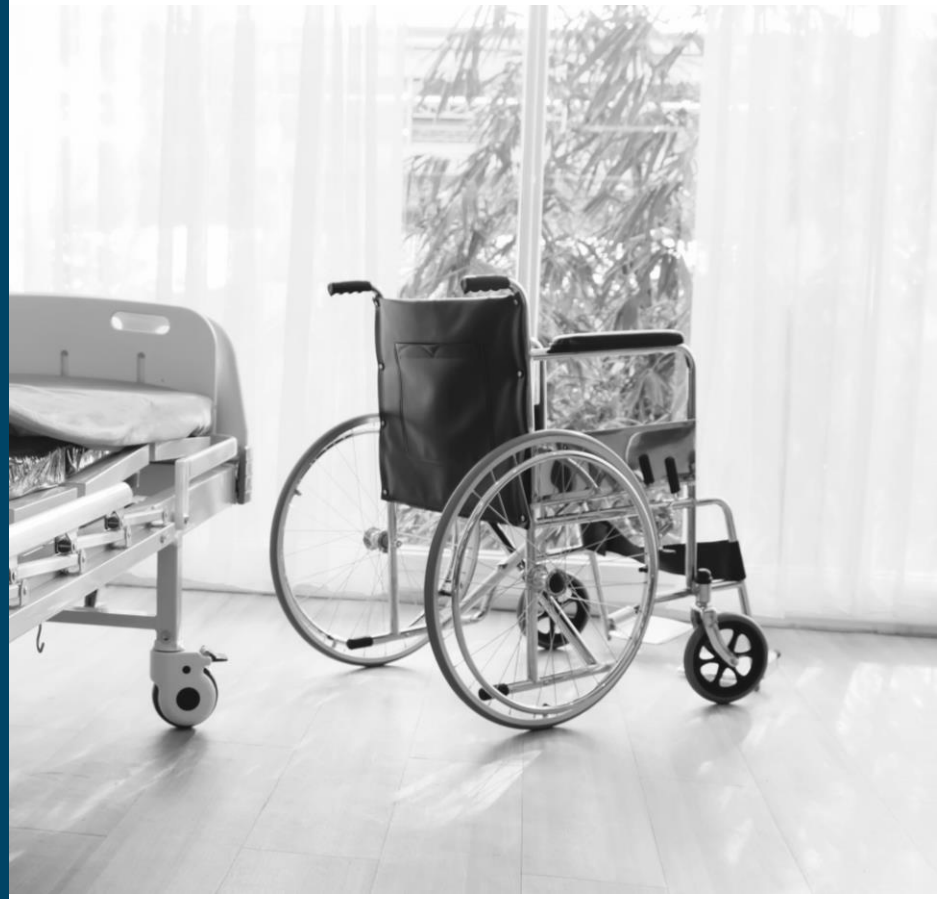

Joint Ventures Between DME Suppliers & Sleep Labs

Joint Ventures Between DME Suppliers & Sleep Labs

- A joint venture (“JV”) arises when two or more parties own something together.
- It is not uncommon for a DME supplier (“ABC Medical Equipment”) and a sleep lab (“XYZ Sleep Lab”) to set up a JV (“DEF Sleep Equipment and Supplies”) that sells CPAPs and disposables to patients diagnosed with obstructive sleep apnea.

Joint Ventures Between DME Suppliers & Sleep Labs

- In conducting an analysis under the AKS, we need to first consider whether the JV complies with the Small Investment Interest safe harbor to the AKS. Assuming that DEF cannot meet the two 60-40 tests of the safe harbor, the safe harbor cannot be met. So, we need to determine if the JV complies with the
  - OIG's 1989 Special Fraud Alert ("Joint Ventures") and
  - OIG's April 2003 Special Advisory Bulletin ("Contractual Joint Ventures").

Joint Ventures Between DME Suppliers & Sleep Labs

- The key requirements of the Special Fraud Alert and Special Advisory Bulletin are the following:
  - ABC and XYZ must each put up the initial investment in accordance with each party's percentage ownership interest in DEF.
  - If future capital contributions are necessary, each owner must pay its pro rata share of the capital contribution.
  - XYZ will have no obligation, express or implied, to refer to DEF.
  - XYZ cannot be forced to relinquish its ownership interest in DEF if XYZ does not send a certain number of referrals to DEF.

