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COMPETITIVE BIDDING: WHAT DO YOU DO IF YOU ARE AWARDED…OR ARE NOT AWARDED… A COMPETITIVE BID CONTRACT?

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by Jeffrey S. Baird, Esq.
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BIOGRAPHY - JEFFREY S. BAIRD, ESQ.

Jeffrey S. Baird, Esq., is the Chairman of the Health Care Group of the Amarillo, Texas based law firm of Brown & Fortunato, P.C. The firm's Health Care Group has a large national health care practice with clients throughout the United States. The Health Care Group represents durable medical equipment companies, pharmacies, drug wholesalers and repackagers, long term care facilities, home health agencies, hospitals, physicians and other health care providers. The Health Care Group represents clients in the areas of advising on fraud and abuse issues; defense of criminal and civil fraud investigations; defense of qui tam actions; corporate compliance; HIPAA compliance; accreditation preparation; mergers and acquisitions; joint equity arrangements, affiliations and alliances; reimbursement issues, including audits and requests for overpayments; provider and provider number issues; requirements pertaining to licenses, permits and certifications; survey certification and licensing issues; peer review and credentialing; pharmacy compounding; Food and Drug Administration regulatory issues; hospital operational issues; hospital medical staff relationships; and hospitals/health care organizations in transitional environments. The Health Care Group works closely with the Department of Justice, Office of Inspector General, Centers for Medicare and Medicaid Services, National Supplier Clearinghouse, DME Medicare Administrative Contractors, ZPICs and other Medicare contractors, Food and Drug Administration, and other federal and state regulatory agencies. Mr. Baird has authored numerous articles and is a frequent lecturer throughout the country. He serves on the Medtrade Education Advisory Board, the AAHomecare Regulatory Council, the AAHomecare Audit Task Force and the AAHomecare Audit Educator Work Group. Mr. Baird earned a B.B.A. from the University of Iowa and received his law degree from the University of Tulsa College of Law. Mr. Baird is Board Certified in Health Law by the Texas Board of Legal Specialization.

BIOGRAPHY – MARK HIGLEY, VICE PRESIDENT - DEVELOPMENT

Mark Higley is Vice President of Development of the VGM Group with responsibilities including corporate business development, market research and industry analysis. His current projects include analysis of governmental, regulatory and compliance issues affecting the DMEPOS industry, such as national competitive bidding, accreditation, the DRA, HIPAA and other recent provider issues (MIPPA legislation, clarification policies, quality and supplier standards, fraud and abuse, etc.). He sits on the AAHomecare Regulatory Committee and a frequent speaker at HME industry events. Mark received his master's of business administration in marketing research from the University of Iowa, and earned undergraduate degrees in Finance and Economics. Prior to his 1998 employment with VGM, Mark held a variety of executive positions with the Arena Football League, Chicago, IL, and as a financial analyst with Deere & Company, Moline, IL.

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You Have Been Awarded a Competitive Bid Contract: Now What Do You Do?

The "good news" is that you have been awarded a competitive bid contract. However, the "bad news" is that you have been awarded competitive bid contract. In other words, what are your rights and obligations under the contact? How can you make money under the competitive bid contract on light of that fact that the reimbursement will be so low?

Payment under the Competitive Bidding Program

CMS will pay the supplier 80% of the single payment amount for the item in the CBA where the beneficiary maintains a permanent residence. The remaining 20% will be the beneficiary's coinsurance responsibility.

The single payment amounts will remain in effect for the full three-year term of the contracts; they will not be adjusted for inflation.

Contract suppliers will be required to accept assignment.

A contract supplier is required to furnish competitively bid items to any beneficiary who resides in the CBA, or who visits the CBA, and who requests those items from that contract supplier.

Suppliers may still use ABNs for items for which Medicare might not pay.

A beneficiary who resides in a CBA and requires equipment or supplies while away from home and in another CBA will be required to obtain items from a contract supplier in the CBA into which he or she has traveled. A beneficiary who resides in a CBA who travels to a non-competitive bid area may obtain items from any Medicare-enrolled supplier. In either case, the supplier will be paid based on the single payment amount for the item in the area where the beneficiary resides.

A beneficiary who does not reside in a CBA who requires equipment or supplies while away from home in a CBA will be required to obtain items from a contract supplier. In that case, however, the payment amount will be based on the lower of the actual charge or the applicable DMEPOS fee schedule amount.

Contractual Obligations

Maintain billing privileges. A contract supplier must maintain Medicare billing privileges, state licenses, and accreditation during the entire term of the contract. In addition, a contract supplier must comply with all requirements of the competitive bidding program.

Accept assignment. A contract supplier must accept assignment on all items under its contract.

Accept single payment amounts. A contract supplier is paid based on the single payment amounts. Single payment amounts are published on the CBIC's website at www.dmecompetitivebid.com. On the left side of the homepage, there is a button link to "Single Payment Amounts."

Nondiscrimination (i.e., No "Medicare-only" items). A contract supplier may not discriminate against a Medicare beneficiary. If a contract supplier offers a particular brand and model for an item (covered by the contract) to a non-Medicare beneficiary, then the same brand and model must be available to a Medicare beneficiary. Conversely, if a contract supplier offers a particular brand and model for an item to a Medicare beneficiary, then the same brand and model must also be available to a non-Medicare beneficiary.

Furnish items to any Medicare beneficiary. A contract supplier must furnish items covered by its contract to any Medicare beneficiary who (i) maintains a permanent residence in or visits a competitive bidding area, and (ii) requests such items from the contract supplier. There is an exception for skilled nursing facilities and nursing facilities that were awarded contracts as specialty suppliers.

Furnish specific brand or mode of delivery.

(a) If a physician or treating practitioner prescribes a particular brand of an item or mode of delivery, the contract supplier must—

(1) Furnish the particular brand or mode of delivery as prescribed by the physician or treating practitioner;

(2) Consult with the physician or treating practitioner to find an appropriate alternative brand of item or mode of delivery for the beneficiary and obtain a revised written prescription from the physician or treating practitioner; or

(3) Assist the beneficiary in locating a contract supplier that can furnish the particular brand of item or mode of delivery prescribed by the physician or treating practitioner.

(b) Medicare does not make an additional payment to a contract supplier that furnishes a particular brand or mode of delivery for an item.

(c) A contract supplier is prohibited from submitting a claim to Medicare if it furnishes an item different from that specified in the written prescription received from the beneficiary's physician or treating practitioner.

(d) A physician or treating practitioner may prescribe a particular brand of an item or a particular mode of delivery for an item, if he or she determines that the particular brand or mode of delivery would avoid an adverse medical outcome for the beneficiary. The physician or treating practitioner must document the reason in the beneficiary's medical record why the particular brand or mode of delivery is medically necessary to avoid an adverse medical outcome.

Disclose subcontracting arrangements.

(a) Initial disclosure. Not later than 10 days after the date a supplier enters into a competitive bidding contract, the supplier must disclose information on both of the following:

(1) Each subcontracting arrangement that the supplier has in furnishing items and services under the competitive bidding contract.

(2) Whether the subcontractor meets the DMEPOS accreditation requirements. All suppliers, including those that perform subcontracted services, must be accredited unless an exemption to accreditation is applicable. All subcontractors must be accredited to perform equipment set-up and patient instruction, unless an exemption is applicable.

(b) Subsequent disclosure. Not later than 10 days after the date a contract supplier enters into a subcontracting arrangement, the contract supplier must disclose information on both of the following:

(1) The subcontracting arrangement that the supplier has in furnishing items and services under the competitive bidding contract.

(2) Whether the subcontractor meets the DMEPOS accreditation requirements. All suppliers, including those that perform subcontracted services, must be accredited unless an exemption to accreditation is applicable. All subcontractors must be accredited to perform equipment set-up and patient instruction, unless an exemption is applicable.

Notify CMS of changes in ownership. A contract supplier is required to notify CMS if it is negotiating a change in ownership 60 days before the anticipated effective date of the change.

Transition to a contract supplier. When a beneficiary chooses to switch from a noncontract supplier to a contract supplier (for a rental item), the contract supplier will work with the noncontract supplier to make arrangements for pickup and delivery that are suitable to the beneficiary. A beneficiary may elect to transition to a contract supplier at any time and the contract supplier is required to accept the beneficiary as a customer.

The noncontract supplier is responsible for furnishing the item until the first rental anniversary date of the equipment that occurs after the start of the competitive bidding program, and the contract supplier may not bill for the new equipment until the first rental anniversary date. The anniversary date is the day of the month on which the item was first delivered to the beneficiary. Thus, the date of pickup and delivery should be the first anniversary date of the equipment. CMS needs to issue guidance addressing when a beneficiary insists on a pickup/delivery date that is substantially prior to the anniversary date.

Change of Ownership (CHOW)

1. A competitive bidding contract may not be sold or transferred. If CMS determines that a contract has been sold or transferred, the contract will be terminated.

2. A contract supplier may undergo a change of ownership. Here is what the rule says:

> (a) A contract supplier must notify CMS if it is negotiating a change in ownership 60 days before the anticipated date of the change.
>
> (b) CMS may award a contract to an entity that merges with, or acquires, a contract supplier if—
>
> > (1) The successor entity meets all requirements applicable to contract suppliers for the applicable competitive bidding program;
> >
> > (2) The successor entity submits to CMS certain documentation (e.g., disclosure on legal actions, licenses, accreditation, financial documents, etc.) if such documentation has not previously been submitted by the successor entity or the contract supplier that is being acquired, or is no longer current. This documentation must be submitted within 30 days prior to the anticipated effective date of the change of ownership. A successor entity is not required to duplicate previously submitted information if the previously submitted information is still current;
> >
> > (3) The successor entity is acquiring the assets of the existing contract supplier, it submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, a signed novation agreement acceptable to CMS stating that it will assume all obligations under the contract; or

(4) A new entity will be formed as a result of the merger or acquisition, the existing contract supplier submits to CMS, at least 30 days before the anticipated effective date of the change of ownership, its final draft of a novation agreement for CMS review. The successor entity must submit to CMS, within 30 days after the effective date of the change of ownership and executed novation agreement acceptable to CMS.

3. In addition, the parties will need to comply with the NSC's rules and procedures regarding changes of ownership.

4. A Novation Agreement needs to include the following:

(a) The agreement should clearly delineate the parties involved and must be between the transferee (purchaser) and CMS.

(b) CMS shall not incur any costs associated with the contract transfer.

(c) The transferee should agree to purchase all assets necessary to perform the terms of the contract.

(d) The transferee must assume all rights, obligations, and liabilities of the competitive bidding contract that may have occurred from the transferor (seller) of the competitive bidding contract from the effective date of the contract as if the transferee were the original party to the contract.

(e) The agreement must state that CMS does not waive its rights against the transferor insofar as the transferor may have violated federal law with respect to the DMEPOS contract.

(f) The transferee must assume the entire competitive bidding contract from the transferor, which includes all of the CBAs and product categories awarded under the contract.

(g) The transferee should ensure the efficient transfer of services to Medicare beneficiaries required under the competitive bidding contract, such that Medicare beneficiaries continue to receive uninterrupted services.

(h) The agreement must be signed by the appropriate representatives of the respective companies with certification and warranty by each party that it has full power and authority to enter into a novation agreement.

Breach and Termination

Breach of contract.

(a) Any deviation from contract requirements, including a failure to comply with governmental agency or licensing organization requirements, constitutes a breach of contract on the part of the contract supplier.

(b) In the event a contract supplier breaches its contract, CMS may take one or more of the following actions:

(1) Require the contract supplier to submit a corrective action plan;

(2) Suspend the contract supplier's contract;

(3) Terminate the contract;

(4) Preclude the contract supplier from participating in the competitive bidding program;

(5) Revoke the supplier number of the contract supplier; or

(6) Avail itself of other remedies allowed by law.

(c) There is no provision for breach of contract by CMS.

Appealing contract termination. CMS has published a fact sheet on proposed regulations that would establish an appeals process for when a supplier is determined to be in breach of contract. The following is based on the fact sheet. As of this writing, CMS has not published the actual text of the proposed regulation.

(a) Notice of termination. A contract supplier who is considered by CMS to be in breach of contract will be notified by certified mail that its competitive bidding contract will be terminated within 45 days from the date of notice. In most cases, the notice will indicate that the supplier may submit a corrective action plan to address the breach.

(b) Right to hearing. A contract supplier who receives such notice of breach will have the right to request a hearing before a CBIC hearing officer ("HO"). The CBIC must receive the supplier's request for a hearing within 30 days from the date of the notice of breach. The HO, who would not have been involved in the initial determination of breach, will conduct a review and make a recommendation based on all information submitted and presented at the hearing. The HO will issue a written recommendation to CMS within 30 days of the

hearing. The recommendation will include the HO's reasoning behind his or her recommendation to CMS.

(c) CMS decision in 30 days. Within 30 days of receiving the HO's recommendation, CMS will make a final determination based on the HO's recommendation, record of the hearing, evidence and documents considered by the HO. If CMS decides to terminate the supplier's contract, then it will notify the supplier of such termination by certified mail.

Questions and Answers

Q1. As a part of the bidding process, suppliers were required to indicate their capacity for particular items. Is a contract supplier limited to or required to meet the capacity it stated in its bid?

A1. No. CMS has stated that there is no guarantee that a contract supplier will receive any business as a result of having a competitive bidding contract, and CMS has stated that a contract supplier is free to increase its business. The supplier's capacity was used solely in the bidding process to determine the number of suppliers needed for a particular product category in a particular CBA.

Q2. Must a contract supplier provide services to every Medicare beneficiary that request services?

A2. Yes. A contract supplier is required to furnish items under its competitive bidding contract to any Medicare beneficiary who (i) maintains a permanent residence in the CBA or visits the CBA, and (ii) requests such items from the supplier.

Q3. May a supplier terminate the contract?

A3. There is no provision in the contract or regulations for a supplier to terminate the contract. Based on currently available information, CMS will likely view a contract supplier that wants to terminate the contract as being in breach of contract, because the contract requires performance for the full duration of the contract. When CMS determines that a supplier is in breach of contract, it may take certain actions, such as terminate the contract, preclude the supplier from participating in future competitive bidding programs, or revoke the supplier's Medicare billing privileges. The action that CMS takes in a particular case will likely depend on the circumstances. It is possible that CMS will allow a supplier who simply wants "out" of the contract to "walk away" by terminating the contract without further action.

Subcontracting in the Competitive Bidding Program

Introduction

Many contract suppliers will need subcontractors to help them fulfill their responsibilities under the competitive bidding contracts. For example, a contract supplier that expects a growth in business due to being awarded a competitive bidding contract may want subcontracts in place to ensure prompt delivery of items to Medicare beneficiaries. At the same time, the CBIC has issued guidelines on subcontracting that contract suppliers need to follow to ensure compliance with the competitive bidding contract. This presentation is set out in a "Q&A" format.

Questions and Answers

Q1. Is a contract supplier required to disclose its subcontractor arrangements?

A1. Yes. There is an initial and subsequent disclosure requirement. Not later than 10 days after the date a supplier enters into a competitive bidding contract, the supplier must disclose information on (i) each subcontracting arrangement that the supplier has in furnishing items and services under the competitive bidding contract; and (ii) whether the subcontractor is accredited or exempt from accreditation. Once a supplier is in a competitive bid contract and the supplier enters into a subcontract arrangement, then, not later than 10 days after entering into such arrangement, the supplier must disclose information on (i) the subcontract arrangement that the supplier has in furnishing items and services under the competitive bidding contract; and (ii) whether the subcontractor is accredited or exempt from accreditation.

Q2. What services may a subcontractor perform?

A2. Under current guidance, a subcontractor may perform the following services: (i) purchase of inventory; (ii) delivery and instruction; and (iii) maintenance and repair of rented equipment. The CBIC has stated that a supplier may not subcontract for the following services: (i) intake and assessment; (ii) coordination of care with physicians; (iii) submission of claims on behalf of beneficiaries; (iv) ownership and responsibility for equipment furnished to beneficiaries; and (v) ensuring product safety. A supplier may not subcontract with an entity or person that is excluded from Medicare, a state health care program, or any federal government executive branch procurement program or activity.

Q3. What does "purchase of inventory" mean?

A3. Subcontracting for the "purchase of inventory" means that a contract supplier may have a contract to purchase inventory from a third party. The supplier must have title to the equipment when it is furnished to the beneficiary. According to the NSC, the contract must contain at least the following elements: (i) the signature of both parties; (ii) a credit limit ("cash on delivery" is not acceptable); (iii) credit terms (net due); (iv) both parties are identified; and (v) effective date for the contract (if the contract is to last indefinitely, then it should so state).

There is no minimum credit limit, but the NSC will be looking for a reasonable credit limit. The NSC includes the following example as an unreasonable credit limit:

> If a supplier provides electric wheelchairs and the supplier only has one wheelchair in stock and submits a contract for $500 in credit, this would not show compliance with this standard. Due to the cost of electric wheelchairs, this supplier does not have sufficient inventory in stock nor does the supplier have a contract to show enough inventory can be purchased to fill beneficiary orders.

Q4. May a supplier use a billing contractor to submit claims?

A4. Yes. A supplier may use a billing contractor to submit claims on behalf of the supplier. Also, when a beneficiary requests that the supplier submit a claim on behalf of the beneficiary, the supplier may use its billing contractor to submit the claim. The CBIC has stated that a billing contractor is not considered a subcontractor under its subcontracting guidelines.

Q5. Do subcontractors need to be accredited?

A5. A subcontractor that only performs the "purchase of inventory" service need not be accredited. A subcontractor that only delivers the item (such as UPS or FedEx) need not be accredited. Similarly, a subcontractor that only repairs equipment that a supplier is renting to a beneficiary need not be accredited. A manufacturer that performs warranty repairs need not be accredited.

However, a subcontractor that performs equipment set-up or patient instruction must be accredited unless the subcontractor is exempt from accreditation under Medicare rules or guidelines. Also, a supplier that is enrolled in Medicare as a DMEPOS supplier and performs subcontracted services must be accredited, unless the supplier is exempt from accreditation. All suppliers enrolled in Medicare as a DMEPOS supplier are required to be accredited.

The following are exempt from DMEPOS accreditation:

- Suppliers providing drug and pharmaceuticals only
- Physicians, including dentists
- Audiologist
- Optometrists
- Orthotists
- Prosthetists, including occularists
- Opticians
- Occupational Therapist
- Physical Therapists

The NSC takes the position that the exemption only extends to the normal scope of services for the supplier and any products or services provided outside the normal range of services will require accreditation.

Due to the health care reform law, pharmacies were not required to be accredited until January 1, 2011. Also, pharmacies that meet certain criteria will be exempt from DMEPOS accreditation. To qualify for the exemption, a pharmacy must meet all of the following:

1. The total billings by the pharmacy for DMEPOS are less than 5 percent of total pharmacy sales (i.e., pharmacy revenue) for the previous 3 calendar years.

2. The pharmacy has been enrolled as a supplier of durable medical equipment, prosthetics, orthotics and supplies and has been issued a provider number for at least 5 years.

3. No final adverse action has been imposed on the pharmacy in the past 5 years.

4. The pharmacy submits an attestation, in the manner and at the timeframe to be determined, that the pharmacy meets the criteria listed above.

5. The pharmacy agrees to submit materials as requested during the course of an audit conducted on a random sample of pharmacies selected annually.

Note that new pharmacies (i.e., those enrolled in Medicare for less than 5 years) will not qualify for the exemption. For chain pharmacies (i.e., a pharmacy with more than 25 locations), CMS will look at the entire chain as a single entity when determining whether the exemption applies. This means that, for a chain pharmacy, the aggregate DMEPOS sales from all locations will need to be less than 5% of the aggregate pharmacy sales from all locations to qualify for the exemption. In contrast, CMS will view a pharmacy that is a part of a franchise separate from the other pharmacies in the franchise.

Q6. Do subcontractors need to have surety bonds?

A6. A subcontractor need not have a DMEPOS surety bond, unless it is enrolled in Medicare as a DMEPOS supplier. All DMEPOS suppliers are required to submit a valid surety bond to the NSC.

Q7. Is a supplier responsible for services performed by a subcontractor?

A7. Yes. The CBIC has stated, "The primary suppliers are accountable for ensuring that all of the services associated with furnishing the item, including subcontracted services, are performed in compliance with the physician's order and Medicare rules and guidelines." The

"primary supplier" is the supplier that is enrolled in Medicare as a DMEPOS supplier and bills Medicare for reimbursement of the item or service furnished to the beneficiary.

Q8. Can a contract supplier simply refer a beneficiary to a subcontractor if the contract supplier chooses not to carry certain items within a product category?

