An Industry in Transition: Hot Button Issues Facing DMEPOS Suppliers

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Introduction

The DME industry, in its present form, has been around for about 35 years. The industry grew up unregulated. 35 years ago, hardly anybody on Capitol Hill, and hardly anybody with HCFA (now CMS) knew what DME suppliers did. So little money was paid to the DME industry (e.g., as compared to money paid to hospitals and physicians), that the DME industry did not appear on the government's radar screen.

While the vast majority of DME suppliers were honest and caring, there was a minority of suppliers that committed fraud.....they were intent on "gaming the system." This is not unique to DME suppliers. Physicians, politicians, attorneys and televangelists do the same thing. Unfortunately, the honest suppliers do not garner the press; an honest supplier does not make for an interesting story. The small group of dishonest players received the press. And the stories were salacious.

The public started seeing stories of fraudsters in Houston and south Florida. The DME industry, in turn, became "low hanging fruit" for CMS, Capitol Hill, the Department of Justice, and the OIG. Railing against the small number of dishonest DME suppliers made for interesting sound bites. The DME industry caught the attention of government regulators.

As the government is want to do, it overreacted. The pendulum swung way too far to the right. Within a relatively short period of time, the DME industry was caught in a "perfect storm" of (i) competitive bidding; (ii) post-payment audits; (iii) prepayment reviews; (iv) stringent documentation requirements; and (v) lower reimbursement.

Back in the "Leave it to Beaver" days, it was relatively easy for a DME supplier to make money. The supplier would sell a product to the Medicare patient and Medicare would pay the supplier more than the supplier's cost. Those days are gone. "Leave it to Beaver" has been replaced by "Modern Family." The old Medicare fee-for-service model is antiquated. A DME supplier can no longer survive by billing Medicare under the low reimbursement rates, particularly when the supplier knows that a portion of the money may be taken back pursuant to a post-payment audit.

In order to survive, the DME supplier must think outside the box. While this is sobering, there is good news. There were 23 million of the Greatest Generation and there were 20 million of the Korean War generation. Compare those two figures to the 78 million Baby Boomers (those born between 1946 and 1964). Boomers are now retiring at the rate of 10,000 per day. Boomers will live to be 85 years old and until they die, they expect to be running triathlons and going to Rolling Stones concerts. Boomers do not expect to be living in long term care facilities. Unfortunately for Boomers, they are also human and their bodies will start breaking down when they reach 70. Boomers will need what the DME industry has to offer. This is a long way of
saying that the demand for DME will only increase exponentially. Coupled with this is the fact that Boomers expect to pay for a portion of their health care out-of-pocket. In addition, for a Boomer, his/her most precious asset is time. Many Boomers will not want to waste their time having to fulfill Medicare reimbursement requirements. The Boomer will pull out his/her American Express and simply pay for the item.

So what does all of this mean for the DME supplier in 2015? It means that there will be a great demand for what the supplier has to offer. However, the supplier will have to be creative in meeting that demand and getting paid. In short, the market outlook for 2015 is good for the DME industry.....and the market outlook will only get better in the years ahead as the Boomers age. The DME supplier will need to be innovative as it meets the growing demand for DME. These materials will discuss the “hot button” issues facing DME suppliers.

**Legal Guidelines for Marketing**

The lifeblood of any successful business is innovative marketing and building referral networks. However, unlike non-healthcare industries, the federal government has set out a number of restrictive guidelines that DME companies must follow.

Under the Medicare anti-kickback statute (42 U.S.C. § 1320a-7b), it is a felony for a provider 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.

The beneficiary inducement statute (42 U.S.C. § 1320a-7a (a)), imposes civil monetary penalties upon a provider that offers or gives remuneration to any Medicare beneficiary 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. This 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.

Under the telephone solicitation statute (42 U.S.C. § 1395m(a)(17)), a DME supplier 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.

The Stark physician self-referral statute (42 U.S.C. § 1395nn)) provides 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.

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.