Joint Ventures Between DME Suppliers & Sleep Labs

- The key requirements of the Special Fraud Alert and Special Advisory Bulletin are the following (cont'd):
  - The number of referrals from XYZ to DEF cannot be tracked.
  - XYZ will ensure patient choice. That is, OSA patients will have the right to select any DME supplier for their CPAPs/supplies.
  - Profit distributions to ABC and XYZ will be based solely on each party's percentage ownership interest in ABC. For example, if XYZ owns 50% of DEF and if all of XYZ's referrals go to a supplier other than DEF, XYZ is still entitled to receive 50% of any profits distributed by DEF.

Joint Ventures Between DME Suppliers & Sleep Labs

- The key requirements of the Special Fraud Alert and Special Advisory Bulletin are the following (cont'd):
  - Either ABC or XYZ has the right to sell its equity interest in DEF to another party. However, such a sale can be subject to a right of first refusal owned by the non-selling party.

Joint Ventures Between DME Suppliers & Sleep Labs

- The key requirements of the Special Fraud Alert and Special Advisory Bulletin are the following (cont'd):
  - DEF needs to have operational responsibilities and financial risk. Said another way, DEF must have skin in the game. DEF cannot be run on a turnkey basis by ABC. For example, DEF must have its own employees, and DEF must have inventory and equipment. ABC and/or XYZ can provide some services to DEF. Such services must be memorialized in a written agreement, and DEF must pay fair market value compensation for the services.
  - DEF needs to actively market to the community. DEF needs to strive to lessen its dependence on referrals from XYZ

Joint Ventures Between DME Suppliers & Sleep Labs

- If a JV (between a DME supplier and sleep lab) is structured to comply with the preceding 10 bullets, the risk is low that a governmental enforcement agency will assert that the joint venture violates the AKS.
- You will also need to consider Stark.
- If XYZ is owned by physicians, unless the Stark rural provider exception is met, Stark prohibits XYZ and the physicians from referring Medicare and Medicaid patients to DEF.

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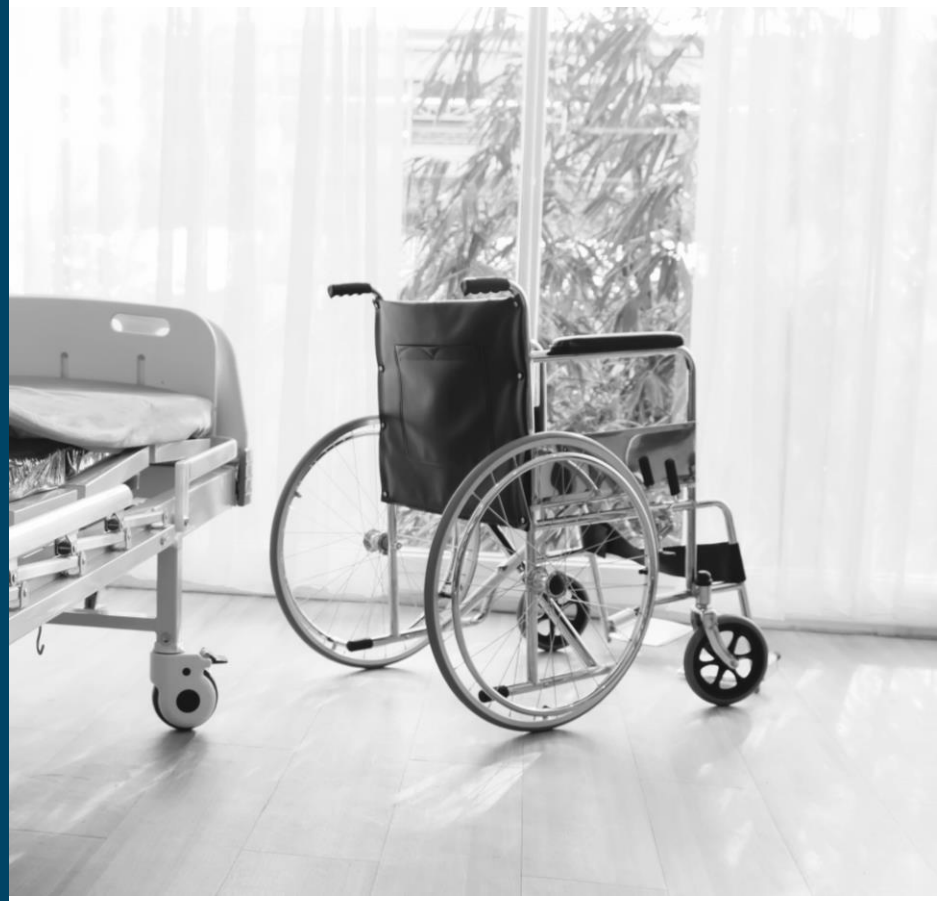