A8: A subcontractor may perform only certain services on behalf of the supplier, and the subcontractor may not simply "take over" the patient. The CBIC's response is somewhat confusing:

> Contract suppliers are required to provide all items within a product category. However, as with any Medicare enrolled supplier, a supplier may subcontract for the purchase of inventory, delivery and instruction on the use of an item, or the maintenance and repair of rented equipment. Therefore, a contract supplier may subcontract for the purchase of inventory from a subcontractor and for the delivery and instructions on the use of the equipment. In accordance with the quality standards and the supplier standards, it is expected that beneficiaries and referral agents will communicate with the contract supplier when arranging for DMEPOS items and services. Also, remember that contract suppliers are 100% responsible for services furnished to beneficiaries and that subcontractors can't do everything. Please review the Subcontracting Fact Sheet and FAQs on this website for more information.

In its response, the CBIC enumerates the services that a subcontractor may perform, but then vaguely limits the subcontractor by stating that "subcontractors can't do everything." To some, such statement might suggest that a subcontractor could do "close to" everything, but that would not be consistent with other subcontracting guidance.

See section below, entitled "Subcontracting (Whether Inside of or Outside of, a Competitive Bid Area)."

National Mail Order Competition for Diabetic Supplies

Expansion of Round 2

- Announced by CMS August 19, 2011.
- Product categories: oxygen, power and manual wheelchairs and scooters, enteral, CPAP and RADs, hospital beds, walkers, negative pressure wound therapy pumps, Group 2 support surfaces.
- Also includes National Mail Order Competition for Diabetic Testing Supplies to cover all 50 states, D.C., and territories (Puerto Rico, Guam, U.S. Virgin Islands, and American Samoa).

- Not much information released – press release on August 19 from CMS and Educational Information page on CBIC website.

- Bidder registration will open in Fall 2011 and bidding begins Winter 2012.

Licensing for National Mail Order Competition

- To bid in National Mail Order Competition, a supplier must have all required licenses for all 50 states, D.C., and territories on file with the NSC BEFORE bidding. Failure to have all required licenses may result in rejection of bid.

- Tennessee:

    - Home Medical Equipment Facility licensure required to provide glucose meters to TN residents (license not required to supply testing strips).

    - Physical location within the state is a requirement to be eligible for licensure.

    - Thus, to obtain licensure in TN, as required to bid in the National Competition, a supplier has to open a location in Tennessee.

    - The TN license will state only the address for the TN location - from an NSC standpoint in reviewing the bids, the TN location will need to be enrolled with the NSC by the supplier as a "new location" to associate that TN location with the supplier number making the bid.

    - Bottom Line: As it stands now, to bid in the National Competition, only suppliers with Tennessee locations licensed by the state of Tennessee and enrolled with Medicare as DME suppliers will be able to bid. Not likely that a supplier could open new location, get Tennessee license, get accredited, surety, etc., and get its supplier number at the location before bidding.

- North Carolina:

    - Requires licensure to provide testing strips and supplies to NC residents (license is not required for glucose meters).

    - Application process requires the "person in charge" at supplier location to make a personal appearance before the Board of Pharmacy before license number will be given.

- Once you submit your application, the Board of Pharmacy will notify you when you are to appear at a meeting. 2 meetings held per month.

- If application is successful, license number granted at meeting.

Products

- 50% Rule:

  - A bidder has to show that its bid covers a sufficient number of different types of diabetic testing strip products so that, in the aggregate and taking into account volume for the different products, the bid accounts for at least 50% of all such types of products on the market.

  - In December 2010, the OIG put out a report showing the market shares for diabetic testing strip types.

- Anti- Switching:

  - Contract suppliers are prohibited from influencing or incentivizing beneficiaries to switch their current brand to the supplier's preferred brand (or, in the case of new beneficiaries, to choose the supplier's preferred brand).

    - Prohibited from furnishing information about alternative brands to influence decision unless information requested by beneficiary.

    - For new beneficiaries or beneficiaries that need a new meter, the supplier may provide assistance in selecting a meter only if the beneficiary requests such assistance.
    - Generally, must furnish strips and supplies that work with the beneficiary's current meter.

  - Compliance with the Anti-Switching Rule will be monitored by the quarterly reports submitted by the contract suppliers.

  - Bottom Line: intent is to keep suppliers from switching beneficiaries to lowest cost brand to increase profits. Suppliers must still provide education on use of meters, etc., but should only be involved in decision of which meter to use if beneficiary requests information.

Walking into a Location vs. Delivery to Patient's Home

- "Mail Order" and "Non-Mail Order" are defined to prevent suppliers from circumventing competitive bidding (i.e. using delivery trucks to deliver supplies to beneficiaries' homes).

- "Mail Order Item" means any item shipped or delivered to the beneficiary's home, regardless of the method of delivery.

- "Non-Mail Order Item" means any item that a beneficiary or caregiver purchases at a local pharmacy or supplier storefront rather than having the item delivered to the beneficiary's home.

- Mail Order Items are included in the National Competition; Non-Mail Order Items are not.

- Bottom Line:

    - A beneficiary can still walk into his or her local store and get diabetic testing supplies. This is excluded from the National Competition.

    - Suppliers cannot use home delivery by company cars/third party delivery services to get around competitive bidding and the National Competition.

Innovative Marketing

See section below, entitled "Marketing and Joint Ventures." Even though you have been awarded a contract, it does not mean the Medicare beneficiaries will automatically flood to your door. You will have to compete against other contract suppliers for the beneficiaries' business. It will be particularly important for you to build up your volume of patients to compensate for the lower reimbursement. In order to accomplish this, it is critical for the HME supplier to engage in innovative marketing. . . while remaining within legal parameters.

You Have Not Been Awarded a Competitive Bid Contract: Now What Do You Do?

Let us look at the worst case scenario. Despite diligent efforts to bid in one or more product categories, the DME supplier is not awarded a competitive bid contract, meaning that the supplier cannot bill Medicare in its CBA for products covered by competitive bidding. There is no good way to paint such a scenario in a positive light. As suggested in the old Charles Schwab commercial, despite putting lipstick on a pig, it is still a pig. Nevertheless, the losing bidder must "play the hand it has been dealt." The following are responsive steps that a DME supplier can take if it is not awarded a competitive bid contract.

Continue As a "Grandfathered" Supplier

There will be a "grandfathering" process for oxygen equipment and supplies; inexpensive or routinely-purchased items furnished on a rental basis; items requiring frequent and substantial servicing; and capped rental items furnished on a rental basis. Only DME suppliers that began furnishing these grandfathered items prior to implementation of competitive bidding may be eligible to participate as a grandfathered supplier.

Beneficiaries may choose to continue renting the item from the grandfathered supplier, provided the grandfathered supplier is willing to continue furnishing the item under the same terms as the contract supplier (e.g., at the same price as the contract supplier). The beneficiary may choose to switch from a grandfathered supplier to a contract supplier at any time. If a DME supplier chooses to be a grandfathered supplier, then it must do so for all beneficiaries who request the services.

For items requiring frequent and substantial servicing and oxygen equipment, the grandfathered supplier will be paid the bid payment amount. For capped rental items and inexpensive or routinely-purchased items, the grandfathered supplier will be paid the lower of the actual charge or rental fee schedule amount. Grandfathering is also applicable to DME suppliers that lose their contract status in a subsequent competitive bidding period.

Subcontracting (Whether Inside of, Or Outside of, a Competitive Bid Area)

According to CMS guidance, a DME supplier cannot subcontract out "intake, assessment, and coordination of care with the physician." These terms are not defined. On the other hand, a DME supplier can subcontract out delivery, patient education, set-up, repair and maintenance, and obtaining documentation from the physician that supports medical necessity (e.g., physician progress notes).

At the end of the day, a subcontract agreement cannot violate the Medicare anti-kickback statute, which states that a health care provider cannot give anything of value to a person or entity in exchange for referring Medicare patients or in exchange for arranging for the referral of Medicare patients. In addition, there is the "one purpose" test contained in court decisions. This test provides that if "one purpose" behind payment to a referral source is to induce referrals, then the anti-kickback statute is violated even if the referral source provides legitimate non-referral services and the payment is the fair market value equivalent of the services. An example of a subcontractor arrangement is where a provider (that was not awarded a CB contract) and wants to preserve its relationship with referral sources, seeks to become a subcontractor for a CB winner ("contract supplier"). The subcontractor will end up referring (or arranging for the referral of) Medicare beneficiaries to the contract supplier. Under the subcontract agreement, the contract supplier will pay compensation to the subcontractor for services other than referring patients. Nevertheless, the parties will need to contend with the "one purpose" test. What the subcontract agreement cannot provide is percentage compensation. In other words, the agreement cannot say that the contract supplier will pay 75% of the payments (that the contract

supplier receives from Medicare) to the subcontractor. The safest approach is for the contract supplier to pay a fixed annual fee to the subcontractor and for the annual fee to be the fair market value equivalent of the subcontractor's services. Such a compensation arrangement is a key element of the Personal Services and Management Contracts safe harbor to the anti-kickback statute. A middle ground approach – one that entails a kickback risk – is for the compensation to be on a fee schedule basis (e.g., $75 per delivery, $125 per service call, etc.). The problem with a fee schedule is that the money paid by the contract supplier varies based on the volume of business generated by the subcontractor. If the parties adopt this middle ground approach, then the risk can be reduced by other elements of the subcontract arrangement (e.g., the contract supplier purchases the inventory from the manufacturer as opposed to purchasing the inventory from the subcontractor and/or the subcontractor provides services to patients of the contract supplier who are not referred by the subcontractor).

Attached as Exhibit "A" is a template Subcontract Agreement.

Products and Services Not Subject to Competitive Bidding

The competitive bidding program only covers defined product categories, featuring enumerated items. Suppliers may sell products, not covered in the competitive bidding program's product categories, without going through the bidding process.

Cash Sales

See section below, entitled "Provisions of Discounts to Cash Customers."

Long Term Care Facilities

Most residents in long term care facilities may receive DME reimbursed by Medicare Part B as if those patients were residents of their own homes. For those long term care facilities that are not paid a per diem rate for the patient's care, DME suppliers may either bill Medicare directly for provision of the equipment, or, in some cases, facilities may choose to contract with the DME supplier to provide the equipment directly to the facility and the facility will then provide it as a benefit to its residents.

Hospices

The hospice benefit paid to the hospice facility includes the equipment and products used to service the beneficiary. DME suppliers are not entitled to receive reimbursement from Medicare for equipment provided to hospice patients. Hospices, however, may purchase this equipment directly from DME suppliers. The DME supplier should approach hospice providers in its market to inquire about their source of medical equipment and to determine if the hospice is a potential purchaser of equipment or supplies.

Veterans Administration ("VA") Hospitals and Facilities

The VA is a large purchaser of DME and routinely sends out requests for proposals asking that DME suppliers submit a bid to different VA regions or facilities that service patients. The Department of Veterans Affairs operates a nationwide system of hospitals, clinics, Veterans Integrated Service Networks (VISN), data processing centers, and National Cemeteries which require a broad spectrum of goods and services. It purchases these goods and services on a national, regional, and local level. So no matter how large or small your business is, VA is a potential customer. The VA purchases a majority of its requirements for direct delivery through its local Acquisition and Material Management office. You are encouraged to contact each facility for inclusion in its procurement process. Some of the items the VA purchases are pharmaceuticals and medical and surgical supplies; perishable subsistence; equipment, supplies, and materials for facility operation; prosthetic and orthopedic aid; medical gasses; and other items.

The VA uses several methods to purchase items. Acquisitions are accomplished by sealed bidding, negotiation, or simplified acquisition procedures. Each of these methods is designed to promote full and open competition to the maximum extent possible, which in turn allows all responsible bidders/offerors an opportunity to compete. The most suitable, efficient, and economical procedure will be used, taking into consideration the circumstances of each acquisition. Depending on the commodity (supplies, non-personal services, construction, etc.), most acquisitions at a medical center are of a definite-delivery/indefinite-quantity type. Much of the purchasing is accomplished through the use of mandatory sources such as Federal Supply Schedules and supply depots. A significant portion, however, will be acquired from sources obtained through the publication of solicitations in the Federal Business Opportunities (FedBizOpps), solicitation mailing lists, commercial advertising, or any other accepted means that will provide the procuring activity with a sufficient number of responsible bidders/offerors to ensure full and open competition. Federal Business Opportunities (FedBizOpps) can be searched at www.fbo.gov. Simply typing in "durable medical equipment" or "dme" into the Keyword/Solicitation # field will bring up opportunities for contracts with the Department of Veterans Affairs as well as other federal agencies.

The Office of Small and Disadvantaged Business Utilization (OSDBU) was established in the Department of Veterans Affairs (VA) to assist and support the interests of small business. The Small Business Program website is http://www.va.gov/osdbu/. A mission of this office is to provide outreach and liaison support to businesses (large and small) and other members of the private sector. Additionally, OSDBU is responsible for monitoring VA implementation and execution of the following socioeconomic procurement programs:

- Service-Disabled Veteran-Owned Small Business
- Veteran-Owned Small Business
- Small Disadvantaged Business (includes Section 8(a))
- Historically Underutilized Business (HUB) Zone Small Business
- Women-Owned Small Business

VA Federal Supply Schedule Program (FSS) establishes long-term government wide contracts that allow VA facilities and other government agencies to acquire a vast array of medical equipment and supplies directly from commercial suppliers. While VA FSS contractors enjoy expanded opportunities to connect with the Government marketplace, being a contractor can require significant investment of time and expenditure of resources. It is important you take the time to make an informed decision about your need and ability to participate in the VA FSS program. *See* *http://www.va.gov/oamm/oa/nac/fsss/prospective.cfm* for more information.

TRICARE

TRICARE is the health care program for uniformed service members, their families, and survivors. TRICARE is another large purchaser of DME which offers both contract and noncontract opportunities for suppliers. TRICARE uses military treatment facilities (also known as direct care) as the main delivery system and augments direct care with a network of civilian providers and facilities. The program is available worldwide and managed regionally in six separate TRICARE regions jointly by the TRICARE Management Activity (TMA) and TRICARE Regional Offices: (1) North, (2) South, (3) West, (4) Eurasia-Africa, (5) Latin America & Canada, and (6) Pacific. Each TRICARE region has its own managed care support contractor (MCSC) who is responsible for administering the TRICARE program in each region. The TRICARE regional contractors assist the TRICARE Regional Offices/TRICARE Area Offices and military treatment facility commanders. The MCSCs are responsible for establishing the provider networks in each TRICARE region.

- North: **Health Net Federal Services, Inc.**
- South: **Humana Military Healthcare Services, Inc.**
- West: **TriWest Healthcare Alliance**
- Overseas: **International SOS**

At a minimum, all TRICARE providers must be authorized/certified under TRICARE Regulation and must have their authorized/certification status verified by the MCSCs in each region. To find links to certification information as well as contract opportunities, visit http://www.tricare.mil/tma/ams/ams_mcsc.aspx.

TRICARE has an established "hierarchy" of provider types. Understanding the different types will help you decide what type of TRICARE provider you want to be. A TRICARE-authorized provider is a provider who meets TRICARE's licensing and certification requirements and has been certified by the managed care support contractor to provide care to TRICARE beneficiaries. There are two types of TRICARE-authorized providers:

- Network providers sign a contractual agreement with the managed care support contractor and agree to provide care at a negotiated rate and file claims for beneficiaries.

- Non-network providers must be certified, but they do not sign a contractual agreement with the managed care support contractor. There are two types of non-network providers.

Participating providers agree to file claims for beneficiaries, to accept payment directly from TRICARE and to accept the TRICARE maximum allowable charge as payment in full for their services. Non-participating providers do not agree to accept the TRICARE maximum allowable charge or file beneficiary claims. Non-network providers can choose to participate on a claim-by-claim basis. You do not choose to be either participating or non-participating all of the time. The maximum amount that TRICARE can pay a provider for a procedure or service is known as the TRICARE allowable charge. The TRICARE allowable charge is tied by law to Medicare's allowable charge whenever practical and may vary based on the prevailing rate in a given location.

To become a Network Provider, the first thing you need to do to become a TRICARE provider is to become certified. Then, you need to decide if you want to join the network. Once you decide to become a certified network or non-network provider, your managed care support contractor (MCSC) will provide you with all the information you need to care for TRICARE beneficiaries.

To become a Certified Non-network Provider, commonly referred to as a TRICARE Standard (Certified) Provider, the provider does not have a contractual relationship with the regional contractors, but must be certified to provide care to TRICARE beneficiaries. To be certified, you must be a facility, doctor or other healthcare professional that meets the licensing and certification requirements of TRICARE regulations and practices for your area of healthcare. Once you are certified, you may or may not agree to "accept assignment" - that is, accept the TRICARE maximum allowable charge as payment in full for services. If you don't agree, then you are considered authorized, non-participating providers. You may elect to accept assignment on a claim-by-claim basis. If you want to become a TRICARE Standard (Certified) provider, you must complete the appropriate Standard provider certification documents for your region and mail or fax them to the address on the form.

Medicaid and Other State Programs

All states have medical assistance programs, such as Medicaid. Medicaid programs generally require enrollment, and many Medicaid programs restrict enrollment to in-state or border-state entities. Despite that restriction, many Medicaid programs also have waiver programs that allow the state to cover a wide range of items and services. For example, there are specific waiver programs for mentally and physically disabled patients. In addition, many states also have worker’s compensation programs and health care programs for state and county employees. A DME supplier should consider enrolling in its state’s programs and enrolling in other states’ programs as well.

Cash Sales

There are approximately 78 million baby boomers, most of whom have savings and retirement accounts. Many baby boomers are accustomed to "paying their way" and recognize the potential future unreliability of the Medicare and Social Security programs. These boomers will be inclined to simply purchase medical equipment than to have to expend the time to obtain Medicare qualification. Innovative DME suppliers are focusing on the cash market. Some are building impressive showroom floors. Others are promoting and selling items through websites. This is the wave of the future. See previous discussion regarding OIG guidance on discounts to cash customers.

Internet Cash Sales and Non-Medicare Covered Items

Many suppliers are beginning to think about selling items via the internet for cash. Having a strong internet presence allows a supplier to reach customers on a national basis. At the same time, cash sales do not entail the oftentimes burdensome requirements of government and commercial payors. In addition, selling non-Medicare covered items allows a supplier to increase the sales revenue without having to worry about payor requirements of billing and documentation. A supplier seeking to sell items over the internet should look into state licensure requirements. For example, a DME supplier located in Texas looking to sell DME items for cash over the internet to residents in California should verify whether California requires that the supplier obtain a license or registration to do so. Suppliers should also consider the prohibition on charging Medicare substantially in excess of its usual charges. See previous discussion regarding OIG guidance on discounts to cash customers.

Use of ABNs

Sometimes, a Medicare beneficiary will want an upgrade item. An upgrade is an item with features that go beyond what is medically necessary. An upgrade may include an excess component such as an item feature or service which is in addition to, or more extensive and/or more expensive than, the item that is reasonable and necessary under Medicare's coverage requirements. By using an Advance Beneficiary Notice (ABN), which notifies the beneficiary in writing of Medicare's likely denial, a DME supplier may furnish a beneficiary an upgrade item and collect money from the beneficiary if and when the claim is denied. The purpose of an ABN is to inform the beneficiary that Medicare will probably not pay for a certain item or service in a specific situation, even if Medicare might pay for the item or service under different circumstances. This allows the beneficiary to make an informed consumer decision about whether or not to receive the item or service for which he/she may have to pay out of pocket or through other insurance. ABNs apply to assigned and non-assigned claims.

Workers' Compensation

Those injured on the job have access to workers' compensation insurance. There are workers' compensation programs at both the federal and state levels. These insurance programs

are another source of business for DME providers. Each of these programs has its own system for enrolling/registering providers, and you will need to gain entrance to certified workers' compensation health care networks. The following website provides links to every state workers' compensation website to determine the procedures for providing DME through the respective states' programs: http://physicianpartner.com/pdf/wc-links.pdf.

State Prison Systems

Many state prison systems require DME or pharmaceuticals for prisoners. Many states have moved towards having specific prison facilities designated as "medical detention centers." DME suppliers interested in determining whether the department of corrections in their state contracts independently with DME suppliers for this service should visit http://www.corrections.com/links/viewlinks.asp?cat=30 for links to specific state boards of correction or prison systems and collect information regarding the appropriate contact person at the state level.

Resort Hotels and Casinos

Many large resort hotels have begun providing wheelchairs, scooters, and other medical equipment to their guests as a way of making the guests feel more at home. DME suppliers that are located in a marketplace with large hotels and casinos should contact the hotels directly to determine if there is a contracting process and how suppliers may participate.