A 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 response, the OIG will issue an advisory opinion concerning whether or not there is likelihood that the arrangement will implicate the anti-kickback statute.

The OIG publishes Special Fraud Alerts and Special Advisory Bulletins that discuss business arrangements that the OIG believes may be abusive, and educate providers concerning fraudulent and/or abusive practices.

All states have enacted statutes prohibiting kickbacks, fee splitting, patient brokering, or self-referrals. Some state statutes apply only when the payer is a state health care program, while other statutes apply regardless of the identity of the payer.

Building a Referral Network

Providing Gifts and “Other Things of Value” to Physicians

The DME supplier can provide gifts, entertainment, trips, meals, and similar items to a physician so long as the combined values of all of these items do not exceed $392 in a 12 month period. The DME supplier can pay the physician for legitimate services so long as the arrangement complies with the Personal Services and Management Contracts safe harbor and the Personal Services exception to Stark.

Joint Venture With Hospital

Assume that ABC Medical Equipment, Inc. is a local DME supplier. Assume that St. Mary’s Hospital is a local hospital that wants to get into the DME business. The two entities decide to form a joint venture. Such a joint venture can be structured in different ways. Here are some concrete steps that can be taken to set up one type of joint venture.

- ABC will initially set up and own 100% of St. Mary’s Medical Equipment, Inc. (“SMME”).
- SMME will obtain a surety bond, accreditation, state licensure, and a PTAN.
• When a PTAN is issued to SMME, then SMME will sell stock to St. Mary’s that will result in St. Mary’s owning an equity interest in SMME. The purchase price for the stock will be fair market value.

• SMME will need to have operational responsibilities and financial risk. For example, SMME will (i) own delivery vehicles, (ii) employ delivery drivers, (iii) purchase and maintain inventory, and (iv) employ patient/documentation intake personnel. ABC can provide some services to SMME such as billing services and after-hour emergency repair services; SMME will need to pay fair market value compensation to ABC for the services.

• Assume that St. Mary’s owns 25% of SMME. Profit distribution to St. Mary’s will be based on 25% of net profits. St. Mary’s will have no obligation to refer patients to SMME. In the event that St. Mary’s does refer patients to SMME, then St. Mary’s will need to insure patient freedom of choice.

Consignment Arrangement with Hospital Emergency Room

In a typical consignment arrangement with a hospital ER, (i) the DME supplier will place orthotic products (e.g., braces) in a “closet” in the hospital ER; (ii) the physician will order a product, such as a brace, for the patient to wear home ... and utilize in the home; (iii) at the time of discharge, the hospital staff will pull the brace out of the consignment “closet” and place it on the patient; (iv) the patient will wear the brace home; and (v) the DME supplier will collect the required documents and bill for the brace.

42 CFR § 411.15(m)(1), the outpatient bundling regulation, provides that “any service furnished to an inpatient of a hospital or to a hospital outpatient . . . during an encounter . . . by an entity other than the hospital” is excluded from Medicare coverage, subject to certain exceptions. However, in an amendment to this regulation, CMS stated in the preamble to the Notice of Proposed Rulemaking the following:

Sometimes a hospital may furnish an item or services for which a patient will have a continuing need. For example, a hospital may furnish a DME item such as a wheelchair...DME is defined under section 1861(n) of the Act as equipment used in the patient’s home or in another institution used as his home other than a hospital or skilled nursing facility (SNF). By definition, DME is not something that is provided for use in the hospital setting. Therefore, we do not believe that the DME benefit provides for any item or service that is expected to be used by the patient while in the hospital as an inpatient or outpatient...The covered Part B benefit for DME as described under section 1861(n) of the Act is intended for equipment used in the home, so a hospital that furnishes DME to its patients is not providing a hospital service to its patients, but is acting in the capacity of a supplier of DME, not a provider of hospital services. For these reasons, we will not require bundling of DME for hospital patients.
Depending on the specific product dispensed, a credible argument may be made that (i) the outpatient facility patient will have a continuing need for the orthotic product once the patient returns home and (ii) it is permissible for the DME supplier to bill for an orthotic product dispensed to an outpatient facility patient. This argument is further supported by Chapter 20, Section 110.3 of the Medicare Claims Processing Manual, which allows a DME supplier to deliver DME, prosthetics, and orthotics (but not supplies) to an inpatient up to two days before discharge if certain conditions are met.