Medicare CPAP Payment Prohibition

Medicare CPAP Payment Prohibition

- If the patient is covered by Medicare, the DME supplier can have no involvement with a home sleep test (“HST”).

Medicare CPAP Payment Prohibition

- Let's make a distinction:
  - Overnight Oxygen Qualification Test
    - A DME supplier can have some involvement with an overnight oxygen qualification test provided to a Medicare patient. The supplier can
      - own the oximeter,
      - deliver the oximeter to the Medicare beneficiary's home,
      - pick up the oximeter the next morning, and
      - transmit the raw data to the IDTF.
    - If the physician orders oxygen for the beneficiary and if the beneficiary chooses to obtain the concentrator from the DME supplier that served as courier for the oximeter, the DME supplier can provide the concentrator to the beneficiary.

Medicare CPAP Payment Prohibition

- Let's make a distinction (cont'd):
  - HST
    - Logic would suggest that a DME supplier can have the same involvement with an HST and be able to provide the CPAP to the Medicare beneficiary. This is not the case. Assume that ABC Medical Equipment, Inc., owns HST devices. The beneficiary's physician orders an HST for the beneficiary. At the physician's request, ABC delivers the HST device to the beneficiary, assists the beneficiary with set-up and use of the HST device, retrieves the HST from the beneficiary the next morning, and transmits the test results to the physician. If the physician orders a CPAP for the beneficiary and if the beneficiary elects to obtain the CPAP from ABC, then if ABC provides the CPAP, it violates the Medicare CPAP payment prohibition.

Medicare CPAP Payment Prohibition

- The Medicare CPAP payment prohibition states as follows:
  - No Medicare payment will be made to the supplier of a CPAP device if that supplier or its affiliate is, directly or indirectly, the provider of the sleep test used to diagnose the beneficiary with obstructive sleep apnea. This prohibition does not apply if the sleep test is an attended facility-based polysomnogram.
- It is important to understand how Medicare defines an "affiliate."
  - "Affiliate," for purposes of the prohibition, is "a person or organization that is related to another person or organization through a compensation arrangement or ownership." The term "compensation arrangement" is not defined in the section of the CMS regulations that the prohibition appears, but the same term is used in and defined by the Stark statute as "any arrangement involving any remuneration … ."

Medicare CPAP Payment Prohibition

- Medicare will not pay ABC for the CPAP if ABC is the "provider of the sleep test." That term is defined as "the individual or entity that directly or indirectly administers and/or interprets the sleep test and/or furnishes the sleep test device used to administer the sleep test." When promulgating this definition, CMS provided some clarity in the Final Rule when it stated the following:
  - We have defined a provider of sleep test as an individual or entity that directly or indirectly administers and/or interprets the test and/or furnishes the sleep test device. By indirect, we mean that one or more intermediary actors are used to accomplish the sleep test to its end. For example, if a DME supplier contracted with a sleep test provider to furnish HST, that supplier would indirectly provide the HST. Directly providing the test means there are no intermediary actors—no intervening persons or entities between them.

Medicare CPAP Payment Prohibition

- This payment prohibition applies to Medicare fee-for-service patients.
  As to whether or not there is a similar prohibition with commercial insurance patients (including Medicare Advantage patients), the supplier will need to examine the insurance contracts and the insurance company's payment/coverage guidelines.
- If a supplier determines that it has violated the payment prohibition, the supplier needs to refund the money it has been paid for the CPAPs and the disposables.

Medicare CPAP Payment Prohibition

- Where the payment prohibition can come into play for the DME supplier is when it is about to sell. In conducting due diligence, if the buyer determines that the payment prohibition has been violated, it is likely that:
  - the purchase price will be lowered or
  - the buyer will walk away.

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Questions?

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Thank you

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