Airports

Airports are frequent purchasers of wheelchairs and other medical equipment for use by customers traveling through the airport. Many of these pieces of equipment are provided by local DME suppliers. Suppliers wishing to obtain more information should contact the airport facilities manager to discuss the contracting process.

Expanding Into Geographical Areas Outside CBAs/"Hub and Spoke" Model

A DME supplier can open up one or more locations outside a CBA and concentrate on servicing customers in the outlying areas. The standard way to do this is for the supplier to obtain a Part B supplier number for each of the new locations. There is a method, however, to expand into new geographical areas without having to obtain new supplier numbers. This method is known as the "hub and spoke." Here is how it works:

(i) ABC Medical Equipment, Inc. ("ABC") is located in Dallas, TX; it has a supplier number attached to its Dallas location;
(ii) 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;
(iii) ABC opens a warehouse in Denton and hires a delivery driver to service the Denton area:
(iv) the warehouse is not open to customers;

(v) the phone number published in the Denton phone book is a toll-free number that goes to the Dallas location;
(vi) when a physician calls in an order, the call goes to Dallas; likewise, when a customer calls ABC, the call goes to Dallas;
(vii) ABC's employee handles the intake, assessment, and coordination of care; in short, the "point of sale" occurs in Dallas;
(viii) 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
(ix) 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."

Suggest to Medicare Fee-For-Service Patients that They Sign Up for Medicare Advantage Plans

Competitive bidding applies to Medicare fee-for-service patients; it does not apply to Medicare Advantage patients. The HME supplier should endeavor to become a supplier under as many Medicare Advantage plans as possible. The HME supplier can suggest to its Medicare fee-for-service patients that they sign up for Medicare Advantage plans under which the Medicare supplier is a provider.

Managed Care Contracts

The HME supplier should take aggressive steps to become a provider under a number of managed care contracts. See section below, entitled "Tools to Negotiate Managed Care Contracts."

Provisions of Discounts to Cash Customers

Increasingly, HME companies are moving into the "cash and carry" market. That is, companies are striving to sell items to non-Medicare customers who desire to pay cash. Because of the cost-savings resulting in not having to submit claims to Medicare, HME companies price products, that are sold for cash, less than the Medicare allowable for the same items. In so doing, however, it is important that the company adhere to OIG guidance addressing discounts to cash customers.

An HME company is prohibited from charging Medicare substantially in excess of the company's usual charges, unless there is good cause. *See* 42 U.S.C. § 1320a-7(b)(6)(A); 42 CFR § 1001.701(a)(1). The current regulations do not give any guidance on what constitutes "substantially in excess" or "usual charges." "[U]nusual circumstances or medical complications requiring additional time, effort, expense" would be considered good cause. 42 CFR § 1001.701(c)(1). An HME company that violates this prohibition is subject to exclusion from federal health care programs. 42 CFR § 1001.701(a).

While there have been some efforts by the OIG to define "substantially in excess" and "usual charges," no final rule has been issued. In a 1998 advisory opinion, the OIG said that charging Medicare 21% - 32% more than cash-and-carry customers would likely violate the statute, and suggested that a "useful benchmark" was to compare the profit margins on a cash sale and a Medicare sale. *OIG Advisory Opinion No. 98-8* (July 6, 1998) ("*Opinion 98-8*"). According to the OIG, the statute would not be violated if the profit margin on a Medicare sale was less than or equal to the margin on the cash sale. In another advisory opinion the following year, dealing with laboratory services, the OIG said that the test was whether "the charge to Medicare or Medicaid substantially exceeds the amount the laboratory most frequently charges or has contractually agreed to accept from non-Federal payors." *OIG Advisory Opinion No. 99-13* (Nov. 30, 1999). In a guidance letter issued in 2000, the OIG's chief counsel said that the law could be violated if "a provider's charge to Medicare is substantially in excess of its median non-Medicare/Medicaid charge." *Letter to American Ambulance Ass'n.* (April 20, 2000).

The most recently proposed rules contemplate the "usual charge" to be either the average or median of the supplier's charges to payors other than Medicare (and some others). *See generally* 68 FR 53939 (Sept. 15, 2003). Under these proposed rules, an HME company's usual charge should not be less than 83% of the Medicare fee schedule amount (i.e., up to a 17% discount from the Medicare fee schedule). There would be an exception for good cause, which would allow a company's usual charges to be less than 83% of the Medicare fee schedule, if the company can prove unusual circumstances requiring additional time, effort or expense, or increased costs of serving Medicare and Medicaid beneficiaries.

The proposed rules would include charges of affiliate companies into the calculation of a supplier's usual charges. An affiliated company is any entity that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with the HME company. The proposed rules explicitly exclude fees set by Medicare, State health care programs, and other Federal health care programs (except TriCare). By implication, charges not specifically excluded will be included. However, CMS declined to promulgate the proposed rules into a final rule. 72 FR 33430, 33432 (June 18, 2007).

Based on the above discussion, there is no bright line rule (e.g. 17% discount) when a discount will require a showing of good cause. It is reasonable to infer, however, that a relatively large differential between Medicare and non-Medicare prices will more readily be viewed as "substantially in excess." There is also no clear guidance on what would constitute good cause. In *Opinion 98-8*, the suppliers justified the price differential by stating that furnishing Medicare beneficiaries involved significant additional costs: documentation requirements, claims processing, and delivery and distribution. The OIG responded that the supplier's charges to Medicare for some products would be substantially in excess of its usual charges. While the OIG agreed that the additional costs incurred by the suppliers "solely attributable to complying with Medicare requirements may constitute 'good cause,' there was insufficient information for the OIG to determine "whether [the suppliers'] proposed fee structure is sufficiently related to its anticipated additional costs attributable to Medicare…." This suggests that the OIG would scrutinize an HME company's financials closely if the

company asserted cost savings to justify its discount to other customers. Therefore, an HME company that intends on relying on costs savings to show good cause should anticipate such scrutiny.

Another issue is whether the entity operating the retail business could be organized or structured to insulate affiliated companies from liability under the substantially in excess regulations. *Opinion 98-8* involved parent and subsidiary suppliers. Only the subsidiary intended on becoming a Medicare supplier and furnishing DME to Medicare beneficiaries; the parent intended on continuing to serve only non-Medicare customers. Nevertheless, the OIG made it clear that the parent's prices would be considered in its analysis. The proposed rule also indicated that CMS considers the prices of affiliate companies in its analysis. While the guidance discussed is not binding law, the OIG and CMS have been consistent in their treatment of affiliate organizations. Consequently, it is unlikely that an HME company may insulate itself by forming a separate legal entity to operate the retail business.

Tools to Negotiate Managed Care Contracts

Introduction

Negotiating contracts with managed care organizations ("MCOs") can be a painful experience for providers, as health maintenance organizations and preferred provider organizations demand ever-larger discounts. Effective negotiation of payor contracts will become increasingly important to providers if the federal government succeeds in its plan to shift large numbers of Medicare beneficiaries into the new Medicare Advantage managed care plans. Too often, however, providers focus only on the payment rates provided in managed care contracts, and accept the remaining portions of the contracts as they are presented. MCO representatives encourage this approach, by telling providers that the body of the contract cannot be changed. That statement is almost never true. In most cases virtually everything in a contract is negotiable. If a provider can separate the important from the unimportant provisions, reducing the issues for negotiation to a manageable number, then the provider stands a good chance of obtaining a significantly more favorable contract.

Effective contract negotiation requires a careful and critical reading of every provision of the contract, because unfavorable terms can appear almost anywhere in a contract. No checklist can anticipate all of the issues that might be raised by a particular contract. As a starting point, however, here are some of the issues the provider should be aware of when reviewing a proposed managed care contract.

Preparing for the Negotiation Process

In entering into contract negotiations with MCOs, providers must take several steps to insure that their rights are protected under the contract. Step one is always to obtain a copy of the contract proposed by the payor and to review it carefully. In almost every instance, providers will be starting from a contract prepared by - and in most cases, insisted on by - the MCO. It is

generally the stance of the MCO that it has little or no leeway in altering the terms of the contract. A clear understanding of the proposed contract is the best starting place for negotiating terms advantageous to the provider.

After the provider has read the contract, and has a basic understanding of its terms, the provider should begin preparing a list of questions to ask the MCO regarding the particular contract. Among the questions to be included should be those regarding the number of years the specific contract form has been used; whether or not the MCO knows of other providers that would be willing to discuss the terms of the contract (e.g. other provider references the MCO could provide); the most commonly modified terms of the contract; and any significant modifications made to the contract within the past 12 to 18 months.

By taking these steps, providers will arm themselves with basic questions for the MCO. However, the next step is even more important. The provider must review the contract in complete detail, and prepare a list of issues to be addressed in negotiations with the MCO.

Statutory and Regulatory Protection

Most statutory and regulatory provisions governing the content of managed care contracts are governed by state law. For example, a number of states have enacted statutes that provide for strict prompt payment guidelines as well as specific provisions governing the content of managed care contracts. Most notably, these provisions require that HMO and PPO providers pay clean claims within a certain number of days following receipt. In addition, the statutes lay out the elements of a clean claim and the steps that both a provider and an MCO should follow in the claim submission process.

Payment Methodologies

Most managed care contracts will contain reimbursement provisions based on a discounted fee schedule amount. In most scenarios, the plan will either have developed a fee schedule for the products to be covered by the contract or the contract will provide for reimbursement based on a percentage of the Medicare applicable fee schedule. In either case, it is important that the provider spend time analyzing the reimbursement provisions to determine whether the reimbursement amounts listed are economically feasible. Only by carefully reviewing these provisions and actually "running the numbers" can a provider determine what to expect.

In contract situations where the reimbursement levels are untested, but may seem attractive, providers may wish to enter into a contract for an initial term of one year with a longer renewal term. This gives the parties flexibility while not obligating the provider to a long term contract on terms that may or may not be acceptable over time.

Contract Terms and Provisions

In analyzing the contract terms and provisions, providers should avoid merely focusing on the payment terms and include in their overview an analysis of the more standard and mundane terms. In analyzing the standard terms, the provider should take particular note of the following:

- Identification of the Parties

Although this seems simple, it is important to note that most payors identify providers by tax identification numbers. If a provider has any subsidiaries or affiliated organizations, then they would need to be listed as parties to the agreement or contracted with separately if they are to be part of the plan.

- Covered Persons/ Silent PPOs

What is left out of a contract can be just as important as what is included. PPO contracts should include some kind of protection against so-called "silent PPO" practices. The phrase "silent PPO" refers to the practice of some payors of "selling" access to their contracted rates to other payors with which the provider does not participate, after the provider has already provided services to a member of the noncontracted plan. As a result, the provider is paid at a sharply discounted rate for services for which it was expecting full payment. The best protection against this practice is to include a provision in the contract to the effect that the contract rates will be available only to plans that offer members financial incentives (such as reduced copayments) to use participating providers. Other ways of protecting against silent PPO practices are to require members to present identification cards at the time services are provided as a condition to receiving discounted rates, or requiring the PPO to provide a regularly-updated list of all the plans that are entitled to the benefit of the PPO's negotiated discounts.

- Plan Participation

One large national payor includes in its standard contracts a provision that the provider must furnish services to members of all of the payor's plans at the contract rates, even if the payor does not designate the provider as a participating provider in a particular plan. Under this provision, the provider is required to give discounts to members of plans in which it does not participate, but receives no benefit in return. The provider will not be listed in the directory of participating providers, and so it is unlikely to receive any increase in patient volume in exchange for the discounts. If a provider comes across this provision in a contract, the provider should ask that it be deleted. If a provider cannot get it deleted, at least it should know what plans it will and will not have participating status.

- Payor Policies

Some PPO and third-party administrator contracts contain provisions to the effect that if there is a conflict between the contract and the policies of a particular payor, the payor's policies take precedence. This kind of provision can be problematic because the provider often does not receive policies from all of the payors covered under a multi-payor contract. If a provider encounters this kind of provision, it should ask that it be revised to include only those policies of which the provider has received written notice.

- Most Favored Nation Clauses

Often providers are asked to enter into managed care contracts that contain so-called "most favored customer" clauses. These clauses are contractual provisions that require a provider to accept from the plan the lowest price that the provider accepts from other plans. In other words, the provider must offer the plan the lowest price it accepts from its most favored customers. Providers should be aware that if they are required to provide the lowest price to a plan's enrollees, this could create an administrative burden in identifying and earmarking those enrollees and keeping track of the payments received under every plan to insure that those enrollees are given the best price.

- "Medical Necessity"

Many providers must provide documentation regarding medical necessity for services or items furnished. In these instances it is vitally important that a provider know what documentation it should maintain to support medical necessity. In many cases, the medical necessity documentation required is significantly more burdensome than many providers believe; accordingly these requirements should be spelled out in detail through the policies and procedures of the managed care plan, as well as referenced in the contract itself.

- Utilization Review

Many managed care plans require providers to agree to take part in either quality improvement or utilization review programs. For the most part, providers are asked to participate by providing information to the plan on their utilization and quality improvement initiatives and to allow the plan to establish and implement quality improvement and utilization review programs for the provider. These programs should be set forth in the policies and procedures manual provided by the managed care plan at the time of contract. It is important that providers read and understand the utilization management and quality improvement initiatives and the plan policies and procedures so they know what to expect from the plan.

- Covered Services

Under most managed care contracts, providers are required to provide covered products and services to the plan enrollees. The contract should carefully describe the services or products that must be delivered. A payor may require that the provider provide all covered products and services to enrollees or it may limit the provider's obligation to products and services it customarily provides. In either case, it is important that providers understand what is anticipated under the contract and be prepared to provide whatever supplies or services are contemplated under the contract.

- Delivery Terms

The contract should carefully spell out the provider's obligation to ship or deliver the product to the patient, including method of delivery and amount of reimbursement for shipping or delivery charges.

- Insurance and Indemnification

Insurance and indemnification clauses in contracts are designed to protect the parties against risks and liabilities created under the contract. The principal concerns of insurance and indemnification clauses are professional and derivative liability flowing from use of products furnished by the provider. Many providers do not pay close attention to insurance and indemnification clauses because they feel that exposure is remote. In the case of insurance clauses, each party should carry its own professional and general liability insurance for its own acts or omissions. Providers should only be required to insure against their own liability and not the liability of the payor. In the case of indemnification provisions, the principal objective of the provider should be to require that it shoulder the burdens that fall upon the provider as a result of claims arising from its conduct.

- Limitation of Liability

In some contracts, indemnification provisions are accompanied by a section limiting the payor's liability for damages under the contract. One major payor routinely includes a provision stating that the payor's liability for any claim arising under the contract is limited to the amount that the payor has paid the provider under the contract during the previous 12 months. Another payor's standard contract limits its liability to the fee schedule amount for the services that are the subject of the claim. Provisions like these are unreasonably one-sided, and should be deleted.

- Hold Harmless

This concept is seen most often in its benign form, that is, where the provider agrees to hold an enrollee harmless and not seek reimbursement directly from him or her

for covered services rendered. This is a fairly standard and nonnegotiable provision in managed care contracts. This is where the definition of "covered services" is critical. Providers should watch for provisions that require them to hold the payor harmless from findings of provider negligence arising from the provider's compliance with the payor's policies.

- Claims Processing

Claims processing provisions routinely lead to conflict between payors and providers. One of the reasons for this high rate of conflict is that many states now have prompt payment statutes that dictate the time frame which the payor must pay any clean claim presented by the provider. There are, however, two time limits that are of specific concern under claims processing. First, the contract will likely contain a clause requiring the provider to submit a claim within a certain time frame in order to be paid. Secondly, the contract will likely contain a clause requiring the payor to pay a clean claim within a certain amount of time. Many contracts may not impose requirements on the payor since the state laws provide adequate protection. By way of example, Texas law requires that an HMO or PPO pay clean claims within 45 days of receipt.

Quite often, however, disputes arise regarding exactly what is meant by a "clean" claim. In order to avoid these questions, the provider could request that the contract discuss what constitutes a clean claim by describing the information required and discussing a method for resolving disagreements between the parties.

The contract should also include specific penalties such as late payment penalties, interest payments, and, in some cases, termination of the contract in the event of continued delays or non-payment.

- Marketing

The provider should request the right to review all marketing materials referring to the provider before they are used by the payor. A provider should not insist, however, on reviewing all provider lists provided to patients that merely contain the name of the provider.

Since the MCO may be using the provider's name, address and telephone number in its marketing materials, it is vital to ensure that the information provided to the payor is accurate and complete. Incorrect information in an organization's marketing materials can prevent a provider from enjoying the benefits of the managed care contract

- Termination Provisions

Most payors' standard provider contracts permit either party to terminate the contract for the other party's breach, following a specified cure period. The same cure

period, usually thirty or sixty days, applies to all breaches. If the payor fails to pay the provider for its services, the provider cannot terminate the contract until the end of the cure period, even if the payment failure continues. If possible, the provider should try to have a separate termination provision inserted for payment defaults (as is common in other kinds of contracts), permitting the provider to terminate if the payor fails to pay claims within the time specified in the contract and the failure continues for five days after written notice from the provider.

- Post-Termination Services

Managed care contracts vary considerably in their requirements for provision of services following termination. Some are relatively reasonable, requiring only that the provider continue providing services to existing patients until they can be transferred to the care of another provider, with a limit of sixty or ninety days. Others require the provider to continue providing services on the payor's demand for a full year, and others contain no time limit at all. The provider's obligation to provide post-termination services should be limited to no more than 90 days, and the contract should explicitly require the payor to use its best efforts to transfer patients to another provider promptly.

- Overpayments

In some states, state law limits the time during which a payor may recoup an overpayment. If a payor is not in a state with such a law, it should consider trying to have such a provision included in the contract. The provision could say, for example, that neither party will be entitled to an adjustment in any payment after one year from the payment date.

- No-Disparagement

These are basically "no slander" clauses under which the provider agrees not to disparage the payor. Unfortunately, "disparagement" is almost never defined. Consequently, payors read this term broadly.

- Documentation Review

In many instances, providers will be required to adhere to policies, procedures, and guidelines set forth by the payor. It is vital that providers review these policies, procedures, and guidelines prior to executing the managed care contract.

- Consent to Release of Information

Although the HIPAA privacy standards do not require consent for release of information from a provider to a payor, some state laws still require the patient's consent. Contracts used by several payors include provisions stating that the consent contained in

the payor's enrollment form "is hereby deemed satisfactory by Provider," or similar language. If the provider has not seen the payor's enrollment form, it should not stipulate that the payor's form of consent is sufficient. A preferable provision, if the provider can obtain it, is one that says that the payor represents that its form of consent is sufficient under state law.

- Business Associate Provisions

Some third-party payors continue to include HIPAA business associate provisions in their provider agreements, even though the Office of Civil Rights has made it clear that payors and providers generally are not business associates. There are some cases in which business associate language is appropriate, because one party is providing services to or on behalf of the other. For example, some parts of the credentialing function are sometimes delegated by the payor to the provider. That delegation may create a business associate relationship. However, if the only relationship is that of payor and payee, there is no business associate relationship, and business associate provisions are unnecessary in the agreement. Including business associate provisions where they are not needed can create ambiguities about the obligations of the parties with respect to protected health information.

- Dispute Resolution

Most contracts will contain provisions discussing how disputes between the parties are resolved. In many cases, disputes will be submitted to arbitration or mediation and may preclude the possibility of litigation. It is important to understand the process for conflict resolution so that providers know whether they are surrendering a right to have their claims settled by a jury by submitting disputes to arbitration or mediation.

- Passive Amendment

Be aware of passive amendment provisions that state that amendments to the contract offered in writing to the provider, which are not expressly rejected in writing by the provider within a certain time frame, are automatically deemed accepted by the provider. In the managed care arena, passive amendment provisions are most often used to add new payor products and payment schedules when the provider has agreed in advance to accept all new products meeting certain criteria.

- Incorporation of Collateral Documents

Many important terms are attached to the contract or are incorporated by reference in exhibits, schedules and handbooks. Typically, utilization review, quality assurance programs, payment terms and provider due-process rights are contained in collateral documents. The payor will argue that the terms of the contract do not articulate the mutual promises of the parties, but that the contract instead includes what is written in

the contract as modified by the more specific terms in the payor's manuals and other collateral documents. The payor will claim that because it has the right to modify its manuals during the term of the contract, it also has the right to modify the contract itself.