Assisting Hospitals in Preventing Readmissions

Hospitals, like all other providers, are being squeezed by reimbursement cuts. Hospitals need to protect their revenue stream and cut costs. One way to accomplish this is to prevent readmissions for diseases covered by the Hospital Readmissions Reduction Program (“HRRP”). If a patient is readmitted after discharge within a certain period of time, for a particular disease, then the hospital can be subjected to future payment reductions from Medicare. And so hospitals are beginning to contract with other providers to monitor/work with discharged patients so that they are not readmitted soon after being discharged.

In 2013, the OIG published an advisory opinion (“AO No. 13-10”) that addresses the assistance that other providers can provide to a hospital in order to prevent readmissions. Inasmuch as an increasing number of DME suppliers are entering into arrangements with hospitals to prevent readmissions, the AO provides valuable guidance.

In concluding that it would not impose sanctions, the OIG stated: (i) the arrangement was unlikely to lead to increased costs or overutilization of Federal reimbursement services; (ii) the services could save money for the Federal government by decreasing readmissions; (iii) the services were not separately reimbursable by the Federal government; (iv) the arrangement was unlikely to interfere with clinical decision-making; (v) the Applicant would implement safeguards to prevent the arrangement from being used to increase drug sales by the manufacturer; (vi) the arrangement was unlikely to result in inappropriate patient steering; and (vii) the hospital was compensating the Applicant for the services.

Medical Director Agreement

A DME supplier can enter into a Medical Director Agreement with a referring physician. The arrangement will need to comply with the Personal Services and Management Contracts safe harbor and with the Personal Services exception to Stark.

Loan/Consignment Closet

A DME supplier may place inventory on the premises of the referral source. The inventory must be for the convenience only of the referral source’s patients and the referral source cannot financially benefit, directly or indirectly, from the inventory. It is important that the referral source ensure patient choice.
Employee Liaison

A DME supplier may designate an employee to be on the referral source premises for a certain number of hours each week. The employee may educate the referral source staff regarding DME and related services. The employee may work with a patient, after a referral is made to the DME supplier (but before the patient leaves the referral source’s premises), in order for there to be a smooth transition when the patient goes home. The employee liaison may not assume responsibilities that the referral source is required to fulfill.

Promotional Items to Customers and Potential Customers

The DME supplier can offer an item of nominal value (i.e., retail value of not more than $10) to prospective customers covered by a government health care program. Over a 12-month period, the supplier may not give items to any one prospective customer (covered by a government health care program) that have a combined retail value greater than $50.

Health Fairs, Luncheons, Kiosks, and Open Houses

The DME supplier can participate in local health fairs, can put on a short program during lunch at a senior citizens’ center, and can place a kiosk in a mall that promotes the supplier’s products and services. When appropriate, the supplier can hold an open house. During the open house, it is appropriate for the supplier to conduct a drawing in which the prize is something like an iPad. Even though the iPad has a value in excess of $10, the chance of a person winning the iPad is very small.

Avoid Paying Commissions to 1099 Independent Contractor Sales Reps

Under the law, there is a huge difference between a W2 employee and a 1099 independent contractor. There is no such thing as a "1099 employee" and there is no such thing as a "W2 independent contractor." Only a human being can be an employee; an "it" cannot be an employee. In other words, while John Smith (a human being) can be an employee, John Smith Marketing Group, LLC (an "it") cannot be an employee. John Smith is either a W2 employee.....or a 1099 independent contractor......but not both.

