



"HUB & SPOKE" CENTRALIZED INTAKE & OTHER STEPS TO STREAMLINE OPERATIONS

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INTRODUCTION



DMEPOS

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- Running a DME operation is complicated. There are many moving parts.
- The following slides discuss a number of important issues that the supplier must navigate in order to (i) be profitable and (ii) operate within the bounds of the law.
- With reduced reimbursement, stringent documentation requirements, and competitive bidding re-entering the picture in the next year, profit margins for DME suppliers are tight.
- The DME supplier has no choice but to reduce expenses and improve efficiencies.
- This webinar will present ideas to reduce expenses and improve efficiencies, while remaining within legal parameters.







- In today's environment, the DME supplier has no choice but to streamline its operation.
 One way to accomplish this is for the supplier to centralize its intake operations.
- Let's look at a supplier that is organized as a legal entity with a single tax identification number ("Tax ID") and with multiple locations. Assume that each location has its own PTAN.
- The various locations route received telephone calls to a designated main location.
- Personnel at the main location perform eligibility checks and verify a beneficiary's qualifications for the equipment. Physicians fax orders for equipment to a centralized fax number associated with the main location.



- The issue of a centralized intake center, or call center, implicates the DMEPOS Quality Standards.
- With regard to the Quality Standards, a supplier is responsible for performing "intake and assessment." The NSC has stated, in other context, that a supplier may not subcontract out or otherwise delegate to a third party its intake and assessment responsibilities. Unfortunately, neither CMS nor the NSC has issued additional significant guidance regarding what constitutes "intake and assessment."



- Based on a review of the limited Medicare guidelines available and informal guidance from the NSC, locations sharing the same Tax ID are likely to be considered the same supplier and, therefore, may centralize their intake operations at a single location if the following policies and/or procedures are implemented:
 - Each separate location must maintain its own local telephone number.
 - Calls to a location's local telephone number must allow a beneficiary to speak with a live representative at that location, if so desired by the beneficiary.
 - At the time of intake, the beneficiary will be assigned to the nearest supplier location, as
 determined by the beneficiary's zip code.
 - Intake personnel at the centralized call center or the main location must advise the beneficiary that the aforementioned nearest supplier location will be his or her supplier with regards to the equipment.



- The location that dispenses the equipment must be the one that bills Medicare for the item using its PTAN.
- Paperwork provided to the beneficiary from the entity must clearly indicate the specific location from which the equipment will be dispensed.
- The equipment being dispensed must come from the inventory of the location that sets up the beneficiary and bills for the equipment.
- If necessary, the beneficiary must go to the specific location that dispensed the equipment for any service or repair.



- The analysis is limited to the centralization of intake operations among locations that share the same Tax ID under a single entity. In circumstances involving entities or locations with two or more distinct Tax IDs, such entities or locations are considered to be separate suppliers.
- Accordingly, in order to reduce the risk of violating the Quality Standards, additional procedures should be implemented if establishing a centralized intake or call center for multiple legal entities.



- In those situations, in addition to the above provisions, to the extent that the centralized intake or call center obtains or collects eligibility information or other documentation regarding the beneficiary or the order (e.g., medical records), the centralized call center must provide such documentation to the primary supplier prior to furnishing the equipment to the beneficiary.
- Upon receipt, the primary supplier must review the documentation and independently determine whether there is medical necessity for the item prior to authorizing the centralized call center to furnish the equipment to the beneficiary.



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- The hub and spoke model is a method to expand into new geographical areas without having to obtain new supplier numbers.
- Here is how the model works:
 - ABC Medical Equipment, Inc. ("ABC") is located in Dallas, TX; it has a supplier number attached to its Dallas location;
 - ABC decides to expand into Denton, TX, but does not want to go through the expense and time to obtain a supplier number for a location in Denton;
 - ABC opens a warehouse in Denton and hires a delivery driver to service the Denton area;
 - The warehouse is not open to customers;



- Here is how the model works (cont'd):
 - The phone number published in the Denton phone book is a toll-free number that goes to the Dallas location;
 - When a physician calls in an order, the call goes to Dallas; likewise, when a customer calls ABC, the call goes to Dallas;
 - ABC's employee handles the intake, assessment, and coordination of care; in short, the "point of sale" occurs in Dallas;
 - The Dallas employee instructs the Denton delivery driver to pick up a piece of equipment from the warehouse and deliver it to the customer's house; and



- Here is how the model works (cont'd):
 - If the customer has a piece of equipment that needs to be repaired, then the delivery driver drops a "loaner" off at the customer's house, picks up the equipment to be repaired, has the equipment repaired, delivers the repaired equipment to the customer's house, and picks up the "loaner."