- Set-Off Provisions

A set-off provision allows the payor to control the money during a dispute. It allows the payor to withhold disputed amounts from future payments to the provider. Because these provisions allow the payor to make a unilateral decision, they are susceptible to great abuse. As a general rule, set-off provisions should be avoided. However, because set-off provisions can serve a valid purpose when they are exercised in good faith as a means to correct true mistakes, completely eliminating them may not be possible. The next best option is to build limitations and protections into set-off provisions.

- Missing or Inadequate Provisions

Frequently, the interpretation of a contract hinges on a single word or phrase that has no defined meaning. This may occur simply because the parties do not consider the potentially competing definitions of a specific term, or because the payor chooses to define a term in a way that is advantageous to it.

- Remedy for Unexcused Delay in Payment

It is reasonable to negotiate a contractual provision obligating the payor to pay interest if payment is not made within a specified period after the receipt of a clean claim. State prompt-pay laws have created a similar remedy by requiring a payor to pay a specified rate of interest if payment is not made within a certain number of days of receiving a "clean" or "complete" claim. However, these laws often give definitions of clean or complete claims that are too vague to be of practical assistance in enforcing the prompt-pay penalty. Providers should work with the payor to specifically define "complete claim" in the context of what that payor expects, consistent with the applicable state's prompt-pay regulations.

- Payment Forfeiture for Late Claims

Payors want claims to be submitted in a timely fashion so they can better manage their accounts. However, payors should not be allowed to require providers to forfeit all payments on claims that miss the deadline. To avoid such disputes, providers should attempt to negotiate a more reasonable incentive for the prompt submission of claims.

- Audit Definitions

The contract should define the scope of audit rights. The most common scope of an audit is one that determines whether all services appear on the bill and whether the provider's records support the bill. Payors often try to expand this scope in an attempt to second guess medical necessity issues through an audit. Although it is appropriate for a payor to have a role in determining medical necessity, these issues are best addressed through the contract's utilization review provisions, where the parties can specify standards and procedures. Payors also perform audits as a way of challenging a provider's rates. This practice is inappropriate because rates are addressed separately in the contract, and no provider intends to give a payor a unilateral right to revise its rates through an audit. The time limits within which an audit can be performed should be specified.

- Attorney's Fees

Payors may include in the contract a clause requiring the losing party in a dispute to pay the attorney's fees of the winning party. Payors have a greater incentive and greater resources with which to litigate or arbitrate a dispute. The added risk that they also may have to pay the provider's attorney's fees is usually not material in their calculations. For providers, however, the added risk of paying attorney's fees may act as a disincentive to pursue the matter.

- Discretion Left to the Payor

An obvious dangerous clause is one that allows the payor to define a term of the contract unilaterally. It sometimes may be necessary to leave some terms of the contract to the payor's discretion, but these terms should relate to minor issues only. Even then, the payor's discretion should be severely limited by identifying standards under which it can be exercised.

- Claims Processing

Claims processing is one of the most routinely disputed provisions of contracts between payors and providers. At the source of many of these conflicts are state laws requiring prompt payment of clean claims submitted to payors. There are two key time limits that are of specific concern to providers in claims processing: First, the contract will contain a clause requiring the provider to submit a claim within a certain time period after provision of services in order to be paid. Secondly, the contract should contain a clause requiring the payor to pay a clean claim within a certain amount of time. The provider should request that the contract discuss what constitutes a clean claim by describing the information required and discussing a method for resolving disagreements between the parties. The contract should also include specific penalties such as late

payment penalties, interest payments, and, in some cases, termination of the contract in the event of continued delay or non-payment.

- Reimbursement

The most important clause in a contract is the reimbursement provision. Contracts should include a provision to renegotiate the reimbursement provision based on defined events. Providers should be realistically self-critical in evaluating their ability to fulfill the contract terms. The primary risk to the provider lies in whether it understands clearly enough its costs to provide the products and services for which the provider is contracting. Providers should carefully analyze the reimbursement provisions to determine whether the reimbursement amounts listed provide adequate compensation for the services provided.

Renewal Provisions

Parties may wish to include specific provisions for automatic renewal of the contract. Generally, these provisions require that any party not wishing to renew the contract take affirmative steps to terminate or the contract continues for another term. The key challenge in dealing with renewal terms is managing any increase in compensation for the renewal terms. If the compensation is not renegotiated, the contract will renew under the same financial terms as the previous year. Any provider that has numerous contracts in place at any given time should maintain a calendar or docket system containing renewal dates as well as notice dates for intention to terminate.

Innovative Marketing

Because you have not been awarded a competitive bid contract, it becomes particularly crucial that you engage in innovative marketing. . . while remaining within legal parameters. See section below, entitled "Marketing and Joint Ventures."

Marketing and Joint Ventures
(Applicable Whether Or Not You Have Been Awarded a Competitive Bid Contract)

Legal Guidelines

I. Federal

A. Statutes

1. Medicare/Medicaid Anti-Kickback Statute (42 U.S.C. § 1320a-7b) ("anti-kickback statute")

It is a felony for a person or entity to knowingly or willfully solicit or receive any remuneration in return for referring an individual for the furnishing or arranging for the furnishing of any item for which payment may be made under a federal health care program, or in return for purchasing, leasing or arranging for or recommending the purchasing or leasing of any item for which payment may be made under federal health care programs. Likewise, it is a felony for a person or entity to knowingly or willfully offer or pay any remuneration to induce a person to refer a person for the furnishing or arranging for the furnishing of any item for which payment may be made under a federal health care program, or the purchase or lease or the recommendation of the purchase or lease of any item for which payment may be made under a federal health care program. These prohibitions do not apply to any amount paid by an employer to an employee.

2. Beneficiary Inducement Statute (42 U.S.C. § 1320a-7a (a)) ("inducement statute")

This statute imposes civil monetary penalties upon a person or entity that offers or gives remuneration to any Medicare beneficiary (or beneficiary under a state health care program) that the offeror knows, or should know, is likely to influence the recipient to order an item for which payment may be made under a federal or state health care program. In the preamble to the regulations implementing this provision, the OIG stated that the statute does not prohibit the giving of incentives that are of "nominal value." The OIG defines "nominal value" as no more than $10.00 per item or $50.00 in the aggregate to any one beneficiary on an annual basis. "Nominal value" is based on the retail purchase price of the item.

3. Anti-Solicitation Statute (42 U.S.C. § 1395m(a)(17))

A supplier of a covered item may not contact a Medicare beneficiary by telephone regarding the furnishing of a covered item unless (i) the beneficiary has given written permission for the contact, or (ii) a supplier has previously provided the covered item to the beneficiary and the supplier is contacting the beneficiary regarding the covered item, or (iii) if the telephone contact is regarding the furnishing of the covered item other than

an item already furnished to the beneficiary, the supplier has furnished at least one covered item to the beneficiary during the preceding 15 months.

4. False Claims Act (31 U.S.C. § 3729)

Any person or entity who knowingly presents to a federal health care program a fraudulent claim for payment, or knowingly uses a false record or statement to obtain payment from a federal program, is subject to civil monetary penalties.

5. False, Fictitious or Fraudulent Claims (18 U.S.C. § 287)

Whoever makes or presents to any person or officer in the civil military, or naval service of the United States, or to any department or agency thereof, any claim upon or against the United States, or any department or agency thereof, knowing such claim to be false, fictitious, or fraudulent, shall be imprisoned not more than five years and shall be subject to a fine in the amount provided in this title.

6. Stark Statute (42 U.S.C. § 1395nn)

The "Stark" provisions of the Omnibus Budget Reconciliation Act of 1993, as amended, provide that if a physician has a financial relationship with an entity providing designated health services ("DHS"), then the physician may not refer patients to the entity unless one of the statutory or regulatory exceptions applies. Designated health services include (i) durable medical equipment, (ii) parenteral and enteral nutrients, (iii) prosthetics, orthotics and prosthetic devices and supplies, and (iv) outpatient prescription drugs, among others. There are several exceptions to Stark, including the rural exception. This provides that the Stark prohibitions do not apply in a rural area where the entity furnishes substantially all (not less than 75%) of its DHS to residents of the rural area.

B. Safe Harbors

Safe harbor regulations issued under the anti-kickback statute provide "bright line" tests defining arrangements that do not violate the statute. If a business arrangement clearly falls within a safe harbor, then it is not violative of the anti-kickback statute. If the arrangement does not clearly fall within a safe harbor, then it must be examined in light of the anti-kickback statute and related court decisions to determine if it violates the statute. Of the various safe harbors, five are particularly pertinent to suppliers.

1. Small Investment Interests

For investments in small entities, "remuneration" does not include a return on the investment if a number of standards are met, including the following: (i) no more than forty percent of the investment can be owned by persons who can generate business for

or transact business with the entity, and (ii) no more than forty percent of the gross revenue may come from business generated by investors.

2. Space Rental

Remuneration does not include a lessee's payment to a lessor as long as a number of standards are met, including the following: (i) the lease agreement must be in writing and signed by the parties, (ii) the lease must specify the premises covered by the lease, (iii) if the lease gives the lessee periodic access to the premises, then it must specify exactly the schedule, the intervals, the precise length, and the exact rent for each interval, (iv) the term must be for not less than one year, and (v) the aggregate rental charge must be set in advance, be consistent with fair market value, and must not take into account business generated between the lessor and the lessee.

3. Equipment Rental

Remuneration does not include any payment by a lessee of equipment to the lessor of equipment as long as a number of standards are met, including the following: (i) the lease agreement must be in writing and signed by the parties, (ii) the lease must specify the equipment, (iii) for equipment to be leased over periods of time, the lease must specify exactly the scheduled intervals, their precise length and exact rent for each interval, (iv) the term of the lease must be for not less than one year, and (v) the rent must be set in advance, be consistent with fair market value, and must not take into account any business generated between the lessor and the lessee.

4. Personal Services and Management Contracts

Remuneration does not include any payment made to an independent contractor as long as a number of standards are met, including the following: (i) the agreement must be in writing and signed by the parties, (ii) the agreement must specify the services to be provided, (iii) if the agreement provides for services on a sporadic or part-time basis, then it must specify exactly the scheduled intervals, their precise length and the exact charge for each interval, (iv) the term of the agreement must be for not less than one year, (v) the compensation must be set in advance, be consistent with fair market value, and must not take into account any business generated between the parties, and (vi) the services performed must not involve a business arrangement that violates any state or federal law.

5. Employees

Remuneration does not include any amount paid by an employer to an employee, who has a bona fide employment relationship with the employer, for employment in the furnishing of any item or service for which payment may be made, in whole or in part, under Medicare or under a state health care program.

C. OIG Advisory Opinions

A health care provider may submit to the OIG a request for an advisory opinion concerning a business arrangement that the provider has entered into or wishes to enter into in the future. In submitting the advisory opinion request, the provider must give to the OIG specific facts. In response, the OIG will issue an advisory opinion concerning whether or not there is a likelihood that the arrangement will implicate the anti-kickback statute. Although advisory opinions may not be relied on by anyone except the requesting parties, they provide valuable insight into the OIG's views on certain kinds of arrangements. Past advisory opinions are available online at http://oig.hhs.gov/fraud/advisoryopinions.html.

D. OIG Special Fraud Alerts and Special Advisory Bulletins

From time to time, the OIG publishes Special Fraud Alerts and Special Advisory Bulletins that discuss business arrangements that the OIG believes may be abusive, and educate the DME and pharmacy industries concerning fraudulent and/or abusive practices that the OIG has observed and is observing in the industry. These documents reflect the OIG's opinions regarding the application of the fraud and abuse laws. Some of the Special Fraud Alerts and Special Advisory Bulletins relevant to the supplier are the following:

1. Special Fraud Alert: Joint Venture Arrangements

The OIG's first Fraud Alert, issued in 1989, concerned joint venture arrangements between clinical laboratories, suppliers and other providers and their referral sources. In the 1980s, it was common for a supplier to enter into a partnership with a hospital or other entity to form a new supplier. The investors would invest little capital in the partnership, which would contract out substantially all of its operations to the DME investor. In the OIG's view, these ventures were not legitimate businesses, but simply mechanisms to lock up referral streams and compensate referral sources for referring business, in violation of the anti-kickback statute. The Fraud Alert included a list of "questionable features" which could suggest an anti-kickback violation. Those questionable features included selection of investors on the basis of their ability to generate referrals; an investor engaged in the same line of business as the venture and acting as a subcontractor; and disproportionately large returns on small investments.

2. Special Fraud Alert: Routine Waiver of Copayments or Deductibles under Medicare Part B

In this Special Fraud Alert, the OIG stated that routine waiver of Medicare cost-sharing amounts "is unlawful because it results in (1) false claims, (2) violations of the anti-kickback statute, and (3) excessive utilization of items and services paid for by Medicare." It listed some "suspect marketing practices" including advertisements stating "Medicare Accepted As Payment in Full" or "No Out-Of-Pocket Expense;" routine use of "financial hardship" forms with no good faith attempt to determine the beneficiary's

actual financial condition; and collection of copayments and deductibles only from beneficiaries who have Medicare supplemental insurance. Waiver of copayments is a significant issue for suppliers of high-cost DME, particularly power wheelchairs and scooters, because high copayments (approximately $1000.00 in the case of a K0011 power wheelchair) are a major disincentive to potential customers.

3. OIG's April 2003 Special Advisory Bulletin: Contractual Joint Ventures

In April 2003, the OIG published a Special Advisory Bulletin entitled "Contractual Joint Ventures." The Advisory Bulletin focuses on a situation where a health care provider in one line of business ("Owner") expands into a related line of business by contracting with an existing provider ("Manager"). The Owner's line of business is to provide new products to the Owner's existing patient base. The Manager not only manages the new line of products, but also supplies the Owner with inventory, employees, physical space, billing and other services. In essence, the Owner contracts out substantially the entire operation to the Manager and the Owner pockets the profits from this new line of business. These ventures are very similar to those described in the 1989 Special Fraud Alert, except that the supplier does not own equity in the venture.

According to the bulletin, the practical effect of the relationship between the Owner and the Manager is for the Owner to have the opportunity to bill for business that is, in reality, provided by either the Manager or by a "joint venture" formed by the Owner and Manager. According to the bulletin, the OIG looks at this type of arrangement as nothing more than a kickback, with remuneration (in form of profits retained by the Owner) flowing back to the Owner.

Therefore, if a supplier desires to open up a mail order respiratory pharmacy, then it must assume financial risk and operational responsibilities in operating the pharmacy, Likewise, if a hospital contracts with a supplier for management services for the hospital's DME operation, then while the supplier can provide certain management and administrative services, the financial risk and operational responsibilities of the DME operation must be borne by the hospital.

4. Special Fraud Alert: Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer

A number of suppliers rent space in the offices of physicians or other practitioners. The OIG is concerned that in such arrangements, the rental payments may be disguised kickbacks to the physician in violation of the anti-kickback statute. One of the specific concerns of the OIG is "consignment closet" arrangements between suppliers and physicians. It is common for suppliers to place certain items of equipment and supplies in physicians' offices for the convenience of physicians and patients. If a patient needs crutches, for example, the physician can dispense the crutches at the time of the office visit. The physician's office then informs the supplier, which bills for the crutches

and replenishes the consignment closet inventory. These arrangements serve a legitimate purpose, but in the past some suppliers paid excessive amounts of rent to the physicians for the space used to store the consignment inventory, as a way of disguising payments for referrals.

The questionable features of suspect rental arrangements for space in physicians' offices may be reflected in three areas: (1) the appropriateness of rental agreements; (2) the rental amounts; and (3) time and space considerations. Separately or together, specific details of these arrangements may result in an arrangement that violates the anti-kickback statute. The Space Rental safe harbor to the anti-kickback statute can protect legitimate arrangements. Arrangements for office equipment or personal services of physicians' office staff can also be structured to comply with the Equipment Rental safe harbor and Personal Services and Management Contracts safe harbor.

5. Offering Gifts and Other Inducements to Beneficiaries

A person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services may be liable for civil money penalties. The statute and implementing regulations contain a limited number of exceptions.

Unless a supplier's practices fit within an exception or are the subject of a favorable advisory opinion, any gifts or free services to beneficiaries should not exceed $10 per item and $50 annually. The OIG is considering the possibility of safe harbors for two kinds of arrangements: complimentary local transportation and government-sponsored clinical trials.

6. Telemarketing by Durable Medical Equipment Suppliers

The beneficiary inducement statute prohibits suppliers from making unsolicited telephone calls to Medicare beneficiaries regarding the furnishing of a covered item, except in three specific situations: (i) the beneficiary has given written permission to the supplier to make contact by telephone; (ii) the contact is regarding a covered item the supplier has already furnished the beneficiary; or (iii) the supplier has furnished at least one covered item to the beneficiary during the preceding fifteen months. The statute also specifically prohibits payment to a supplier that knowingly submits a claim generated pursuant to a prohibited telephone solicitation. Accordingly, such claims for payment are false and violators are potentially subject to criminal, civil, and administrative penalties, including exclusion from federal health care programs.

Suppliers cannot do indirectly that which they are prohibited from doing directly. A supplier is responsible for verifying that marketing activities performed by third parties with whom the supplier contracts or otherwise does business do not involve prohibited

activity and that information purchased from such third parties was neither obtained, nor derived, from prohibited activity. If a claim for payment is submitted for items or services generated by a prohibited solicitation, both the supplier and the telemarketer are potentially liable for criminal, civil, and administrative penalties for causing the filing of a false claim.

Special Fraud Alerts and Special Advisory Bulletins are available online at http://oig.hhs.gov/fraud/fraudalerts.html.

E. Supplier Standards

1. Supplier Standard No. 1.

A supplier must operate its business in compliance with applicable federal and state statutory and regulatory requirements.

2. Supplier Standard No. 11

A supplier may not directly solicit a Medicare beneficiary. A supplier may call a beneficiary only if one of the following exceptions applies: (1) the beneficiary has given written permission; or (ii) the supplier has furnished a Medicare-covered item to the beneficiary and the supplier is contacting the beneficiary to coordinate delivery of the item.

II. States

All states have enacted statutes prohibiting kickbacks fee splitting, patient brokering, or self-referrals. Some statutes refer to definitions and standards found in the federal statutes while others are materially different. Some state statutes apply only when the payor is a state health care program, while other statutes apply regardless of the identity of the payor.

Texas has an anti-kickback statute that applies regardless of payor. Tex. Occ. Code § 102.001(a) provides in relevant part:

> A person commits an offense if the person knowingly offers to pay or agrees to accept, directly or indirectly, overtly or covertly any remuneration in cash or in kind to or from another for securing or soliciting a patient or patronage for or from a person licensed, certified, or registered by a state health care regulatory agency.

The above statute adopts the exceptions and safe harbors to the Medicare/Medicaid Anti-kickback Statute. Tex. Occ. Code § 102.003 provides:

Section 102.001 permits any payment, business arrangement, or payment practice permitted by 42 U.S.C. Section 1320a-7b(b) or any regulation adopted under that law.

In addition, Texas also has an anti-kickback statute that applies only to the Texas Medicaid program. Tex Hum. Res. Code § 32.039 provides, in relevant part:

(a) In this section:

(1-a) "Inducement" includes a service, cash in any amount, entertainment, or any item of value…

(b) A person commits a violation if the person…

(1-a) engages in conduct that violates Section 102.001, Occupations Code;

(1-b) solicits or receives, directly or indirectly, overtly or covertly any remuneration, including any kickback, bribe, or rebate, in cash or in kind for referring an individual to a person for the furnishing of, or for arranging the furnishing of, any item or service for which payment may be made, in whole or in part, under the medical assistance program, provided that this subdivision does not prohibit the referral of a patient to another practitioner within a multispecialty group or university medical services research and development plan (practice plan) for medically necessary services;

(1-c) solicits or receives, directly or indirectly, overtly or covertly any remuneration, including any kickback, bribe, or rebate, in cash or in kind for purchasing, leasing, or ordering, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item for which payment may be made, in whole or in part, under the medical assistance program;

(1-d) offers or pays, directly or indirectly, overtly or covertly any remuneration, including any kickback, bribe, or rebate, in cash or in kind to induce a person to refer an individual to another person for the furnishing of, or for arranging the furnishing of, any item or service for which payment may be made, in whole or in part, under the medical assistance program, provided that this subdivision does not prohibit the referral of a patient to another practitioner within a multispecialty group or university medical services research and development plan (practice plan) for medically necessary services;

(1-e) offers or pays, directly or indirectly, overtly or covertly any remuneration, including any kickback, bribe, or rebate, in cash or in kind to induce a person to purchase, lease, or order, or arrange for or recommend the purchase, lease, or order of, any good, facility, service, or item for which payment may be made, in whole or in part, under the medical assistance program;

(1-f) provides, offers, or receives an inducement in a manner or for a purpose not otherwise prohibited by this section or Section 102.001, Occupations Code, to or from a person, including a recipient, provider, employee or agent of a provider, third-party vendor, or public servant, for the purpose of influencing or being influenced in a decision regarding: (A) selection of a provider or receipt of a good or service under the medical assistance program; (B) the use of goods or

services provided under the medical assistance program; or (C) the inclusion or exclusion of goods or services available under the medical assistance program.