There are both an exception and a safe harbor to the Medicare anti-kickback statute that say that it is permissible for a health care provider (such as a DME supplier) to pay commissions to a bona fide full-time or part-time W2 employee. The reasoning behind this exception is because the supplier has the obligation to supervise and control its employee, and the supplier is liable for the acts of its employee. On the other hand, a supplier has no duty to supervise and control a 1099 independent contractor, and the supplier is not liable for the acts of a 1099 independent contractor. And so while it is permissible for a DME supplier to pay commissions to a bona fide employee who generates business to the supplier (in which the payer is a government program), it is a violation of the anti-kickback statute if the supplier pays commissions to a 1099 independent contractor who generates business to the supplier (in which the payer is a government program). The anti-kickback statute cuts both ways: the payer of the money (the
DME supplier) and the recipient of the money (the 1099 independent contractor) are both liable under the statute.....which is a criminal statute.

A 1989 statement by the Department of Health and Human Services is illuminating: "We are aware of many examples of abusive practices by sales personnel who are paid as independent contractors and who are not under appropriate supervision. We believe that if individuals and entities desire to pay a salesperson on the basis of the amount of business they generate, then to be exempt from civil or criminal prosecution, they should make these salespersons employees where they can and should exert appropriate supervision for the individual's acts."

Also instructive is an OIG Advisory Opinion that addressed a proposed arrangement in which a sales representative for a medical supply manufacturer would be paid a monthly commission based on a percentage of amounts invoiced for products sold pursuant to the sales representative's efforts. According to the OIG: "Sales agents are in the business of recommending or arranging for the purchase of the items or services they offer for sale on behalf of their principals, typically manufacturers, or other sellers (collectively, "Sellers"). Accordingly, any compensation arrangement between a Seller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the ant-kickback statute, irrespective of the methodology used to compensate the agent. Moreover, because such agents are independent contractors, they are less accountable to the Seller than an employee.....For these reasons, this Office has a longstanding concern with independent sales agency arrangements." However, the AO did state that in some circumstances, these type of arrangements may be permissible if the sales rep's contact is structured to fit the Personal Services and Management Contracts safe harbor to the anti-kickback statute.

When promulgating the proposed rule containing this safe harbor, the Department of Health and Human Services ("DHHS") highlighted that it was crafted in light of the fact that arrangements for services frequently arise between health care providers/suppliers and their referral sources. According to DHHS, it established the safe harbor "for joint ventures and other arrangements involving payments for personal services or management contracts, but only if certain standards are met and safeguards are present to limit the opportunity to provide financial incentives in exchange for referrals."

Although a 1099 independent contractor relationship may be established under the safe harbor, such an arrangement must comply with the specific elements of the safe harbor, including the following: (i) payments to the 1099 independent contractor must be pursuant to a written agreement with a term of at least one year, and (ii) the aggregate compensation paid to an independent contractor must be set in advance, consistent with fair market value, and not determined in a manner that takes into account the volume or value of any referrals or business generated.

Note also that the OIG has taken the position that if a 1099 independent contractor paid on a production basis is generating both commercial and federally funded health care program referrals, any arrangement where the independent contractor is paid commissions only for the

AN INDUSTRY IN TRANSITION: HOT BUTTON ISSUES FACING DMEPOS SUPPLIERS PAGE 7 OF 71
referrals of commercial patients, and is paid nothing for the patients covered by a government program, nevertheless violates the anti-kickback statute. The reasoning is that the commissions for the commercial patients, in reality, also serve as compensation for the patients covered by a government program. As stated by the OIG: "[A]s a threshold matter, we must address whether the "carve out" of Federal business is dispositive of the question of whether the Existing Arrangement implicates the anti-kickback statute. It is not. The OIG has a long-standing concern about arrangements pursuant to which parties "carve out" Federal health care program beneficiaries or business generated by Federal health care programs from otherwise questionable financial arrangements. Such arrangements implicate and may violate the anti-kickback statute by disguising remuneration for Federal business through the payment of amounts purportedly related to non-Federal business."