- On July 23, 2007, CMS issued a letter to Medicare Part C and D plan sponsors addressing the performance of the plan sponsors' activities outside of the United States.
- In the letter, CMS asked each plan sponsor to submit information about offshore subcontractors plus an attestation that the plan sponsor has taken steps to address the risks associated with sending "protected health information," as defined by HIPAA ("PHI"), to foreign subcontractors.
- The letter directed plan sponsors to mail hard copies of the information and attestations to CMS.



- On September 20, 2007, CMS issued another letter that addressed questions arising from the July 23 letter.
- In the September 20 letter, CMS stated that the subcontractor relationships the plan sponsors are required to disclose must include all downstream subcontractors. 42 C.F.R. 1001.952(t)(2)(i), (iii), and Medicare Managed Care Manual, Chapter 11, Section 10 define a "downstream contractor" as a party that enters into an agreement below the level of the agreement between the plan sponsor and a first tier subcontractor down to the level of the ultimate provider of health and/or administrative services.



- The September 20 letter further stated that "Medicare-related work" that triggers the reporting and attestation requirements includes claims processing and data entry.
- On August 26, 2008, CMS issued a letter announcing the launch of the Offshore Subcontractor Data module in the Health Plan Management System website.
- This module allows plan sponsors to submit the required information and attestations electronically rather than by hard copy.
- Based on CMS's requirement that Medicare Part C and D plan sponsors gather and submit information about offshore subcontractors, we can conclude that CMS does not prohibit a DME supplier from using an offshore subcontractor in connection with PHI from Medicare beneficiaries.



- Because CMS issued its directive to plan sponsors to submit information and attestations to the Offshore Subcontractor Data Module, a downstream subcontractor is not directly required to submit information to the module. DME suppliers (that contract with offshore subcontractors) may be required by their network agreements to provide information and attestations to the Part C and D plans that those suppliers are in network with.
- In this case, the suppliers may seek information and attestations from the offshore subcontractors.
- As of yet, CMS has not issued a directive to downstream subcontractors to enter information into the Offshore Subcontractor Data module.



The bottom line is that CMS guidance does not prohibit a DME supplier that bills
 Medicare under the fee-for-service program, or a supplier that is in network with a
 Medicare managed care plan, from using an offshore subcontractor to perform claims
 processing services.





EMPLOYEE LIAISON



DMEPOS

EMPLOYEE LIAISON

- A DME supplier can designate an employee to be on the hospital premises for a certain number of hours each week.
- The employee may educate the hospital staff regarding medical equipment (to be used in the home) and related services. The employee may also work with a patient, after a referral is made to the supplier (but before the patient is discharged), in order for there to be a smooth transition when the patient goes home.
- The employee liaison may not assume responsibilities that the hospital is required to fulfill.
- Doing so will save the hospital money, which will likely constitute a violation of the Medicare anti-kickback statute.





MEDICAL DIRECTOR AGREEMENT



MEDICAL DIRECTOR AGREEMENT

- A DME supplier can enter into an independent contractor Medical Director Agreement with a physician.
- The MDA must comply with the
 - Personal Services and Management Contracts safe harbor and
 - the Personal Services exception to the Stark physician self-referral statute.



MEDICAL DIRECTOR AGREEMENT

- Among other requirements:
 - The MDA must be in writing and have a term of at least one year.
 - The physician must provide substantive services.
 - The compensation to the physician must be fixed one year in advance and be the fair market value equivalent of the physician's services.







EDUCATIONAL RESOURCES

UTILIZATION OF MARKETING COMPANY

BE AWARE OF KICKBACK PROBLEMS

- In the real world, it is common for a business to "outsource" marketing to a marketing company.
- Unfortunately, what works in the real world often does not work in the DME universe. An
 example of this has to do with marketing companies.
- If a marketing company generates patients for a supplier, when at least some of the patients are covered by a government health care program, then the supplier cannot pay commissions to the marketing company. Doing so will violate the AKS.
- The Office of Inspector General (the "OIG") has adopted safe harbors that provide immunity for arrangements that satisfy certain requirements.