For comparison, the state of New Jersey has only one anti-kickback statute, and the statute applies only to the state Medicaid program. N.J. Stat. Ann. § 30:4D-17 (1968) provides, in relevant part:

> (c) Any provider, or any person, firm, partnership, corporation or entity who solicits, offers, or receives any kickback, rebate or bribe in connection with:
>
> (1) The furnishing of items or services for which payment is or may be made in whole or in part under this act [Medicaid]; or
>
> (2) The furnishing of items or services whose cost is or may be reported in whole or in part in order to obtain benefits or payments under this act; or
>
> (3) The receipt of any benefit or payment under this act, is guilty of a high misdemeanor and, upon conviction thereof, shall be liable to a penalty of not more than $10,000.00 or to imprisonment for not more than 3 years or both.
>
> This subsection shall not apply to (A) a discount or other reduction in price under this act if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made under this act; and (B) any amount paid by an employer to an employee who has a bona fide employment relationship with such employer for employment in the provision of covered items or services.

Innovative Marketing

I. Use of Employees

It is acceptable for an HME company to pay commissions, bonuses and other production-based compensation to bona fide full-time and part-time employees who market the company's products and services. There is a specific exception to the anti-kickback statute for payments to bona fide employees. Likewise, there is an "employee" safe harbor that provides that payments to a bona fide employee do not constitute illegal remuneration in violation of the anti-kickback statute. Normally, marketing through a bona fide employee is acceptable under state statutes. The reasoning behind this exception and safe harbor is that an employer has the duty to train, control and supervise its employees. In addition, under the doctrine of respondeat superior, an employer is liable for the acts of its employees that are conducted within the course and scope of the employees' employment. As a result, the employer is motivated to exercise control over its marketing employees.

It is critical that the employee be a "bona fide" employee as opposed to being a "sham" employee. The IRS has published extensive guidance that addresses whether a person is an employee or an independent contractor. In scrutinizing whether a person is an employee versus

an independent contractor, the government (e.g., the Department of Justice and the OIG) will look at "substance over form." For example, if an HME company has a written employment agreement with a person, withholds taxes and Social Security from the person's paycheck, and issues a W2 to the person, such factors by themselves do not establish an employment relationship. Other important factors are whether the employer is supervising, training and controlling the employee. Therefore, if the company calls a person an employee and pays the person as if he or she is an employee, but otherwise treats the employee as if he or she is an independent contractor, then the government will likely conclude that the person is an independent contractor.

If an HME company pays commissions, bonuses and other production-based compensation to an independent contractor to market to Medicare/Medicaid patients, then the anti-kickback statute will likely be violated. The only possible mechanism for an HME company to pay an independent contractor (a person who receives a 1099) for marketing to Medicare/Medicaid patients is for the company to pay a fixed annual fee to the contractor that is the fair market value equivalent of the person's efforts, not his or her results. In other words, the relationship with the independent contractor needs to fall within the guidelines of the Personal Services and Management Contracts safe harbor.

Assume that the independent contractor wishes to market only to commercial/cash-paying patients. This is acceptable unless applicable state law says otherwise.

II. Use of Independent Contractors

As discussed above, an HME company cannot pay commissions, bonuses or other production-based payments to independent contractors for marketing to Medicare/Medicaid patients. To do so would violate the anti-kickback statute. The only mechanism to pay an independent contractor for marketing to Medicare/Medicaid patients is to fit (or substantially fit) the relationship within the Personal Services and Management Contracts safe harbor. Among other requirements, payment to the independent contractor must be fixed one year in advance and must be the fair market value equivalent of the contractor's services. As discussed above, an independent contractor can market to commercial/cash-paying customers only if there is no state law that says otherwise.

III. Media Advertising

It is acceptable for the HME company to advertise on television, on radio, in the newspaper and in other media outlets.

IV. Approaching Physicians and Other Referral Sources

It is acceptable for the HME company to call on physicians, hospital discharge planners, home health agencies, and other referral sources in order to market the company's products and services. Under federal law, the HME company cannot directly or indirectly give something of

value to the referral sources for referrals. Stark allows an HME company to furnish non-cash items (such as meals) to a physician so long as the cost of the meals, in the aggregate, does not exceed $300 over 12 months. There is not a similar exception to the anti-kickback statute. However, if this $300 Stark exception is followed, it is unlikely that the government will allege that the meals furnished to a physician violate the anti-kickback statute. Assume that the referral source will refer only commercial/cash-paying customers to the HME company. As to whether the HME company can give anything of value to the referral source will be determined by state law. In targeting referral sources, the HME company should take the following steps:

- Make a list of all current physician referral sources.
- Make a list of all other healthcare professionals who refer patients to you.
- Categorize this list by specialty area or disease state.
- Create an "A" list of referral sources within a 3 to 5 mile radius of your location who refer over half of your patients. Visit these monthly.
- Create a "B" list of potential referral sources within this area who do not currently refer patients. Visit them monthly for 2-3 times to see if you will begin to get their patients.
- Call referral source to introduce yourself and explain that literature will be mailed.
- Mail literature with a cover letter outlining what you can do for the referral source.
- Call back one week later to verify that the letter was received and set up an appointment.
- Learn as much as possible from your contact or online about the referral source.
- Meet with the referral source to present your products and services and learn about the referral source's needs.
- Mail a thank-you note for meeting with you.

In marketing to new referral sources, the HME company should take the following steps:

- First Visit: Present your business card and brochure specific to the referral source's patient base. Question and learn about the referral source's patients' home health care needs.
- Second Visit: Present a catalog or sales folder. Demonstrate your complete product and service offering. Set up an in-service.
- Third Visit: Present an in-service with a vendor representative and include breakfast or lunch.
- Send thank-you cards after each visit.
- Call your contact at the end of every month to find out how his/her patients like your program/products/services.

In marketing to current referral sources, the HME company should take the following steps:

- Offer in-services on new products and services that are needed by the referral source's patients.
- Bring knowledgeable individuals, such as vendor representatives, to conduct product trainings.
- Bring breakfast or lunch.
- Try to schedule monthly in-services for key referral sources.
- Mail monthly.
- Call monthly.

Marketing tools for new referral sources include the following:

- Fliers
- Brochures
- Sales Folders
- Catalogs
- Videos
- Sample Program
- In-Services
- Seminars
- Direct Mail
- Open Houses
- Disease Management Programs

The HME company should take the following steps in creating sales tools:

- Request new product information from vendors, trade magazines and distributors.
- Catalog literature by disease state.
- Copy onto your own masthead.
- Take copies of all information on one specific topic/disease state whenever you call on a referral source.
- Become a home health care resource for your referral sources.

A monthly mailing program should include the following:

- Three-month rotational basis program:
  - Generic literature
  - Product literature
  - Product at a price
  - Coordinate with distributor/ manufacturer promotions
  - Include a personal note or business card

- Call the following week to see if the referral source has any questions.

In working with hospital case managers and discharge planners, the following steps are suggested:

- Suggest that the hospital refer to the sales representative, not the HME company.
- Depend upon the person, not the HME company (value personal relationships).
- HME sales person is the point person to oversee the patient from the hospital to the home.
- Count on reliability and accessibility.
  - The hospital should know that the HME company will have an employee waiting at the patient's home when discharged.
  - The hospital should know that it can reach the HME company's representative at all times.

In working with long term care ("LTC") facilities, the following approach should be taken:

- Questions to ask include the following:
  - Who is the administrator?
  - Who is the supervising nurse?
  - Who pays for products?
  - Who is the weekend supervisor?

When conducting a first visit to the administrator of a LTC facility, the HME company should take the following steps:

- Write/call repeatedly to obtain an appointment.
- Be brief.
- Emphasize you are a local company servicing your community.
- Request approval to return and meet with the head of nursing.

When conducting a second visit, this time to the LTC's Director of Nursing:

- Introduce your company, products and services.
- Determine the LTC facility's product/service needs.
- Set up an in-service the following month based upon the above.

In working with visiting nurses associations ("VNAs"), the HME company should take the following steps:

- Determine sources of revenue, i.e. Medicare, workers comp, private insurance.
- Make appointment with the supervisor.
- Find out who currently receives HME referrals and why.

- Determine primary needs, i.e. closed door pharmacy, enteral feeding, custom fit wheelchairs.
- Request permission to attend the VNA's monthly meetings. Offer to provide refreshments.
- Leave samples (with pricing). Request samples from vendors to use.

In working with physical and occupational therapists ("PTs/OTs"), the following steps are suggested:

- Demonstrate expertise in PT's/OT's areas of specialty.
- Show familiarity with HME products.
- Present all options.
- Offer breadth of product in the PT's/OT's areas of specialty.
- Do not push products. Rather, become a resource to help determine which products work best for the PT's/OT's patients.

In working with hospices, the following steps are suggested:

- Remember the standard package: bed, overbed table and bedside commode.
- Remember that oxygen is the number one HME service requested.
- Other top HME services requested are shower benches and wheelchairs.

V. Mail-Outs

On condition that the HME company secures a mailing list in such a way that HIPAA is not violated (e.g., the list comes from a non-covered entity), then the company can mail out promotional literature to the individuals on the list. In so doing, the HME company can include a stamped, self-addressed postcard. In the promotional literature, the HME company can ask the recipient to sign and mail the postcard to the company, which will then give the company the right to call the recipient.

VI. Promotional Items to Customers and Potential Customers

The HME company can offer an item of nominal value (i.e., retail value of not more than $10) to customers/prospective customers covered by a government health care program. For example, the company can run ad in the newspaper that encourages individuals to visit the company; the ad can say that all visitors will receive a coffee mug (that has a retail value of $7.99). Over a 12-month period, the HME company may not give items to any one customer that have a combined retail value greater than $50. As to whether the HME company can offer items to commercial/cash-paying customers and, if so, the value of the items, depends on the applicable state statutes.

VII. Health Fairs, Luncheons, Kiosks, and Open Houses

The HME company can participate in local health fairs. Similarly, the company can put on a short program during lunch at a senior citizens' center, at which time the company can distribute promotional literature. The HME company can place a kiosk in a mall that promotes the company's products and services. On a periodic basis, the HME company can hold an open house. In so doing, the HME company's approach should include the following:

- Focus on a category and/or disease state.
- Plan a luncheon or after work wine and cheese.
- Invite vendors to display and demonstrate their products. Charge them for tables to defer food cost.
- Invite a local hospital/medical/insurance executive to present a brief keynote talk.
- Send formal VIP invitations with RSVP cards. Call to follow-up.
- Invite local newspapers.
- Invite a radio station to broadcast live.

VIII. OIG Restrictions on Provision of Home Oxygen Prior to Qualification and on Conducting Pre-Screens (Pertaining to Medicare Patients)

On November 8, 2006, the OIG posted Advisory Opinion No. 06-20 that sets out a restrictive OIG view towards two business practices pertaining to home oximetry testing. Pursuant to the first practice, the HME company would provide Medicare beneficiaries with free home oxygen until the beneficiaries qualify for Medicare coverage for oxygen. Under the second practice, the HME company would pre-screen beneficiaries by running overnight pulse oximetry tests on them and then reporting the test results to the physician. The OIG stated that the practices would implicate both the Civil Monetary Penalties ("CMP") statute and the Medicare/Medicaid anti-kickback statute. In making this statement, the OIG offered its opinion that (i) both programs would constitute remuneration to the beneficiaries who receive them; (ii) the remuneration provided under the practices would be likely to influence beneficiaries to select the HME company (providing the free services) as their supplier of oxygen or other Medicare - payable goods and services; and (iii) the HME company (providing the free services) would know, or should know, that the provision of items and services under the two practices would be likely to influence beneficiaries' selection of the company for oxygen or other Medicare-payable supplies. In reviewing the Advisory Opinion, the following observations can be made:

- The Advisory Opinion is not intended to prevent the HME company from providing care (ordered by the treating physician) for existing patients of the HME company that are enrolled in disease management programs, COPD pathways or similar types of programs. If an HME company has a patient enrolled in such a program, and if an assessment (including oximetry) is ordered by the treating physician, then the HME company can perform the assessment. Note that the patient must have a diagnosis that fits the need for the assessment. Examples would include COPD or CHF. Documentation would need to support that the assessment was ordered. Assessment documentation would include not

only SpO2, but presumably also auscultation, respiratory rate and pulse rate. If the assessment findings indicate that the patient is experiencing a decline in his/her condition or additional health issues, the patient's physician should be notified. The physician will need to make the decisions regarding further assessment and/or intervention.

- Other than as discussed above, an HME company may not provide a free oximetry screening. In other words, the HME company cannot provide free services that would potentially result in the beneficiary choosing the HME company as his/her supplier.

- An HME company may not set up free oxygen while waiting for a qualifying test. If a physician tells the HME company that an emergency exists and that the patient must immediately be set up on oxygen, then the best case scenario would be for the patient to go to an IDTF for testing. Keep in mind that an emergency room is not a good choice for testing, as Medicare would view that as emergent care; thus, the patient would not be in a "chronic stable state." An alternative is for the HME company to complete an ABN and have the patient sign it in advance of setting the patient up on oxygen. The ABN would advise the patient that Medicare will not pay for oxygen until the patient has a qualifying oxygen test, and inform the patient that he/she will be financially responsible for the oxygen until the patient qualifies. Should the patient later qualify under the appropriate testing standards, the HME company may, at that point, accept assignment.

- The HME company is not prohibited from advising the physician of the need for re-certification testing, or testing needed due to a change in insurance carrier.

Business Arrangements

I. Joint Venture

The government may carefully scrutinize a joint venture between providers in order to ensure that the venture is not merely a sham whereby one entity is paying remuneration to the other entity in exchange for the referral of customers.

The safe harbor applicable to joint ventures is the Small Investment Interest safe harbor, which requires that (i) no more than 40% of the investment may be owned by persons who can generate business for or transact business with the entity; and (ii) no more than 40% of the gross revenue may come from business generated by the investors. This is known as the "60-40" rule.

It is rare that a joint venture will fit within the Small Investment Interest safe harbor because it is difficult to meet the "60-40" rule. If the Small Investment Interest safe harbor is not met, then the government will examine the joint venture under the "one purpose" test. The basic inquiry under this test is whether one purpose of the arrangement is to induce referrals. In deciding whether to exercise its discretion to bring an enforcement action against the parties to a joint venture, the government will look to see whether the venture complies with the guidelines of the OIG's 1989 Special Fraud Alert.

A. Physician Ownership in HME Company

Under Stark, a physician cannot have an ownership interest in an HME company and also refer to it. As an exception, if the HME company is located in a rural area, and if at least 75% of the company's products and services are provided to residents of the rural area, then it is acceptable for the physician to have an ownership interest in the HME company and also refer to it.

B. Physician Ownership in Sleep Lab

A polysomnography does not fall within the Stark definition of DHS. Therefore, Stark does not prohibit a physician from having an ownership interest in a sleep lab, even if the sleep lab is receiving money from Medicare and Medicaid. However, a CPAP falls under DME which, in turn, falls within the definition of DHS. Therefore, if a physician has an ownership interest in a sleep lab and refers to it, then the sleep lab cannot also sell CPAPs and related supplies to Medicare/Medicaid customers.

C. Joint Ownership of a new HME Operation by a Hospital and an Existing HME Company

A hospital and an existing HME company may jointly set up and own a new HME operation (e.g., on the hospital's premises) so long as the OIG's 1989 Special Fraud Alert (Joint Ventures) and 2003 Special Advisory Bulletin (Contractual Joint Ventures) are met. Among other requirements, both owners will need to invest risk capital; the hospital cannot be required to refer patients to the new venture; the existing HME company cannot run the new venture on a turnkey basis; and the hospital must insure patient choice.

D. Commercial/Cash-Paying Customers Only

If the joint venture will pertain only to commercial/cash-paying customers, then the HME company will need to look to applicable state law.

II. Contractual Arrangements

A. Cooperative Marketing Program

A pharmacy, HME company, hospital or any other provider may enter into a cooperative marketing program. The costs and expenses of the program must be proportionately shared by the provider. For example, this type of arrangement allows an independent HME company and pharmacy to offer the same type of combined services that a national HME company/pharmacy can offer. The cooperative marketing program offers "one stop shopping" to customers. Examples of cooperative marketing programs are:

- Joint advertisements in the media.
- A brochure jointly prepared by the entities that promotes the products and services of the entities.
- References to the cooperative arrangement on the letterhead and business cards of each entity.
- A link on each entity's website to the other entity's website (or other entities' websites).
- A display table that educates customers about the services offered by each entity.
- Written information (explaining the services offered by each entity) that is mailed to each entity's customers.

The discussion in the preceding paragraph pertains to cooperative marketing by two or more providers that furnish products and services directly to customers. If a provider desires to enter into a cooperative marketing program with a manufacturer, then the provider needs to be aware of the OIG's Advisory Opinion No. 06-16 that addresses manufacturer-sponsored cooperative marketing programs.

In the opinion, the OIG describes "advertising assistance" to be given by a manufacturer to the HME company. The assistance is to consist of free advertising furnished by the manufacturer for the HME company and/or reimbursement by the manufacturer of the HME company's advertising expenses. In either case, the advertisements feature the manufacturer's products and display the HME company's name and contact information, or the HME company's name and a toll free number of a call center operated by the manufacturer. According to the OIG, the advertising assistance is remuneration to the HME company, and there is a substantial risk that the arrangement would violate the anti-kickback statute. The OIG further states that the call center arrangement (described in the opinion) is especially troublesome because when customers call the call center, they may mistakenly believe they are speaking to the HME company and obtaining objective information, and therefore may be misled into choosing the manufacturer's products. Lastly, the OIG states that the proposed cooperative marketing program has the following potential kickback risks: (i) the arrangement could lead to overutilization and increased program costs; (ii) the availability of advertising assistance takes into account the HME company's purchases from the manufacturer; (iii) the HME company is incentivized to steer patients to the manufacturer's products; and (iv) the HME company is encouraged to purchase products of the manufacturer providing the advertising assistance as opposed to another manufacturer's products.

The regulations governing the advisory opinion process require the requestor of an opinion to provide a "complete and specific description of all relevant information bearing on the arrangement for which an advisory opinion is requested and on the circumstances of the

conduct." 42 CFR § 1008.36(b)(4). The OIG typically requires a requestor to describe a proposed arrangement in considerable detail. In Advisory Opinion No. 06-16, the OIG deviated from its usual practice by opining on a vaguely defined proposal encompassing a broad range of possible cooperative marketing arrangements. No previous advisory opinion has dealt with an entire category of activities. Because the opinion is so general, it is not very helpful in determining what factors the OIG would consider most important in evaluating a cooperative marketing program, or where the boundaries are between permissible and impermissible cooperative marketing activities. To the extent that the advisory opinion suggests that any kind of cooperative marketing activity violates the anti-kickback statute, it appears to be overly broad.

Nevertheless, in light of the broad language of Advisory Opinion No. 06-16, it is prudent to structure a manufacturer-sponsored cooperative marketing arrangement conservatively. If a cooperative marketing program conforms to the following guidelines, it should be difficult for the government to credibly argue that the program violates the anti-kickback statute:

- Advertising for which the manufacturer pays 100% of the cost should not promote the HME company. Rather, the ad should only reference the manufacturer and/or its products.

- If the manufacturer and the HME company share the cost of the ad on an equitable basis, then the ad can reference the HME company.

- If a telephone number is displayed on the ad, then the ad should not mislead the reader or viewer about the identity of the company that answers the phone. Likewise, when the customer calls the number, the person answering the phone should accurately disclose the identity of the company for which the person is working. In short, safeguards should be in place to prevent confusion on the customer's part.

B. Administrative Services Agreement ("ASA")

A hospital may open an HME operation located on hospital premises or at a location leased or owned by the hospital. In so doing, the hospital may contract with an existing HME company to provide administrative services. If an HME company enters into an ASA with a hospital, then it is critical that the agreement comply with the guidance set out in the OIG's April 2003 Special Advisory Bulletin entitled "Contractual Joint Ventures."