**Problems With Utilizing a Marketing Company**

In the non-health care world, it is common for a business (e.g., widget company) to “outsource” marketing to a marketing company. The marketing company generates business for the widget company, the widget company pays commissions to the marketing company, and everybody is happy. Unfortunately, what works in the non-health care world often does not work in the DME universe. An example of this has to do with marketing companies. If a marketing company generates patients for a DME supplier, when at least some of the patients are covered by a government health care program, then the DME supplier cannot pay commissions to the marketing company.

Many courts have adopted the “one purpose test,” which states that if one purpose of a payment is to induce referrals, the anti-kickback statute is violated, notwithstanding that (i) the primary purpose for the payment is to compensate for legitimate, substantive services, and (ii) the compensation is fair market value. *See United States v. Greber*, 760 F.2d 68, 71-72 (3d Cir. 1985). Penalties for violating this statute include up to five years imprisonment plus criminal fines of up to $25,000 per violation, as well as exclusion from federal health care programs and civil monetary penalties. 42 U.S.C. §§ 1320a-7b(a), 1320a-7, 1320a-7a.

The Office of Inspector General (the “OIG”) has adopted safe harbors that provide immunity for arrangements that satisfy certain requirements. The employee safe harbor permits an employer to pay an employee in whatever manner the employer chooses in exchange for the employee assisting in the solicitation of federal health care program business, as long as there is a bona fide employer-employee relationship. 42 C.F.R. § 1001.952(i). The only way that an independent contractor can be paid for marketing or promoting government program items or services is if the arrangement complies with the personal services and management contracts safe harbor. This safe harbor permits payments to referral sources as long as a number of requirements are met. Two of the requirements are that (i) payments must be pursuant to a written agreement with a term of at least one year, and (ii) the aggregate compensation paid to the independent contractor must be set in advance (e.g., $24,000 over the next 12 months), be consistent with fair market value, and not be determined in a manner that takes into account the volume or value of any referrals or business generated between the parties. 42 C.F.R. § 1001.952(d). Because the aggregate compensation is not set in advance, percentage-based
compensation arrangements do not qualify for protection under the personal services and management contracts safe harbor.

The OIG has repeatedly expressed concern about percentage-based compensation arrangements involving 1099 independent contractor sales agents. In Advisory Opinion No. 06-02, the OIG stated that “[p]ercentage compensation arrangements are inherently problematic under the Anti-Kickback Statute, because they relate to the volume or value of business generated between the parties.” Moreover, in Advisory Opinion No. 99-3, the OIG stated:

Sales agents are in the business of recommending or arranging for the purchase of the items or services they offer for sale on behalf of their principals, typically manufacturers, or other sellers (collectively, “Sellers”). Accordingly, any compensation arrangement between a Seller and an independent sales agent for the purpose of selling health care items or services that are directly or indirectly reimbursable by a Federal health care program potentially implicates the anti-kickback statute, irrespective of the methodology used to compensate the agent. Moreover, because such agents are independent contractors, they are less accountable to the Seller than an employee. For these reasons, this Office has a longstanding concern with independent sales agency arrangements.

Further, in its response to comments submitted when the safe harbor regulations were originally proposed, the OIG stated:

[M]any commentators suggested that we broaden the [employee safe harbor] to apply to independent contractors paid on a commission basis. We have declined to adopt this approach because we are aware of many examples of abusive practices by sales personnel who are paid as independent contractors and who are not under appropriate supervision. We believe that if individuals and entities desire to pay a salesperson on the basis of the amount of business they generate, then to be exempt from civil or criminal prosecution, they should make these salespersons employees where they can and should exert appropriate supervision for the individual’s acts.