BE AWARE OF KICKBACK PROBLEMS

- The employee safe harbor permits an employer to pay an employee in whatever manner the employer chooses in exchange for the employee assisting in the solicitation of federal health care program business, as long as there is a bona fide employer-employee relationship.
- The only way that an independent contractor can be paid for marketing or promoting Medicare-covered items or services is if the arrangement complies with, or substantially complies with, the personal services and management contracts safe harbor.
- This safe harbor permits payments to referral sources as long as a number of requirements are met.



BE AWARE OF KICKBACK PROBLEMS

• Two of the requirements are that (i) payments must be pursuant to a written agreement with a term of at least one year, and (ii) the aggregate compensation paid to the independent contractor must be set in advance (e.g., \$24,000 over the next 12 months), be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or business generated between the parties.







- Approximately (i) 35% of all Medicare patients are covered by Medicare Advantage Plans ("MAPs") and (ii) 70% of all state Medicaid patients are covered by Medicaid Managed Care Plans ("MMCPs"). These percentages are increasing.
- A MAP and MMCP essentially operate the same way.
- The MAP, owned by an insurance company, contracts with CMS. Pursuant to the CMS contract, the MAP will (i) cover Medicare beneficiaries ("Medicare Covered Lives") and (ii) contract with health care providers and suppliers to take care of the Medicare Covered Lives. CMS pays the MAP and the MAP pays the provider/supplier.



- The same concept is true with an MMCP.
- The MMCP, owned by an insurance company, contracts with the state Medicaid program.
 Pursuant to the Medicaid contract, the MMCP will (i) cover Medicaid beneficiaries
 ("Medicaid Covered Lives") and (ii) contract with health care providers and suppliers to
 take care of the Medicaid Covered Lives.
- The state Medicaid program pays the MMCP and the MMCP pays the provider/supplier.
 The MAP and MMCP contracts will collectively be referred to as "Third Party Payer Contracts" or "TPP Contracts."



- A challenge faced by many DME suppliers is that MAPs and MMCPs (collectively referred to as "Plans") have "closed panels."
- This means that the Plan tells the DME supplier: "We have enough DME suppliers on our provider/supplier panel. We don't need you. Therefore, we will not sign a TPP Contract with you."
- The end result for the DME supplier is that if a Medicare Covered Life or Medicaid Covered Life (collectively referred to as "patient") wants to obtain a product from the DME supplier, and if the patient is covered by a TPP Contract for which the DME supplier is not on the panel, then the DME supplier must turn the patient away ... unless, of course, the patient is willing to pay cash to the DME supplier without getting reimbursed by the Plan.



- As a "workaround," the DME supplier may want to enter into an arrangement with another DME supplier to gain access to the other DME supplier's TPP Contract. For example, the two suppliers may want to do the following:
 - Supplier A is a party to TPP Contract 1. Supplier B is not a party to TPP Contract 1.
 - When a patient under TPP Contract 1 wants to purchase a product from Supplier B, then Supplier B will take care of the patient.
 - Supplier B will (i) handle intake, assessment and coordination of care (collectively referred to as
 "intake"), (ii) deliver and set up the equipment, and (iii) handle the subsequent maintenance and
 repairs.
 - Supplier A will submit a claim under TPP Contract 1. Upon receipt of payment under TPP Contract 1, Supplier A will (i) pay a large percentage (e.g., 92%) to Supplier B and (ii) retain the balance.



- The problem with this arrangement is that it likely violates the federal anti-kickback statute ("Federal AKS"), the federal False Claims Act ("Federal FCA"), and their state counterparts.
- Here are how the Federal AKS and Federal FCA may come into the picture:



- Federal AKS This statute makes it a felony for Supplier A to give anything of value in exchange for receiving the referral of a patient covered by a government health care program and for Supplier B to receive anything of value in exchange for referring (or arranging for the referral of) a patient covered by a government health care program.
- In the eyes of the Plan, the "supplier" is Supplier A: it is the party to the TPP Contract and it is billing and collecting under the TPP Contract.
 - The kickback issue arises because Supplier B is referring or arranging for the referral of the patient to Supplier A and
 - Supplier A is, in turn, remitting e.g., 92% of the payment to Supplier B.