C. Loan/Consignment Closets

An HME company may place inventory in an office or facility that is not owned by a physician or non-physician practitioner. The inventory must be for the convenience only of the office's/facility's patients and the office/facility cannot financially benefit, directly or indirectly, from the inventory. It is important that the office/facility ensure patient choice. Technically, the HME company can pay rent to the office/facility so long as the rental agreement complies with

the Space Rental safe harbor. However, from a practical standpoint, because the physical space utilized by the placement of the inventory is so small, it is preferable for the HME company to pay no rent to the office/facility.

D. Preferred Provider Agreement ("PPA")

The HME company can enter into a PPA with a hospital whereby, subject to patient choice, the hospital will recommend the HME company to its patients who are about to be discharged.

E. Employee Liaison

An HME company/pharmacy may designate an employee to be on the hospital/physician office premises for a certain number of hours each week. The employee may educate the hospital/physician 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 DME company/pharmacy (but before the patient is discharged/leaves the physician's office), in order for there to be a smooth transition when the patient goes home. The employee liaison may not assume responsibilities that the hospital/physician is required to fulfill. Doing so will save the hospital/physician money, which will likely constitute a violation of the Medicare/Medicaid anti-kickback statute.

F. Medical Director Agreement

An HME company/pharmacy can enter into an independent contractor Medical Director Agreement ("MDA") with a physician, even if the physician is a referral source. The MDA must comply with the (i) Personal Services and Management Contracts safe harbor and (ii) the Personal Services exception to Stark II. Among other requirements:

- The MDA must be in writing and must have a term of at least one year.
- The compensation to the physician must be fixed a year in advance and it must be the fair market equivalent of the actual services rendered.
- The physician must render actual, necessary and substantive services to the HME company/pharmacy.
- The compensation paid by the HME company/pharmacy to the physician must bear no resemblance to referrals by the physician.

G. Purchase of Internet Leads

Lead generation companies ("LGCs") have been around for years in the non-health care space. However, in the last three years, lead companies have come into the health care market in

droves. Unfortunately, most lead companies that have been successful in the widget market are clueless regarding the multiple federal anti-fraud laws in the health care market, such as the Medicare anti-kickback statute and the telephone solicitation statute. Equally as unfortunate, there are too many DME companies that are equally as clueless. What is legal in the widget market may very well not be legal in the HME market.

Here is the government's perception as to what is going on in the DME industry:

- Medicare beneficiaries are being called by LGCs under the guise of a "survey" in which the LGC asks the beneficiary about her refrigerator, her dog food and her laundry detergent. Then the caller says "By the way, does anyone in your house have diabetes?" When the beneficiary says "I do," the caller asks for permission for a diabetic supply company to call her. When the beneficiary says "yes," then the diabetic supply company calls the beneficiary, and then pays money to the LGC for the lead on a "per lead" basis. In short, the LGC is calling the beneficiary to get permission for a DME company to later call her. This is a sham, it is a violation of the telephone solicitation statute, it is a violation of Supplier Standard 11, and the diabetic supply company is liable. This is also likely a violation of the Medicare anti-kickback statute.

- A "final expense life insurance company" sells $7500 life insurance policies to individuals to cover the cost of burial. The company compiles a list of policy holders. The company knows what each policy holder's medical condition is. The life insurance company calls its policy holders and asks them if they would like to talk to a diabetic supply company about diabetic supplies. The policy holder says "yes," and the life insurance company transmits the information to a diabetic supplier. The diabetic supplier then calls the policy holder in order to sell her diabetic testing supplies. The diabetic supply company pays the life insurance company for the lead on a "per lead" basis. This is a sham, it is a violation of the telephone solicitation statute, it is a violation of Supplier Standard 11, and the diabetic supply company is liable. This is also likely a violation of the Medicare anti-kickback statute.

- A television or magazine ad says nothing about DME. The ad generally talks about "life style." The beneficiary calls the toll-free number contained in the ad. Over the phone, the LGC asks the beneficiary if anyone in her home has diabetes. If the beneficiary says "yes," then the LGC asks the beneficiary if a diabetic supply company can call her. The beneficiary says "yes" and the diabetic supplier calls her. The diabetic supplier pays the LGC on a "per lead" basis. This is a violation of the telephone solicitation statute, it is a violation of Supplier Standard 11, and the diabetic supply company is liable. This is also likely a violation of the Medicare anti-kickback statute.

- An internet ad says nothing about DME. The ad generally talks about "life style." The beneficiary checks a box consenting to be called. In response to this electronic "consent-to-be-called," the LGC calls the beneficiary and asks her if anyone in her home has diabetes. If the beneficiary says "yes," then the LGC asks the beneficiary if a diabetic

supply company can call her. The beneficiary says "yes" and the diabetic supplier calls her. The diabetic supplier pays the LGC on a "per lead" basis. This is a violation of the telephone solicitation statute, it is a violation of Supplier Standard 11, and the diabetic supply company is liable. This is also likely a violation of the Medicare anti-kickback statute.

- Often, the diabetic Medicare beneficiary is sick and elderly. The beneficiary may have consented (over the phone) to have a number of diabetic supply companies send diabetic supplies to her. This consent may have arisen from confusion on the beneficiary's part. The government is finding that many beneficiaries are receiving diabetic supplies from multiple companies. The government is finding that many beneficiaries have a closet full of boxes of unopened diabetic supplies.

- Often, a DME company will obtain the beneficiary's physician's name from the beneficiary and fax an order to the physician. The physician will sign the order and send it back to the DME company without even talking to the beneficiary. Alternatively, the physician will not sign the order because the physician has not seen the beneficiary in a long time, or the physician does not believe that the beneficiary needs the equipment described in the order.

Even though these examples are focused on diabetic testing supplies, they apply to all types of DME.

Governmental agencies and contractors are aggressively looking at relationships between LGCs and DME companies. For example, either as part of an unannounced site visit, or pursuant to a letter inquiry, the NSC is asking DME companies about how they are obtaining new customers. In particular, the NSC is asking the DME company whether it is purchasing leads. If the NSC concludes that the telephone solicitation statute and/or Supplier Standard 11 is being violated, then the NSC will suspend the DME company's supplier number. Accrediting Organizations ("AOs") are asking the same questions of their clients. If the AO believes that the DME company's marketing activities are violating the telephone solicitation statute and/or Supplier Standard 11, then the AO will threaten to revoke the accreditation unless the DME company takes corrective steps. The ZPICs are extremely aggressive. Until just recently, the ZPIC would only examine the DME company's patient files and not ask additional questions. This is no longer the case. ZPICs are asking for the names and contact information of the DME company's marketing reps; they are interviewing (in person and/or over the phone) the DME company's patients and the physicians whose names are on the orders; and they are drilling down on whether the DME company is purchasing leads. If the ZPIC concludes that the DME company is violating the telephone solicitation statute and/or Supplier Standard 11, then the ZPIC may instruct all four DME MACs to suspend payments to the DME company. This brings us to the Department of Justice ("DOJ"). Our firm is beginning to see the DOJ investigate lead purchase arrangements. The DOJ's focus is not on the telephone solicitation statute/Supplier Standard 11; rather, the focus is on whether the arrangement violates the Medicare anti-kickback

statute (which is a criminal statute). In short, DME companies that purchase leads are living in a glass house; there are multiple "camel's noses under the tent flap."

So what exactly is the law as it pertains to purchasing leads?

When a DME company signs a lead generation agreement ("LGA") with an LGC, there are two main legal issues that must be addressed. The first one involves the Medicare anti-kickback statute, which provides for criminal penalties for any person or company that solicits, receives, offers or pays any remuneration to a person or company to induce the person/company to refer an individual for Medicare-covered items or services, or to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any Medicare-covered items or services, or to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any Medicare-covered item or service, subject to certain exceptions. It is acceptable to purchase a lead; however, it is a violation of the anti-kickback statute to pay for referral. The line between the two can be blurry. In the eyes of the OIG, there is a distinction between (i) a "raw" or "unqualified" lead and (ii) a "qualified" lead. It is acceptable for an LGC to obtain basic information from a lead (name, address and telephone number) and sell this "raw" lead to a DME company. The DME company can, in turn, pay the LGC on a per lead basis. If, however, the LGC obtains "qualifying" information on the lead (e.g., Medicare number, other insurance information, medical condition, physician's name, products currently being used, etc.) and sells the qualified lead to the DME company which, in turn, pays for the lead on a per lead basis, then it is likely that the government will take the position that the DME company is <u>not</u> buying a lead, but is paying for a referral…….which violates the anti-kickback statute. Unfortunately, the line between a "raw" lead and a qualified lead is blurry. Picture a continuum. On the left side of the continuum is a clear "raw" lead (name, address, and phone number) while on the right side of the continuum is a clear "qualified" lead (diagnosis, medical condition, products currently being used, physician's name, Medicare/insurance information). The chances of the raw lead ending up being a paying customer are low……similar to when a person calls the DME company in response to a newspaper ad. On the other hand, the chances of a qualified lead ending up being a paying customer are appreciably higher……similar to a referral from a physician or a hospital. Purchasing a raw lead is acceptable; it is not paying for a referral. Purchasing a qualified lead (where the compensation is on a per lead basis) is tantamount to paying for a referral which implicates the Medicare anti-kickback statute. As the lead moves along the continuum from the left to the right, there is a line that is crossed where the lead transforms from a raw lead to a qualified lead. Unfortunately, where that line is located is not clear. If in addition to name, address and phone number the LGC collects one additional piece of information (e.g., insurance information), then the lead starts moving from the left to the right. However, is this one piece of additional information sufficient to move the lead from the raw to the qualified category? Probably not. But what about two pieces of additional information? Three pieces of additional information?

Again, it is acceptable for a DME company to purchase a raw lead on a "per lead" basis. It is not acceptable to purchase a qualified lead on a per lead basis. The only possible way for a DME company to acquire qualified leads is for the agreement with the LGC to fall within, or

substantially fall within, the Personal Services and Management Contracts safe harbor to the Medicare anti-kickback statute. Among other requirements, the agreement must have at least a one year term, the compensation must be fixed one year in advance (e.g., $48,000 over the next 12 months), and the compensation must be the fair market value equivalent of the services rendered by the LGC.

One more thing. When it comes to determining if an arrangement violates a federal anti-fraud statute, it is "substance over form." If it looks like a duck, walks like a duck, sounds like a duck……..you get the picture. The following is not acceptable: (i) the LGC obtains qualifying information on the beneficiary; (ii) the LGC only gives the beneficiary's name, address, and phone number to the DME company; and (iii) the DME pays for the lead on a per lead basis. In reality, the LGC is selling a qualified lead to the DME company. In order for the lead to be raw or unqualified, the information obtained by the LGC must be limited to name, address and phone number.

Now let us turn our attention to the telephone solicitation statute and Supplier Standard 11. They essentially say the same thing. The statute/standard says that a DME company (or a person or company on behalf of the DME company) may not call a prospective customer (who is a Medicare beneficiary) unless the beneficiary has first given his written permission to be called. In addition to the "blue ink" signature of the beneficiary, the Federal Electronic Signature Act states that the written permission can be "electronic." An electronic signature will include the beneficiary calling the LGC or DME company in response to an ad. It also entails a beneficiary clicking a "consent-to-be-called" box on a web page. In order for the electronic signature to satisfy the "written permission" requirement of the statute/standard, it must comply with the nuances set out in the E-Sign Act. Note, however, that the NSC has stated in recent letters that only a "blue ink" signature is permissible. This is contrary to the law and, hopefully, this confusion will be cleared up in the near future.

Remember what I said about "If it looks like a duck, walks like a duck……" This analogy applies to the telephone solicitation statute/Supplier Standard 11 the same way that it applies to the Medicare anti-kickback statute. Picture Mrs. Smith, a 70 year old Medicare beneficiary sitting in her living room watching television. Her telephone may not ring…..period. The only time her phone may ring is if Mrs. Smith has first taken an affirmative act such as (i) calling a toll-free number in response to a television ad, newspaper ad, or brochure she receives in the mail, or (ii) checking a "consent-to-be-called" box on a web page. Nobody (e.g., LGC, a call center, a DME company) may call Mrs. Smith for an unrelated reason (taking a survey about her refrigerator, dog food and laundry detergent) and then ask her about her DME needs. If the beneficiary calls a toll-free number in response to a television or magazine ad, or in response to a brochure, then the ad must describe the DME that the beneficiary will be responding to. In addition, CMS has stated that the ad must specifically give the name of the DME company that wishes to sell the DME to the beneficiary. The "consent-to-be called" box on a web page must be equally specific. The box must clearly say something like the following: "I consent to be called by ABC Medical, Inc. about diabetic and ostomy supplies." The consent box cannot obliquely

state that the beneficiary agrees to the privacy policy found in another link (with the consent buried in the middle of the privacy policy).

Here are some practical steps that a DME company can take as it enters into an arrangement with an LGC:

- Require that the LGC accumulate its leads "organically." In other words, the LGC cannot purchase leads from a "lead broker" and then resell them to the DME company. By requiring the LGC to accumulate its lead in-house (e.g., by managing its own web landing sites), then the LGC can insure quality control. It can insure that the leads are being obtained in a way that the telephone solicitation statute and Supplier Standard 11 are not being violated. If the LGC purchases leads from Lead Broker A, which purchased the leads from Lead Broker B, and so on and so forth, then there is no way for the DME company to be sure that the leads were correctly accumulated in the first place.

- If the LGC is receiving phone calls from leads or is calling leads in response to affirmative actions taken by the beneficiaries, then the DME company should require such phone calls to be recorded and the DME company should have access to the recordings. The DME company should have the right to help draft the telephone scripts to be followed by the LGC employees. The DME company should have the right to audit the LGC's operations.

- The DME company should ask the LGC for a list of references.

- The DME company should ask the LGC if it is represented by an experienced health care attorney and if the attorney has given the LGC a formal opinion letter regarding the LGC's operations. The DME company should ask for a copy of the opinion letter.

H. Commercial/Cash-Paying Customers Only

If the contractual arrangement will pertain only to commercial/cash-paying customers, then the HME company will need to look to applicable state law.

EXHIBIT “A”

Template Subcontract Agreement

TEMPLATE SUBCONTRACT AGREEMENT

THIS SUBCONTRACT AGREEMENT ("Agreement") is made and entered into on _____ [date], by and between _____, a _____ _____ ("Supplier"), and _____, a _____ _____ ("Contractor").

BACKGROUND

A. Supplier was awarded a Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") Competitive Bidding Program Contract ("CBP Contract") to provide _____ to Medicare beneficiaries ("patients") residing in the _____ competitive bidding area ("CBA"). Terms used in this Agreement will have the meanings ascribed in the CBP Contract unless otherwise provided.

B. Contractor has experience and expertise in providing DMEPOS, specifically _____.

C. Supplier desires to subcontract with Contractor to provide certain services in support of Supplier's performance of the CBP Contract, and Contractor desires to accept such subcontract arrangement. The purpose of the subcontract arrangement is to ensure that Supplier is capable of providing DMEPOS and related services to all patients in the CBA.

TERMS

In consideration of the mutual covenants contained herein, and other good and valuable consideration, Supplier and Contractor agree as follows:

1. Contractor's Services. Contractor will provide the services described in Schedule A ("Services") on behalf of and as directed by Supplier to Supplier's patients who reside in the CBA.

2. Contractor's Representations, Warranties, and Covenants.

(a) Contractor represents and warrants that:

(i) Contractor, and all persons it employs or engages to perform Services, has all qualifications, accreditations, certifications, and licenses required by federal, state, or local law or third party payor policy or rule (collectively, "Qualification") to fully perform the Services.

(ii) Neither Contractor nor any of its officers, directors, employees or contractors has ever been (1) convicted of a criminal offense related to health care or related to the provision of services paid for by a federal or state health care

program (for example, Medicare and Medicaid); (2) assessed civil money penalties for an offense related to health care or related to the provision of services paid for by a federal or state health care program; (3) excluded from participation in any federal or state health care program; or (4) excluded by any federal agency from receiving federal contracts.

(b) Contractor covenants that:

(i) Contractor will not employ or contract with any individual or entity that is excluded from participation in any federal or state health care program or excluded by any federal agency from receiving federal contracts. If Contractor, or any of its officers, directors, employees, or contractors, becomes the subject of any of the actions described in this paragraph, Contractor will give written notice thereof to Supplier within five days after the date of such action or knowledge of such action.

(ii) Contractor acknowledges that, in the course of performing its duties hereunder, Supplier will disclose to Contractor Confidential Information (as defined below) having a special and unique nature and value relating to Supplier. As a material inducement to Supplier to enter into this Agreement, Contractor agrees that, unless Supplier provides prior written consent, Contractor will not, at any time during or following the term of this Agreement, directly or indirectly, disclose, publish, or divulge, except in connection with the provision of the Services, any Confidential Information which has been obtained by or disclosed to Contractor through or in the course of its relationship with Supplier. As an exception to the foregoing, Contractor may disclose Confidential Information as required to comply with the binding order of a governmental entity that has jurisdiction over it, provided that Contractor (a) gives Supplier reasonable written notice to allow Supplier to seek a protective order or other appropriate remedy, (b) discloses only such information as is required by the governmental entity, and (c) uses commercially reasonable efforts to obtain confidential treatment for any Confidential Information so disclosed.

(1) For purposes of this Agreement, "Confidential Information" will include, without limitation, any agreement to which Supplier is a party (including this Agreement), policies, methods, protocols, manuals, confidential reports, and other matters relating to the operation of the business of Supplier.

(2) If this Agreement is terminated, Contractor will deliver to Supplier, within 10 days of the date of termination, all originals and copies of any and all records, papers, programs, computer software, and documents that bear or contain Confidential Information.

(iii) Contractor will maintain all Qualifications for the duration of this Agreement. Contractor will give Supplier written notice within five days of the loss, suspension, or any other adverse action regarding any Qualification.

(iv) All Services will be provided in accordance with (1) all applicable laws and regulations; (2) Supplier's protocols, policies and procedures (including but not limited to policies regarding safety, infection control, and clinical practice); (3) operational specifications provided by equipment manufacturers and by Supplier; and (4) any standards or procedures imposed by the accreditation organization by which Supplier is accredited. Supplier will provide a copy of Supplier's applicable clinical protocols, policies and procedures to Contractor, and may modify any protocol, policy or procedure by providing 10 days notice to Contractor.

(v) Contractor will cooperate with Supplier in the conduct of quality improvement activities;

(vi) Contractor will cooperate with Supplier in Supplier's efforts to comply with the CBP Contract;

(vii) Contractor will produce any document or information in its possession that Supplier reasonably requires in order to comply with a request from any third party payor, state or federal agency, or accreditation organization; and

(viii) Contractor will maintain all documents and records necessary for it to provide the Services.

3. Compensation.

(a) As full compensation for the Services rendered and Items sold, Supplier will pay Contractor pursuant to Schedule B.

(b) Except as otherwise provided herein, Contractor will be responsible for all expenses incurred by Contractor in rendering the Services.

4. Term and Termination.

(a) This Agreement will be effective of as January 1, 2011 ("Effective Date"), and will continue for a term of three years. This Agreement will automatically renew for successive one-year terms, unless either Party provides the other Party written notice, not less than 30 days before the end of the then current term, of its intention not to renew the Agreement.

(b) In the event a party ("Breaching Party") breaches the terms of this Agreement, the other party ("Non-Breaching Party") will provide to the Breaching Party written notice of the breach. The Breaching Party will cure the breach to the reasonable satisfaction of the Non-Breaching Party by the 15th day following the Breaching Party's receipt of written notice of breach. In the event that the Breaching Party does not cure the breach as specified in the preceding sentence, the Non-Breaching Party may immediately terminate this Agreement by providing written notice of termination to the Breaching Party.

(c) This Agreement may be immediately terminated at any time by mutual written agreement of the parties.

(d) This Agreement may be terminated by either party by providing the other party 30 days prior written notice, if one of the following occurs: (i) Contractor purchases the assets or stock of a Competitive Bid contract suppler and, as a result, is awarded a Competitive Bid contract for the CBA; or (ii) Competitive Bidding in the CBA is delayed or repealed.

(e) In the event of the termination of this Agreement, Contractor will be entitled to accrued but unpaid compensation, as provided in this Agreement, pro-rated through the date of termination. All amounts payable will be paid within 30 days of the date of termination.

5. Insurance and Indemnification.

(a) Throughout the term of this Agreement, Contractor and Supplier will each continually maintain general liability insurance coverage with minimum coverage of $1,000,000.00 per occurrence. Each party will submit proof of such insurance coverage to the other party on request.

(b) Contractor will indemnify and hold harmless Supplier from and against all damages, claims, liabilities and losses (including reasonable attorney's fees) resulting from Contractor's negligence or willful misconduct committed in connection with the performance of Contractor's duties hereunder.