A number of courts have held that marketing agreements are illegal under the anti-kickback statute and are, therefore, unenforceable. See Med. Dev. Network, Inc. v. Prof’l Respiratory Care/Home Med. Equip. Servs., Inc., 673 So. 2d 565 (Fla. Dist. Ct. App. 1996); Nursing Home Consultants, Inc. v. Quantum Health Services, Inc., 926 F. Supp. 835 (E.D. Ark. 1996), aff’d per curiam, 112 F.3d 513 (8th Cir. 1997); Zimmer, Inc. v. Nu Tech Med., Inc., 54 F. Supp. 2d 850 (N.D. Ind. 1999). For example, Medical Development Network involved an agreement wherein a durable medical equipment (“DME”) supplier agreed to pay an independent contractor marketing company (the “Marketer”) a percentage of the DME supplier’s sales in exchange for marketing its products to physicians, nursing homes, and others. When the DME supplier breached the contract, the Marketer sued, and the DME supplier defended on the ground
that the agreement was illegal under the anti-kickback statute. A Florida appeals court agreed and affirmed the trial court’s ruling, holding that the agreement was illegal and unenforceable because the Marketer’s receipt of a percentage of the sales it generates for the DME supplier violated the federal anti-kickback statute.

In recent years, there have been a number of enforcement actions involving commission payments to independent contractors. In one example, a home health agency agreed to pay $130,000 after disclosing that it paid commissions for each patient referred to the home health agency by 1099 independent contractor sales representatives. See OIG, Kickback and Physician Self-Referral, https://oig.hhs.gov/fraud/enforcement/cmp/kickback.asp.

Additionally, the OIG has taken the position that even when an arrangement will only focus on commercial patients and “carve out” beneficiaries of federally-funded health care programs, the arrangement will still likely violate the anti-kickback statute. In Advisory Opinion No. 06-02, the OIG explained as follows:

The “carve out” of Federal business is not dispositive, however, on the question of whether the proposed program potentially violates the anti-kickback statute. The OIG has a long-standing concern about arrangements pursuant to which parties “carve out” referrals of Federal health care beneficiaries or business generated by Federal health care programs from otherwise questionable financial arrangements. Such arrangements may violate the anti-kickback statute by disguising remuneration for Federal referrals through the payment of amounts purportedly related to non-Federal business.

**Purchase of Internet Leads**

When a lead generation company (“LGC”) sells Medicare leads to a DME supplier, then it is important that the arrangement not violate the Medicare anti-kickback statute, nor the telephone solicitation statute.

**Anti-kickback statute**

It is acceptable for the DME supplier to “purchase a lead.” However, it is a violation of the anti-kickback statute for the supplier to “pay for a referral.” Assume that the LGC furnishes leads to the supplier and the supplier, in turn, pays the LGC. The question is this: Is the supplier only buying leads? Or is the supplier paying for referrals?

The OIG addressed this issue in an Advisory Opinion. The OIG distinguished purchasing “raw leads” from purchasing “qualified leads.” A raw lead is when the LGC only collects name, address and phone number of the Medicare beneficiary. A qualified lead is when the LGC collects additional information about the beneficiary such as physician’s name, Medicare number, diagnosis, products the beneficiary is currently using, etc. The chances of a raw lead becoming a paying customer for the supplier are pretty remote. This is akin to the supplier publishing an ad in the newspaper. When a prospective customer calls in response to the ad, then
the supplier will have no idea as to whether or not the caller is a serious prospective customer. On the other hand, the chances of a qualified lead becoming a paying customer increase appreciably. This is akin to a physician referring the beneficiary to the supplier. If the supplier purchases raw leads on a per lead basis, then the anti-kickback statute is likely not implicated. However, if the supplier purchases qualified leads on a per lead basis, then the anti-kickback statute will likely be implicated.

Brown & Fortunato (“B&F”) recently defended a DME supplier that had both a criminal and a civil case brought against it by the Department of Justice (“DOJ”). The supplier purchased qualified leads and paid for them on a per lead basis. The DOJ took the position that the arrangement violated the anti-kickback statute and that the claims, arising from the “kickback” arrangement, constituted false claims. B&F worked out a civil settlement that avoided a criminal conviction. However, the DOJ is pursuing the lead vendors that sold leads to the supplier.