- Federal FCA This statute prohibits Supplier A from submitting "false claims"... and Supplier B cannot conspire (or collaborate) with Supplier A for the submission of false claims.
- When Supplier A submits a claim to the Plan, Supplier A is representing that it is the supplier ... that took care of the patient and, therefore, deserves to be paid. In fact, this is not the case.
- The *true* supplier is Supplier B; it is the entity that does the work. All Supplier A does is submit a claim under the TPP Contract. Hence, the claim submitted is a false claim. And Supplier B will have collaborated with Supplier A in the submission of the false claim.



 So now that we have talked about what Supplier A and Supplier B cannot do, let us talk about what they can do. If Supplier A and Supplier B desire to enter into a Subcontract Agreement ("SA"), then here are the steps they should take:



• Review the TPP Contract - The parties need to review Supplier A's TPP Contract to determine if it addresses subcontract arrangements. The TPP Contract may say nothing about whether or not Supplier A can subcontract out its responsibilities to Supplier B. If the TPP Contract is silent, then in order to avoid problems under the Federal AKS and Federal FCA, the SA should be structured as set out hereafter. On the other end of the spectrum, the TPP Contract may prohibit Supplier A from subcontracting out its services. The TPP Contract may very well take the middle road and provide for one of the following: (i) Supplier A can subcontract out its services but must first notify the Plan of who the subcontractor will be; (ii) Supplier A can subcontract out not more than e.g., 20% of its services; (iii) Supplier A can subcontract out its services only if the Plan approves the subcontractor in advance; or (iv) Supplier A can only subcontract out specifically delineated services.



• Supplier A Must Retain a Level of Operational Responsibilities and Financial Risk – So that it can credibly assert that it is the "supplier," Supplier A must have a level of operational responsibilities and financial risk. For example, Supplier A needs to handle the intake. This means that Supplier A must determine if the patient qualifies for coverage under the TPP Contract. Supplier B can gather information and documents and forward them to Supplier A . . . but it is Supplier A, not Supplier B, that must determine if the patient is to receive the product. If the patient later has a maintenance/repair need, then he needs to call Supplier A; Supplier A can, in turn, direct Supplier B to handle the repair/maintenance. Further, Supplier A will be obligated to pay Supplier B regardless of whether or not the Plan pays Supplier A. In other words, Supplier A's obligation to pay Supplier B for its services is absolute.



• Inventory – Under the SA, Supplier B will deliver the product to the patient "for and on behalf of Supplier A." At the time of delivery, title to the product needs to be in Supplier A's name. This can be accomplished in one of several ways: (i) Supplier A can purchase the inventory, take possession of it, and deliver it to Supplier B; (ii) Supplier A can purchase the inventory, not take possession of it, and direct the manufacturer to deliver the inventory (on behalf of Supplier A) to Supplier B; (iii) Supplier B can purchase the inventory; on a regular basis, Supplier A can purchase inventory from Supplier B and Supplier B can segregate Supplier A's inventory in Supplier B's warehouse; or (iv) Supplier B can purchase the inventory; when Supplier B is about to deliver the product to the patient's home, then title will transfer to Supplier A and Supplier A will have the obligation to purchase the product from Supplier B.



• Supplier B's Services – The SA can provide that Supplier B's services include the following: (i) deliver the product to the patient, educate the patient on how to use the product, and set the product up for the patient; (ii) obtain information and documents from the patient and his physician and transmit them to Supplier A so that Supplier A can conduct the intake; and (iii) at the direction of Supplier A, provide maintenance and repair services to the patient. The labels on the products delivered to the patients need to reflect Supplier A.