(c) Supplier will indemnify and hold harmless Contractor from and against all damages, claims, liabilities and losses (including reasonable attorney's fees) resulting from Supplier's negligence or willful misconduct committed in connection with the performance of Supplier's duties hereunder.

6. Business Associate Agreement. In providing Services hereunder, Contractor will be acting as a business associate of Supplier, as that term is used in the Security Standards for the Protection of Electronic Protected Health Information and the Standards for Privacy of Individually Identifiable Health Information (collectively the "HIPAA Standards"), 45 CFR parts

160 and 164. The parties agree to execute the Business Associate Addendum to this Agreement in compliance with the HIPAA Standards.

7. Miscellaneous.

(a) Relationship of Parties. The relationship between Contractor and Supplier established by this Agreement is solely that of independent contractors. Neither party will be considered the legal representative or agent of the other, nor authorized or empowered to assume any obligation of any kind, implied or expressed, on behalf of the other party, except with the express prior written consent of the other party.

(b) Assignment; Binding Effect. This Agreement will be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns; provided, however, that this Agreement will not be assignable by either party without the other party's written consent.

(c) No Waiver. Neither the waiver by either party of any breach of or default under any of the provisions of this Agreement, nor the failure of either party to enforce any of the provisions of this Agreement or to exercise any right hereunder, will hereafter be construed as a waiver of any subsequent breach or default, or a waiver of any rights or provision hereunder.

(d) Governing Law. This Agreement will be governed by and construed in accordance with the laws of _____. No provision of this Agreement will be applied to or construed in a manner inconsistent with applicable state and federal laws and regulations.

(e) No Third-Party Beneficiaries. No person or entity other than the parties hereto will be entitled to bring any action to enforce any provision of this Agreement against a party hereto.

(f) Severability. No provision of this Agreement which is in violation of any state or federal law or regulation will be effective; provided, however, if one or more provisions of the Agreement are hereinafter determined to be invalid and unenforceable, this will not operate to the detriment or invalidate the remainder of the Agreement unless the unenforceability or invalidity has the effect of substantially changing the terms and conditions of this Agreement or operates in such a manner as to invalidate or defeat the primary purposes or objectives of this Agreement.

(g) Entire Agreement; Amendment. This Agreement is the entire agreement between the parties as to its subject matter, and all prior written or oral agreements, promises or representations are incorporated herein. This Agreement may be amended only by a writing executed by the parties.

(h) Notices. Any notice required or permitted to be given under this Agreement will in writing and will be hand delivered, sent by certified mail with return receipt requested, or delivered by overnight courier service providing written proof of delivery, addressed as follows:

If to Supplier: _____
_____
_____
Attn: _____

If to Contractor: _____
_____
_____
Attn: _____

or to such other address as either party may designate by notice pursuant to this section.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement on the date set forth in the introductory paragraph, to be effective as of the Effective Date.

SUPPLIER:

_____

By: _____
_____, _____

CONTRACTOR:

_____

By: _____
_____, _____

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SCHEDULE A

1. Services.

1.1. Within ___ hours after notification by Supplier that a patient requires on one or more of the following services ("Services"), Contractor will:

(a) Deliver and set up the _____ required by the patient.

(b) Provide education and training to the patient or patient's caregiver on operation and use of _____.

(c) Provide Supplier's contact information, including 24-hour emergency number, to the patient or patient's caregiver, and instruct the patient and/or caregiver to contact Supplier directly regarding any complaint.

(d) Repair malfunctioning or nonfunctioning _____ to a fully operational state.

(e) Maintain _____ according to the manufacturer's recommended maintenance guidelines.

(f) Transmit to Supplier relevant patient information and documents in the form and manner required by Supplier, including, without limitation, proof of delivery.

1.2. Should Contractor receive any patient complaints regarding use of Supplier's _____, Contractor will immediately forward to Supplier such complaints. Contractor will maintain a log that records (i) the date of the complaint, (ii) the identity and contact information of the complainant, (iii) the nature of the complaint and (iv) date and time the complaint is forwarded to Supplier. Contractor will make the log available to Supplier upon Supplier's request.

1.3. Contractor will document the Services provided on forms provided by Supplier and will forward these forms to Supplier on a monthly basis as provided in Schedule B.

1.4. Contractor will assist Supplier, as reasonably requested, in obtaining the necessary forms and documentation for billing and reimbursement for items and services provided by Supplier.

SCHEDULE B
[FIXED ANNUAL FEE]

1. As full compensation for Services rendered, Supplier will pay Contractor a fixed annual fee of $_____, payable in monthly installments of $_____.

2. On or before the 5th of each month, Contractor will deliver to Supplier the completed forms, as referenced in section 1.3 of Schedule A, detailing the Services rendered in the preceding month. Supplier will pay Contractor by either the later of the 30th day of the month or 25 days after receipt of Contractor's completed forms.

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SCHEDULE B
[HOURLY COMPENSATION]

1. As full compensation for Services rendered, Supplier will pay Contractor $_____ per hour.

2. On or before the 5th of each month, Contractor will deliver to Supplier the completed forms, as referenced in section 1.3 of Schedule A, detailing the Services rendered in the preceding month. Supplier will pay Contractor by either the later of the 30th day of the month or 25 days after receipt of Contractor's completed forms.

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SCHEDULE B
[FEE SCHEDULE]

1. In consideration of the Services rendered, Supplier will pay Contractor a fee per Incident of Service, per patient, in accordance with section 2 below.

a. For the purposes of Schedule B, "Incident of Service" means each time a service, as stated in section 2 below, is rendered for an individual patient. When services are rendered to multiple patients during a single visit to a facility housing multiple patients, each individual service rendered will be treated as a separate Incident of Service for the purpose of calculating fees owed by Supplier to Contractor.

b. Example: If, during a single visit to a facility housing multiple patients, Contractor delivers _____ for three patients, delivers _____ for one patient, repairs _____ for one patient, and performs maintenance on _____ for four patients, Contractor will be entitled to payment for three deliveries of nutrition at the rate specified in 2(a) below, one delivery of _____ at the rate specified in 2(b) below, one repair of _____ at the rate specified in 2(c) below, and four maintenances of _____ at the rate specified in 2(d) below.

2. Fees owed by Supplier to Contractor for Services rendered will be calculated according to the following schedule:

a. Delivery of _____, including any associated initial set up and necessary instruction provided to patient and/or patient's caregiver - $_____

b. Repair of _____, including all parts and labor required to return _____ to fully operational state, and any set up and necessary instruction provided to patient and/or patient's caregiver - $_____

c. Maintenance of _____, including all parts and labor required to comply with the _____ manufacturer's recommended maintenance guidelines - $_____

3. On or before the 5th of each month, Contractor will deliver to Supplier the completed forms, as referenced in section 1.3 of Schedule A, detailing the Services rendered in the preceding month. Supplier will pay Contractor by either the later of the 30th day of the month or 25 days after receipt of Contractor's completed forms.

BUSINESS ASSOCIATE ADDENDUM

In performing its services for Supplier hereunder, Contractor will be acting as a business associate of Supplier, as that term is used in the Security Standards for the Protection of Electronic Protected Health Information and the Standards for Privacy of Individually Identifiable Health Information (collectively the "HIPAA Standards"), 45 CFR parts 160 and 164. The following provisions have been included in this Business Associate Addendum ("Addendum") for purposes of complying with the HIPAA Standards and apply with respect to all Protected Health Information ("PHI"), as defined in 45 CFR § 164.501, created or received by Contractor in performing its duties under this Agreement.

1. Compliance with Privacy Standards.

(a) Contractor will not use or disclose PHI other than as permitted or required by this Agreement or as required by law.

(b) Contractor will use appropriate safeguards to prevent use or disclosure of PHI other than as provided for by this Agreement.

(c) Contractor will mitigate, to the extent practicable, any harmful effect that is known to Contractor of a use or disclosure of PHI by Contractor in violation of the requirements of this Agreement.

(d) Contractor will report to Supplier any use or disclosure of PHI not provided for by this Agreement of which Contractor becomes aware.

(e) Contractor will ensure that any agent to whom Contractor provides PHI received from Supplier, or created or received by Contractor on behalf of Supplier, agrees to the same restrictions and conditions that apply to Contractor through this Agreement with respect to such information.

(f) Contractor will make books and records relating to the use and disclosure of PHI received from, or created or received by Contractor on behalf of, Supplier available to the Secretary of Health and Human Services or the Secretary's designee, in a time and manner designated by the Secretary, for purposes of the Secretary determining Supplier's compliance with the HIPAA Standards.

(g) At Supplier's request, Contractor will make available PHI in Contractor's possession to enable Supplier to respond to a request by an individual for access to PHI in accordance with 45 CFR § 164.524.

(h) At Supplier's request, Contractor will make available PHI in Contractor's possession for amendment, and will incorporate any amendments to PHI, in accordance with 42 CFR § 164.526.

(i) Contractor will document and provide to Supplier such disclosures of PHI and information related to such disclosures as would be required for Supplier to respond to a request by an individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528. Upon receipt of a request for an accounting directly from an individual, Contractor will provide to the individual an accounting of disclosures made by Contractor containing the information described in 45 CFR § 164.528.

(j) Contractor may use or disclose PHI to perform services for or on behalf of Supplier as specified in this Agreement, provided that such use or disclosure would not violate the HIPAA Standards if done by Supplier or the minimum necessary policies and procedures of Supplier.

(k) Contractor may use PHI (i) for the proper management and administration of Contractor; or (ii) to carry out Contractor's legal responsibilities.

(l) Contractor may disclose PHI (i) for the proper management and administration of Contractor; or (ii) to carry out Contractor's legal responsibilities, if (A) the disclosure is required by law; or (B)(1) Contractor obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person; and (2) the person notifies Contractor of any instances of which it is aware in which the confidentiality of the information has been breached.

2. Compliance with Security Standards – General.

(a) Contractor will implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic PHI that it creates, receives, maintains, or transmits on behalf of Supplier as required by the HIPAA Standards. Such safeguards will include at least those measures set forth in sections 3, 4 and 5 below.

(b) Contractor will ensure that any agent, including a subcontractor, to whom it provides PHI agrees to implement reasonable and appropriate safeguards to protect it, including at least those measures set forth in sections 3, 4 and 5 below.

(c) Contractor will report to Supplier any security incident (as defined in the HIPAA Standards) of which it becomes aware.

3. Compliance with Security Standards – Administrative Safeguards.

(a) Security management process. Contractor will implement policies and procedures to prevent, detect, contain, and correct security violations. Contractor will:

(i) Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic PHI held by Contractor.

(ii) Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level.

(iii) Apply appropriate sanctions against workforce members who fail to comply with the security policies and procedures of Contractor.

(iv) Implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports.

(b) Assigned security responsibility. Contractor will designate a security official who will be responsible for the development and implementation of the security policies and procedures required by this Agreement.

(c) Workforce security. Contractor will implement policies and procedures to ensure that all members of its workforce have appropriate access to electronic PHI and to prevent those workforce members who do not have access from obtaining access to electronic PHI.

(d) Information access management. Contractor will implement policies and procedures for authorizing access to electronic PHI that are consistent with the applicable requirements of the HIPAA Standards.

(e) Security awareness and training. Contractor will implement a security awareness and training program for all members of its workforce, including management.

(f) Security incident procedures. Contractor will implement policies and procedures to identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents; and document security incidents and their outcomes.

(g) Contingency plan. Contractor will establish policies and procedures for responding to an emergency or other occurrence that damages systems that contain electronic PHI, including at least:

(i) Procedures to create and maintain retrievable exact copies of electronic PHI.

(ii) Procedures to restore lost data.

(iii) Procedures to enable continuation of critical business processes for protection of the security of electronic PHI while operating in emergency mode.

(h) Evaluation. Contractor will perform a periodic technical and nontechnical evaluation that establishes the extent to which an entity's security policies and procedures meet the requirements of the HIPAA Standards.

4. Compliance with Security Standards – Physical Safeguards.

(a) Facility access controls. Contractor will implement policies and procedures to limit physical access to its electronic information systems and the facility or facilities in which they are housed, while ensuring that properly authorized access is allowed.

(b) Workstation use. Contractor will implement policies and procedures that specify the proper functions to be performed, the manner in which those functions are to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstation that can access electronic PHI.

(c) Workstation security. Contractor will implement physical safeguards for all workstations that access electronic PHI to restrict access to authorized users.

(d) Device and media controls. Contractor will implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain electronic PHI into and out of a facility, and the movement of these items within the facility. Contractor will:

(i) Implement policies and procedures to address the final disposition of electronic PHI and the hardware or electronic media on which it is stored.

(ii) Implement procedures for removal of electronic PHI from electronic media before the media are made available for re-use.

5. Compliance with Security Standards – Technical Safeguards.

(a) Access control. Contractor will implement technical policies and procedures for electronic information systems that maintain electronic PHI to allow access only to those persons or software programs that have been granted access rights. Contractor will:

(i) Assign unique names and/or numbers for identifying and tracking user identity.

(ii) Establish procedures for obtaining necessary electronic PHI during an emergency.

(b) Audit controls. Contractor will implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that contain or use electronic PHI.

(c) Integrity. Contractor will implement policies and procedures to protect electronic PHI from improper alteration or destruction.

(d) Person or entity authentication. Contractor will implement procedures to verify the identity of a person or entity seeking access to electronic PHI.

(e) Transmission security. Contractor will implement technical security measures to guard against unauthorized access to electronic PHI that is being transmitted over an electronic communications network.

6. Compliance with Security Standards – Policies and Procedures; Documentation. Contractor will implement reasonable and appropriate policies and procedures to comply with the HIPAA Standards. Contractor will maintain such policies and procedures in written or electronic form, and will maintain a written or electronic record of actions, activities and assessments required by the HIPAA Standards. Contractor will (i) retain such documentation for 6 years from the date of its creation or the date when it last was in effect, whichever is later; (ii) make documentation available to those persons responsible for implementing the procedures to which the documentation pertains; and (iii) review documentation periodically, and update as needed, in response to environmental or operational changes affecting the security of the electronic PHI.

7. Breach.

(a) Contractor will notify Supplier of any unauthorized acquisition, access, use, or disclosure (collectively "Breach") of PHI as soon as practicable, but not later than 5 days after Contractor becomes aware of such Breach. Such notice will include the identification of each individual whose PHI has been, or is reasonably believed by Contractor to have been, accessed, acquired, or disclosed during such Breach.

(b) Upon Supplier's knowledge of a material breach of this Addendum by Contractor, Supplier may either (i) provide an opportunity for Contractor to cure the breach or end the violation, and terminate this Agreement if Contractor does not cure the breach or end the violation within the time specified by Supplier; (ii) immediately terminate this Agreement if Contractor has breached a material term of this Addendum

and cure is not possible; or (iii) if neither termination nor cure is feasible, report the violation to the Secretary.

8. Return or Destruction of PHI upon Termination. Upon termination of this Agreement for any reason, Contractor will return or destroy all PHI received from Supplier, or created or received by Contractor on behalf of Supplier. This provision will apply to PHI that is in the possession of contractors or agents of Contractor. Contractor will retain no copies of PHI except as required by law. In the event that Contractor determines that returning or destroying the PHI is infeasible, Contractor will notify Supplier of the conditions that make return or destruction infeasible, and will extend the protections of this Addendum to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Contractor maintains such PHI.

SUPPLIER:

_____

By: _____

_____, _____

CONTRACTOR:

_____

By: _____

_____, _____

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EXHIBIT “A”

Template Novation Agreement

TEMPLATE NOVATION AGREEMENT

This NOVATION AGREEMENT ("Agreement") is made and entered into on _____ [date], to be effective as of the effective date of the Acquisition (as defined in paragraph B), between the following parties:

1. _____ [i.e., the non-contract supplier] ("Buyer"), Medicare Supplier No. _____; and

2. The Centers for Medicare and Medicaid Services ("CMS").

Background

A. _____ ("Seller") has one or more valid and existing contracts ("CBP Contracts") with CMS to furnish certain items and services under the Medicare DMEPOS Competitive Bidding Program. Terms used in this Agreement will have the meanings ascribed in the CBP Contracts unless otherwise provided. Information regarding Seller is attached hereto as Exhibit A. Copies of the CBP Contracts are attached and incorporated by reference.

B. Seller and Buyer anticipate entering into an agreement, subject to approval by CMS, whereby Buyer will acquire all Seller's assets necessary to perform the terms of the CBP Contracts ("Acquisition") efficiently. The Acquisition is anticipated to close by _____ [date].

C. Pursuant to the Acquisition, Buyer desires to perform all the obligations of and to be bound by the terms of the CBP Contracts.

D. This Agreement is in accordance with the requirements of 42 CFR § 414.422(d)(2) and the CBP Contracts.

E. Buyer and CMS certify and warrant that each has full power and authority to enter into this Agreement.

Terms

In consideration of the above and of the mutual covenants contained herein, the parties agree as follows:

1. Buyer will perform all the obligations of Seller that are enumerated under the CBP Contracts, and Buyer will ensure that Medicare beneficiaries receiving services under the CPB Contracts will receive uninterrupted service during the Acquisition. Buyer agrees to be bound by all the terms of the CBP Contracts in every way as if an original party thereto.

2. CMS accepts the liability of Buyer in lieu of the liability of Seller, and CMS agrees to discharge Seller from the performance of the obligations enumerated in the CBP Contracts. CMS will be bound by the terms of the CBP Contracts in every way as if Buyer was named in the CBP Contracts in place of Seller as a party thereto.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement on the date set forth in the introductory paragraph, to be effective as of the date the Acquisition becomes effective.

BUYER

By: _____
_____, _____

CENTERS FOR MEDICARE AND MEDICAID SERVICES

By: _____
_____, _____

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EXHIBIT A

SELLER'S INFORMATION

Seller's Name:

CBP Contracts awarded (Competitive Bid Area ("CBA") and Product Category ("PC")):

Seller's current location(s):

Name:
PTAN:
Address:
Phone number:
Will the location continue to serve the CBA/PC?
Is the location in compliance with all competitive bidding requirements?
Location is accredited by _____.
Location has requisite licenses from _____.

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EXHIBIT “B”

Template Subcontract Agreement

TEMPLATE SUBCONTRACT AGREEMENT

THIS SUBCONTRACT AGREEMENT ("Agreement") is made and entered into on _____ [date], by and between _____, a _____ _____ ("Supplier"), and _____, a _____ _____ ("Contractor").

BACKGROUND

A. Supplier was awarded a Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies ("DMEPOS") Competitive Bidding Program Contract ("CBP Contract") to provide _____ to Medicare beneficiaries ("patients") residing in the _____ competitive bidding area ("CBA"). Terms used in this Agreement will have the meanings ascribed in the CBP Contract unless otherwise provided.

B. Contractor has experience and expertise in providing DMEPOS, specifically _____.

C. Supplier desires to subcontract with Contractor to provide certain services in support of Supplier's performance of the CBP Contract, and Contractor desires to accept such subcontract arrangement. The purpose of the subcontract arrangement is to ensure that Supplier is capable of providing DMEPOS and related services to all patients in the CBA.

TERMS

In consideration of the mutual covenants contained herein, and other good and valuable consideration, Supplier and Contractor agree as follows:

1. Contractor's Services. Contractor will provide the services described in Schedule A ("Services") on behalf of and as directed by Supplier to Supplier's patients who reside in the CBA.

2. Contractor's Representations, Warranties, and Covenants.

(a) Contractor represents and warrants that:

(i) Contractor, and all persons it employs or engages to perform Services, has all qualifications, accreditations, certifications, and licenses required by federal, state, or local law or third party payor policy or rule (collectively, "Qualification") to fully perform the Services.

(ii) Neither Contractor nor any of its officers, directors, employees or contractors has ever been (1) convicted of a criminal offense related to health care or related to the provision of services paid for by a federal or state health care

program (for example, Medicare and Medicaid); (2) assessed civil money penalties for an offense related to health care or related to the provision of services paid for by a federal or state health care program; (3) excluded from participation in any federal or state health care program; or (4) excluded by any federal agency from receiving federal contracts.

(b) Contractor covenants that:

(i) Contractor will not employ or contract with any individual or entity that is excluded from participation in any federal or state health care program or excluded by any federal agency from receiving federal contracts. If Contractor, or any of its officers, directors, employees, or contractors, becomes the subject of any of the actions described in this paragraph, Contractor will give written notice thereof to Supplier within five days after the date of such action or knowledge of such action.