Let’s look at an example: Assume that (i) the LGC will provide the lead to the supplier; and (ii) the supplier will pay the LGC $100 for the lead. Assume that the information on each lead includes name, address, phone number, physician information, and Medicare number. The question becomes: Does this additional information regarding the lead (physician information and Medicare number) move the lead from the “raw” category to the “qualified” category? If the answer is “yes,” then there is a potential kickback problem. Conversely, if the answer is “no,” then the anti-kickback statute is not implicated.

Telephone Solicitation Statue

This statute essentially says the same thing as Supplier Standard #11. The statute says that the DME supplier cannot call a prospective customer (Medicare beneficiary) unless the beneficiary has given his permission to be called. According to the National Supplier Clearinghouse (“NSC”), the beneficiary’s consent-to-be-called must be specific to a named DME supplier. For example, assume that a prospective customer visits the LGC’s website. Assume that the web page has a “consent-to-be-called” box for the beneficiary to click. According to the NSC, for the electronic consent-to-be-called to be valid, the DME supplier can be the only provider listed on the page and the consent must be specific to the DME supplier.

What all of this means for the supplier and the LGC

The arrangement should be structured one of two ways. First, the only information that the LGC will collect and give to the supplier will be the lead’s name, address and phone number. The LGC will not collect additional “qualifying” information such as physician information, Medicare number, diagnosis, products being used, etc. The supplier can pay for these raw leads on a per lead basis. Alternatively, the LGC will also collect the physician information, Medicare number, and any other qualifying information that the LGC deems pertinent. The compensation paid by the supplier for the LGC’s services will be fixed one year in advance (e.g., $60,000 over the next 12 months, or $5000 per month) and will be the fair market value equivalent of the services rendered by the LGC. As previously mentioned, fixed annual compensation (fair market
value) is an important element to the Personal Services and Management Contracts safe harbor to the anti-kickback statute.

Assume that the LGC is also the manufacturer

Assume that the LGC is also the manufacturer of the products that the leads will purchase. The more conservative (and, thus, preferable) arrangement is for (i) the LGC and the supplier to enter into a standard product purchase agreement in which the supplier agrees to buy products from the manufacturer/LGC in accordance with a price list; and (ii) the manufacturer/LGC will furnish leads to the supplier (including the physician information, Medicare number and other qualifying information) but the supplier will not pay for the leads. This is a standard arrangement that many manufacturers follow. If the manufacturer/LGC insists that the supplier purchase the leads, and if the supplier agrees to do so, then the arrangement needs to be structured as set out in the preceding paragraph.

Assume that the manufacturer/LGC will also serve as the “fulfillment house” for the DME supplier. The manufacturer/LGC will ship the products to the customer on behalf of the DME supplier. At the end of the day, the DME supplier (not the manufacturer/LGC) is the “supplier.” It is the supplier that submits claims to Medicare. When it submits a claim, the DME supplier is representing to Medicare that the supplier has operational responsibilities and financial risk……that is, the DME supplier is truly acting like a “supplier.” If the supplier essentially does nothing except bill and collect money, then the government will likely consider the arrangement to be nothing but a sham, in which (i) the DME supplier is, in reality, “renting out” its PTAN to the manufacturer/LGC and (ii) the DME supplier is collecting money from Medicare for products that the supplier did not, in reality, furnish. The supplier must have operational responsibilities and financial risk. In other words, the supplier must have “skin in the game.” For example, the supplier must handle the “intake, assessment and coordination of care.” The obligation of the supplier to pay the manufacturer/LGC must be absolute. The supplier must pay the manufacturer/LGC even if the supplier does not get paid by the third party payer. If there is a problem with a product, then the beneficiary should call the supplier. If the supplier wants to direct the manufacturer/LGC to furnish a replacement product, then the supplier can do so. The labels on the boxes (that are shipped to the beneficiaries) must reflect the DME supplier’s name, not the manufacturer’s/LGC’s name.