Flow of Money – At the end of the day, Supplier B will be referring (or arranging for the referral of) patients to Supplier A ... and Supplier A will be paying money to Supplier B. The most conservative course of action is as follows: (i) if Supplier A purchases inventory from Supplier B, then the purchase price must be fair market value ("FMV") and must be pursuant to a price list attached to the SA; and (ii) Supplier A pays fixed annual compensation (e.g., \$48,000 over the next 12 months) to Supplier B in which such compensation is the FMV equivalent of Supplier B's services. If fixed annual compensation is not feasible, then a less conservative course of action is as follows: (i) if Supplier A purchases inventory from Supplier B, then the purchase price must be FMV and must be pursuant to a price list attached to the SA; and (ii) Supplier A pays a fixed fee per each unit of service provided by Supplier B, such compensation is the FMV equivalent of Supplier B's services, and the compensation is set out in a fee schedule attached to the SA. If the parties want to strengthen their position that the compensation paid to Supplier B is FMV, then the parties can order an FMV evaluation and report from an independent third party.







SWITCHING SUPPLIERS: NEW PHYSICIAN ORDER NOT REQUIRED

- Until the spring of 2017, the Medicare Program Integrity Manual ("MPIM"), Chapter 5, §
 5.2.7 required a new physician order "when there is a change in the supplier." This
 requirement resulted in hardship to Medicare beneficiaries and DME suppliers.
- There was no logical reason for the beneficiary to be required to obtain a new physician's order just because Supplier A takes over from Supplier B. The original physician's order does not lose its credibility just because a new supplier comes into the picture. The bottom line is that this requirement created a real burden for beneficiaries if a new faceto-face visit was required in order to obtain a new physician's order.



- Likewise, the "new physician order" requirement created an unnecessary burden on the new supplier.
- Before the new supplier could bill for its products and services, it would have to wait for the physician to transmit the new order to the new supplier, which frequently also required waiting for the beneficiary to first see his physician if a new face-to-face visit was required.
- This problem was exacerbated by competitive bidding. Many beneficiaries, residing in CBAs, had to switch suppliers.



- For years, DME industry stakeholders explained to CMS that the requirement of a new physician's order (when a beneficiary switches suppliers) was not necessary and caused unnecessary hardship on both the beneficiary and the new supplier.
- Until the spring of 2017, the industry's concerns fell on deaf ears. It appears, though, that the fall-out from competitive bidding garnered CMS' attention.
- On March 24, 2017, CMS issued Change Request 9886 with an April 24, 2017 effective date. It says, in part:
 - Summary of Changes: "The purpose of this change request (CR) is to instruct contractors to
 accept timely orders and medical documentation, regardless of whether the supplier received
 the documentation directly from the beneficiary's eligible practitioner or from another,
 transferring supplier."



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- On March 24, 2017, CMS issued Change Request 9886 with an April 24, 2017 effective date. It says, in part (cont'd):
 - Background: "The DMEPOS Competitive Bidding Program uses competition amongst suppliers
 to improve the effectiveness of the Medicare methodology for setting DMEPOS payment
 amounts, while ensuring beneficiary access to quality items and services. Industry has
 suggested that competition may be bolstered and provider burden limited by allowing suppliers
 to accept medical documentation from other suppliers who previously held responsibility for
 that beneficiary. This change in the Center for Medicare & Medicaid Services (CMS) instruction
 would permit contractors to accept timely orders and medical documentation, regardless of
 whether the supplier received the documentation directly from the beneficiary's eligible
 practitioner for from a transferring supplier."



- On March 24, 2017, CMS issued Change Request 9886 with an April 24, 2017 effective date. It says, in part (cont'd):
 - Requirement: "Contractors shall accept documentation of the beneficiary's need for an item, regardless of whether the supplier received the documentation directly from the beneficiary's treating physician/practitioner or as transferred from their previous supplier."
 - Requirement: "Contractors shall, in those instances in which the documentation is not transferred, continue to require a new order/documentation be received by the supplier from the treating physician/practitioner."



- Medicare Program Integrity Manual, Chapter 5, § 5.2.7. is amended to read as follows: "A new order is required in the following situations:
 - There is a change in the order for the accessory, supply, drug, etc.;
 - On a regular basis (even if there is no change in the order) only if it is so specified in the documentation section of a particular medical policy;
 - When an item is replaced; and
 - When there is a change in the supplier, if the recipient supplier did not obtain a valid order for the DMEPOS item from the transferring supplier.



This Change Request is good news for DME suppliers. When a Medicare beneficiary switches to a new supplier, for whatever reason, then if the new supplier can secure a valid physician's order from the prior supplier, then the new supplier does not have to obtain a new physician's order.





QUESTIONS?

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THANK YOU

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