(ii) Contractor acknowledges that, in the course of performing its duties hereunder, Supplier will disclose to Contractor Confidential Information (as defined below) having a special and unique nature and value relating to Supplier. As a material inducement to Supplier to enter into this Agreement, Contractor agrees that, unless Supplier provides prior written consent, Contractor will not, at any time during or following the term of this Agreement, directly or indirectly, disclose, publish, or divulge, except in connection with the provision of the Services, any Confidential Information which has been obtained by or disclosed to Contractor through or in the course of its relationship with Supplier. As an exception to the foregoing, Contractor may disclose Confidential Information as required to comply with the binding order of a governmental entity that has jurisdiction over it, provided that Contractor (a) gives Supplier reasonable written notice to allow Supplier to seek a protective order or other appropriate remedy, (b) discloses only such information as is required by the governmental entity, and (c) uses commercially reasonable efforts to obtain confidential treatment for any Confidential Information so disclosed.

(1) For purposes of this Agreement, "Confidential Information" will include, without limitation, any agreement to which Supplier is a party (including this Agreement), policies, methods, protocols, manuals, confidential reports, and other matters relating to the operation of the business of Supplier.

(2) If this Agreement is terminated, Contractor will deliver to Supplier, within 10 days of the date of termination, all originals and copies of any and all records, papers, programs, computer software, and documents that bear or contain Confidential Information.

(iii) Contractor will maintain all Qualifications for the duration of this Agreement. Contractor will give Supplier written notice within five days of the loss, suspension, or any other adverse action regarding any Qualification.

(iv) All Services will be provided in accordance with (1) all applicable laws and regulations; (2) Supplier's protocols, policies and procedures (including but not limited to policies regarding safety, infection control, and clinical practice); (3) operational specifications provided by equipment manufacturers and by Supplier; and (4) any standards or procedures imposed by the accreditation organization by which Supplier is accredited. Supplier will provide a copy of Supplier's applicable clinical protocols, policies and procedures to Contractor, and may modify any protocol, policy or procedure by providing 10 days notice to Contractor.

(v) Contractor will cooperate with Supplier in the conduct of quality improvement activities;

(vi) Contractor will cooperate with Supplier in Supplier's efforts to comply with the CBP Contract;

(vii) Contractor will produce any document or information in its possession that Supplier reasonably requires in order to comply with a request from any third party payor, state or federal agency, or accreditation organization; and

(viii) Contractor will maintain all documents and records necessary for it to provide the Services.

3. Compensation.

(a) As full compensation for the Services rendered and Items sold, Supplier will pay Contractor pursuant to Schedule B.

(b) Except as otherwise provided herein, Contractor will be responsible for all expenses incurred by Contractor in rendering the Services.

4. Term and Termination.

(a) This Agreement will be effective of as January 1, 2011 ("Effective Date"), and will continue for a term of three years. This Agreement will automatically renew for successive one-year terms, unless either Party provides the other Party written notice, not less than 30 days before the end of the then current term, of its intention not to renew the Agreement.

(b) In the event a party ("Breaching Party") breaches the terms of this Agreement, the other party ("Non-Breaching Party") will provide to the Breaching Party written notice of the breach. The Breaching Party will cure the breach to the reasonable satisfaction of the Non-Breaching Party by the 15th day following the Breaching Party's receipt of written notice of breach. In the event that the Breaching Party does not cure the breach as specified in the preceding sentence, the Non-Breaching Party may immediately terminate this Agreement by providing written notice of termination to the Breaching Party.

(c) This Agreement may be immediately terminated at any time by mutual written agreement of the parties.

(d) This Agreement may be terminated by either party by providing the other party 30 days prior written notice, if one of the following occurs: (i) Contractor purchases the assets or stock of a Competitive Bid contract suppler and, as a result, is awarded a Competitive Bid contract for the CBA; or (ii) Competitive Bidding in the CBA is delayed or repealed.

(e) In the event of the termination of this Agreement, Contractor will be entitled to accrued but unpaid compensation, as provided in this Agreement, pro-rated through the date of termination. All amounts payable will be paid within 30 days of the date of termination.

5. Insurance and Indemnification.

(a) Throughout the term of this Agreement, Contractor and Supplier will each continually maintain general liability insurance coverage with minimum coverage of $1,000,000.00 per occurrence. Each party will submit proof of such insurance coverage to the other party on request.

(b) Contractor will indemnify and hold harmless Supplier from and against all damages, claims, liabilities and losses (including reasonable attorney's fees) resulting from Contractor's negligence or willful misconduct committed in connection with the performance of Contractor's duties hereunder.

(c) Supplier will indemnify and hold harmless Contractor from and against all damages, claims, liabilities and losses (including reasonable attorney's fees) resulting from Supplier's negligence or willful misconduct committed in connection with the performance of Supplier's duties hereunder.

6. Business Associate Agreement. In providing Services hereunder, Contractor will be acting as a business associate of Supplier, as that term is used in the Security Standards for the Protection of Electronic Protected Health Information and the Standards for Privacy of Individually Identifiable Health Information (collectively the "HIPAA Standards"), 45 CFR parts

160 and 164. The parties agree to execute the Business Associate Addendum to this Agreement in compliance with the HIPAA Standards.

7. Miscellaneous.

(a) Relationship of Parties. The relationship between Contractor and Supplier established by this Agreement is solely that of independent contractors. Neither party will be considered the legal representative or agent of the other, nor authorized or empowered to assume any obligation of any kind, implied or expressed, on behalf of the other party, except with the express prior written consent of the other party.

(b) Assignment; Binding Effect. This Agreement will be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns; provided, however, that this Agreement will not be assignable by either party without the other party's written consent.

(c) No Waiver. Neither the waiver by either party of any breach of or default under any of the provisions of this Agreement, nor the failure of either party to enforce any of the provisions of this Agreement or to exercise any right hereunder, will hereafter be construed as a waiver of any subsequent breach or default, or a waiver of any rights or provision hereunder.

(d) Governing Law. This Agreement will be governed by and construed in accordance with the laws of _____. No provision of this Agreement will be applied to or construed in a manner inconsistent with applicable state and federal laws and regulations.

(e) No Third-Party Beneficiaries. No person or entity other than the parties hereto will be entitled to bring any action to enforce any provision of this Agreement against a party hereto.

(f) Severability. No provision of this Agreement which is in violation of any state or federal law or regulation will be effective; provided, however, if one or more provisions of the Agreement are hereinafter determined to be invalid and unenforceable, this will not operate to the detriment or invalidate the remainder of the Agreement unless the unenforceability or invalidity has the effect of substantially changing the terms and conditions of this Agreement or operates in such a manner as to invalidate or defeat the primary purposes or objectives of this Agreement.

(g) Entire Agreement; Amendment. This Agreement is the entire agreement between the parties as to its subject matter, and all prior written or oral agreements, promises or representations are incorporated herein. This Agreement may be amended only by a writing executed by the parties.

(h) Notices. Any notice required or permitted to be given under this Agreement will in writing and will be hand delivered, sent by certified mail with return receipt requested, or delivered by overnight courier service providing written proof of delivery, addressed as follows:

If to Supplier: _____
_____
_____
Attn: _____

If to Contractor: _____
_____
_____
Attn: _____

or to such other address as either party may designate by notice pursuant to this section.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement on the date set forth in the introductory paragraph, to be effective as of the Effective Date.

SUPPLIER:

_____

By: _____
_____, _____

CONTRACTOR:

_____

By: _____
_____, _____

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SCHEDULE A

1. Services.

1.1. Within ___ hours after notification by Supplier that a patient requires on one or more of the following services ("Services"), Contractor will:

(a) Deliver and set up the _____ required by the patient.

(b) Provide education and training to the patient or patient's caregiver on operation and use of _____.

(c) Provide Supplier's contact information, including 24-hour emergency number, to the patient or patient's caregiver, and instruct the patient and/or caregiver to contact Supplier directly regarding any complaint.

(d) Repair malfunctioning or nonfunctioning _____ to a fully operational state.

(e) Maintain _____ according to the manufacturer's recommended maintenance guidelines.

(f) Transmit to Supplier relevant patient information and documents in the form and manner required by Supplier, including, without limitation, proof of delivery.

1.2. Should Contractor receive any patient complaints regarding use of Supplier's _____, Contractor will immediately forward to Supplier such complaints. Contractor will maintain a log that records (i) the date of the complaint, (ii) the identity and contact information of the complainant, (iii) the nature of the complaint and (iv) date and time the complaint is forwarded to Supplier. Contractor will make the log available to Supplier upon Supplier's request.

1.3. Contractor will document the Services provided on forms provided by Supplier and will forward these forms to Supplier on a monthly basis as provided in Schedule B.

1.4. Contractor will assist Supplier, as reasonably requested, in obtaining the necessary forms and documentation for billing and reimbursement for items and services provided by Supplier.

SCHEDULE B
[FIXED ANNUAL FEE]

1. As full compensation for Services rendered, Supplier will pay Contractor a fixed annual fee of $_____, payable in monthly installments of $_____.

2. On or before the 5th of each month, Contractor will deliver to Supplier the completed forms, as referenced in section 1.3 of Schedule A, detailing the Services rendered in the preceding month. Supplier will pay Contractor by either the later of the 30th day of the month or 25 days after receipt of Contractor's completed forms.

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SCHEDULE B
[HOURLY COMPENSATION]

1. As full compensation for Services rendered, Supplier will pay Contractor $_____ per hour.

2. On or before the 5th of each month, Contractor will deliver to Supplier the completed forms, as referenced in section 1.3 of Schedule A, detailing the Services rendered in the preceding month. Supplier will pay Contractor by either the later of the 30th day of the month or 25 days after receipt of Contractor's completed forms.

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SCHEDULE B
[FEE SCHEDULE]

1. In consideration of the Services rendered, Supplier will pay Contractor a fee per Incident of Service, per patient, in accordance with section 2 below.

a. For the purposes of Schedule B, "Incident of Service" means each time a service, as stated in section 2 below, is rendered for an individual patient. When services are rendered to multiple patients during a single visit to a facility housing multiple patients, each individual service rendered will be treated as a separate Incident of Service for the purpose of calculating fees owed by Supplier to Contractor.

b. Example: If, during a single visit to a facility housing multiple patients, Contractor delivers _____ for three patients, delivers _____ for one patient, repairs _____ for one patient, and performs maintenance on _____ for four patients, Contractor will be entitled to payment for three deliveries of nutrition at the rate specified in 2(a) below, one delivery of _____ at the rate specified in 2(b) below, one repair of _____ at the rate specified in 2(c) below, and four maintenances of _____ at the rate specified in 2(d) below.

2. Fees owed by Supplier to Contractor for Services rendered will be calculated according to the following schedule:

a. Delivery of _____, including any associated initial set up and necessary instruction provided to patient and/or patient's caregiver - $_____

b. Repair of _____, including all parts and labor required to return _____ to fully operational state, and any set up and necessary instruction provided to patient and/or patient's caregiver - $_____

c. Maintenance of _____, including all parts and labor required to comply with the _____ manufacturer's recommended maintenance guidelines - $_____

3. On or before the 5th of each month, Contractor will deliver to Supplier the completed forms, as referenced in section 1.3 of Schedule A, detailing the Services rendered in the preceding month. Supplier will pay Contractor by either the later of the 30th day of the month or 25 days after receipt of Contractor's completed forms.

BUSINESS ASSOCIATE ADDENDUM

In performing its services for Supplier hereunder, Contractor will be acting as a business associate of Supplier, as that term is used in the Security Standards for the Protection of Electronic Protected Health Information and the Standards for Privacy of Individually Identifiable Health Information (collectively the "HIPAA Standards"), 45 CFR parts 160 and 164. The following provisions have been included in this Business Associate Addendum ("Addendum") for purposes of complying with the HIPAA Standards and apply with respect to all Protected Health Information ("PHI"), as defined in 45 CFR § 164.501, created or received by Contractor in performing its duties under this Agreement.

1. Compliance with Privacy Standards.

(a) Contractor will not use or disclose PHI other than as permitted or required by this Agreement or as required by law.

(b) Contractor will use appropriate safeguards to prevent use or disclosure of PHI other than as provided for by this Agreement.

(c) Contractor will mitigate, to the extent practicable, any harmful effect that is known to Contractor of a use or disclosure of PHI by Contractor in violation of the requirements of this Agreement.

(d) Contractor will report to Supplier any use or disclosure of PHI not provided for by this Agreement of which Contractor becomes aware.

(e) Contractor will ensure that any agent to whom Contractor provides PHI received from Supplier, or created or received by Contractor on behalf of Supplier, agrees to the same restrictions and conditions that apply to Contractor through this Agreement with respect to such information.

(f) Contractor will make books and records relating to the use and disclosure of PHI received from, or created or received by Contractor on behalf of, Supplier available to the Secretary of Health and Human Services or the Secretary's designee, in a time and manner designated by the Secretary, for purposes of the Secretary determining Supplier's compliance with the HIPAA Standards.

(g) At Supplier's request, Contractor will make available PHI in Contractor's possession to enable Supplier to respond to a request by an individual for access to PHI in accordance with 45 CFR § 164.524.

(h) At Supplier's request, Contractor will make available PHI in Contractor's possession for amendment, and will incorporate any amendments to PHI, in accordance with 42 CFR § 164.526.

(i) Contractor will document and provide to Supplier such disclosures of PHI and information related to such disclosures as would be required for Supplier to respond to a request by an individual for an accounting of disclosures of PHI in accordance with 45 CFR § 164.528. Upon receipt of a request for an accounting directly from an individual, Contractor will provide to the individual an accounting of disclosures made by Contractor containing the information described in 45 CFR § 164.528.

(j) Contractor may use or disclose PHI to perform services for or on behalf of Supplier as specified in this Agreement, provided that such use or disclosure would not violate the HIPAA Standards if done by Supplier or the minimum necessary policies and procedures of Supplier.

(k) Contractor may use PHI (i) for the proper management and administration of Contractor; or (ii) to carry out Contractor's legal responsibilities.

(l) Contractor may disclose PHI (i) for the proper management and administration of Contractor; or (ii) to carry out Contractor's legal responsibilities, if (A) the disclosure is required by law; or (B)(1) Contractor obtains reasonable assurances from the person to whom the information is disclosed that it will be held confidentially and used or further disclosed only as required by law or for the purpose for which it was disclosed to the person; and (2) the person notifies Contractor of any instances of which it is aware in which the confidentiality of the information has been breached.

2. Compliance with Security Standards – General.

(a) Contractor will implement administrative, physical, and technical safeguards that reasonably and appropriately protect the confidentiality, integrity, and availability of the electronic PHI that it creates, receives, maintains, or transmits on behalf of Supplier as required by the HIPAA Standards. Such safeguards will include at least those measures set forth in sections 3, 4 and 5 below.

(b) Contractor will ensure that any agent, including a subcontractor, to whom it provides PHI agrees to implement reasonable and appropriate safeguards to protect it, including at least those measures set forth in sections 3, 4 and 5 below.

(c) Contractor will report to Supplier any security incident (as defined in the HIPAA Standards) of which it becomes aware.

3. Compliance with Security Standards – Administrative Safeguards.

(a) Security management process. Contractor will implement policies and procedures to prevent, detect, contain, and correct security violations. Contractor will:

(i) Conduct an accurate and thorough assessment of the potential risks and vulnerabilities to the confidentiality, integrity, and availability of electronic

PHI held by Contractor.

(ii) Implement security measures sufficient to reduce risks and vulnerabilities to a reasonable and appropriate level.

(iii) Apply appropriate sanctions against workforce members who fail to comply with the security policies and procedures of Contractor.

(iv) Implement procedures to regularly review records of information system activity, such as audit logs, access reports, and security incident tracking reports.

(b) Assigned security responsibility. Contractor will designate a security official who will be responsible for the development and implementation of the security policies and procedures required by this Agreement.

(c) Workforce security. Contractor will implement policies and procedures to ensure that all members of its workforce have appropriate access to electronic PHI and to prevent those workforce members who do not have access from obtaining access to electronic PHI.

(d) Information access management. Contractor will implement policies and procedures for authorizing access to electronic PHI that are consistent with the applicable requirements of the HIPAA Standards.

(e) Security awareness and training. Contractor will implement a security awareness and training program for all members of its workforce, including management.

(f) Security incident procedures. Contractor will implement policies and procedures to identify and respond to suspected or known security incidents; mitigate, to the extent practicable, harmful effects of security incidents; and document security incidents and their outcomes.

(g) Contingency plan. Contractor will establish policies and procedures for responding to an emergency or other occurrence that damages systems that contain electronic PHI, including at least:

(i) Procedures to create and maintain retrievable exact copies of electronic PHI.

(ii) Procedures to restore lost data.

(iii) Procedures to enable continuation of critical business processes for protection of the security of electronic PHI while operating in emergency mode.

(h) Evaluation. Contractor will perform a periodic technical and nontechnical evaluation that establishes the extent to which an entity's security policies and procedures meet the requirements of the HIPAA Standards.

4. Compliance with Security Standards – Physical Safeguards.

(a) Facility access controls. Contractor will implement policies and procedures to limit physical access to its electronic information systems and the facility or facilities in which they are housed, while ensuring that properly authorized access is allowed.

(b) Workstation use. Contractor will implement policies and procedures that specify the proper functions to be performed, the manner in which those functions are to be performed, and the physical attributes of the surroundings of a specific workstation or class of workstation that can access electronic PHI.

(c) Workstation security. Contractor will implement physical safeguards for all workstations that access electronic PHI to restrict access to authorized users.

(d) Device and media controls. Contractor will implement policies and procedures that govern the receipt and removal of hardware and electronic media that contain electronic PHI into and out of a facility, and the movement of these items within the facility. Contractor will:

(i) Implement policies and procedures to address the final disposition of electronic PHI and the hardware or electronic media on which it is stored.

(ii) Implement procedures for removal of electronic PHI from electronic media before the media are made available for re-use.

5. Compliance with Security Standards – Technical Safeguards.

(a) Access control. Contractor will implement technical policies and procedures for electronic information systems that maintain electronic PHI to allow access only to those persons or software programs that have been granted access rights. Contractor will:

(i) Assign unique names and/or numbers for identifying and tracking user identity.

(ii) Establish procedures for obtaining necessary electronic PHI during an emergency.

(b) Audit controls. Contractor will implement hardware, software, and/or procedural mechanisms that record and examine activity in information systems that

contain or use electronic PHI.

(c) Integrity. Contractor will implement policies and procedures to protect electronic PHI from improper alteration or destruction.

(d) Person or entity authentication. Contractor will implement procedures to verify the identity of a person or entity seeking access to electronic PHI.

(e) Transmission security. Contractor will implement technical security measures to guard against unauthorized access to electronic PHI that is being transmitted over an electronic communications network.

6. Compliance with Security Standards – Policies and Procedures; Documentation. Contractor will implement reasonable and appropriate policies and procedures to comply with the HIPAA Standards. Contractor will maintain such policies and procedures in written or electronic form, and will maintain a written or electronic record of actions, activities and assessments required by the HIPAA Standards. Contractor will (i) retain such documentation for 6 years from the date of its creation or the date when it last was in effect, whichever is later; (ii) make documentation available to those persons responsible for implementing the procedures to which the documentation pertains; and (iii) review documentation periodically, and update as needed, in response to environmental or operational changes affecting the security of the electronic PHI.

7. Breach.

(a) Contractor will notify Supplier of any unauthorized acquisition, access, use, or disclosure (collectively "Breach") of PHI as soon as practicable, but not later than 5 days after Contractor becomes aware of such Breach. Such notice will include the identification of each individual whose PHI has been, or is reasonably believed by Contractor to have been, accessed, acquired, or disclosed during such Breach.

(b) Upon Supplier's knowledge of a material breach of this Addendum by Contractor, Supplier may either (i) provide an opportunity for Contractor to cure the breach or end the violation, and terminate this Agreement if Contractor does not cure the breach or end the violation within the time specified by Supplier; (ii) immediately terminate this Agreement if Contractor has breached a material term of this Addendum and cure is not possible; or (iii) if neither termination nor cure is feasible, report the violation to the Secretary.

8. Return or Destruction of PHI upon Termination. Upon termination of this Agreement for any reason, Contractor will return or destroy all PHI received from Supplier, or created or received by Contractor on behalf of Supplier. This provision will apply to PHI that is in the possession of contractors or agents of Contractor. Contractor will retain no copies of PHI except as required by law. In the event that Contractor determines that returning or destroying the PHI is infeasible, Contractor will notify Supplier of the conditions that make return or

destruction infeasible, and will extend the protections of this Addendum to such PHI and limit further uses and disclosures of such PHI to those purposes that make the return or destruction infeasible, for so long as Contractor maintains such PHI.

SUPPLIER:

_____

By: _____

_____, _____

CONTRACTOR:

_____

By: _____

_____, _____

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