**“Buying Into” a Competitive Bid Contract**

A frequently asked question is whether a supplier, that was not awarded a Competitive Bidding (“CB”) contract, can “buy its way in the CB program.” The short answer is “yes,” but as is often the case, “the devil is in the details.” The non-contract supplier has four options:

1. 100% Asset Purchase
2. Partial Asset Purchase
3. 100% Stock Purchase
4. Partial Stock Purchase
100% Asset Purchase

Assume that XYZ Medical Equipment, Inc. is awarded a CB contract. XYZ cannot sell its CB contract to ABC. It can, however, sell 100% of its assets to ABC and ask the CBIC to transfer the CB contract to ABC.

For the purpose of this article let’s say that ABC and XYZ sign a letter of intent on January 1, 2015 for ABC to purchase 100% of XYZ’s assets. On January 1, 2015, XYZ will send a notice to the CBIC informing it of the pending sale and of the fact that ABC and XYZ will want ABC to take over XYZ’s CB contract. On February 1, 2015, XYZ and ABC will sign an Asset Purchase Agreement, a Bill of Sale, and a Novation Agreement and will submit the Bill of Sale, the Novation Agreement, and a few other documents to the CBIC. The Novation Agreement states that if the CBIC approves the transfer of the CB contract, then ABC will assume XYZ’s obligations under the CB contract as if ABC was the original party to the contract.

ABC will be required to send in documentation to the CBIC with the Bill of Sale and Novation Agreement that shows that ABC qualifies to be a contract supplier. If ABC previously submitted this documentation when it bid on the round covered by XYZ’s CB contract, but ABC’s bid was denied only because ABC bid too high, then ABC does not need to submit additional documentation. If, however, ABC submitted a bid for the round covered by XYZ’s CB contract, but ABC’s bid was disqualified, then ABC may need to submit documentation that cures the problems that led to the disqualification depending on what the problems were.

On or around March 1, 2015, the CBIC will notify ABC and XYZ whether or not the CBIC approves the transfer of the CB contract. If the CBIC approves the transfer and signs off on the Novation Agreement, then XYZ’s PTAN will be removed from the CB contract and ABC’s PTAN will be added to the CB contract. Because the Bill of Sale will be executed before a CBIC decision is rendered, XYZ’s assets will have been transferred, and ABC will presumably have paid money for the assets. This places XYZ in the unenviable position of transferring its assets before CBIC approval, and this places ABC in the unenviable position of paying money before CBIC approval. In order to protect XYZ, the Asset Purchase Agreement will be drafted to ensure that if the CBIC does not approve then the assets will go back to XYZ. In order to protect ABC, the purchase proceeds will be placed in escrow. If the CBIC approves, then the proceeds will be released from escrow back to ABC.

The dates set out above are just examples. The rules state that XYZ must notify the CBIC of the sale at least 60 days before closing and the rules state that the parties must execute and submit the Novation Agreement at least 30 days before closing. There is a possibility that CBIC approval can be obtained in an expedited fashion. For example, if XYZ notifies the CBIC of the sale on January 1, 2015, and the parties submit the Novation Agreement and Bill of Sale on January 8, 2015, then the CBIC may approve the transfer of the contract in mid-February. If the CBIC does approve, the effective date of the transfer of the contract should be made retroactive to the date of the Bill of Sale.
Partial Asset Purchase

Instead of purchasing 100% of XYZ’s assets, ABC can purchase those assets of XYZ that are associated with XYZ’s CB contract. XYZ will retain the balance of its assets and XYZ will continue to own and run its business that is not associated with the CB contract that ABC is taking over. All other requirements, pertaining to a 100% asset purchase, remain the same for a partial asset purchase.

100% Stock Purchase

Let’s assume that John Smith is the sole stockholder of XYZ. Smith can sell all of his stock to ABC. As a result, XYZ (a contract supplier) becomes a wholly-owned subsidiary corporation of ABC (a non-contract supplier). This does not mean that ABC can “bill its Medicare CB patients through its subsidiary, XYZ.” Even though ABC owns XYZ, they are still separate entities (with different tax ID numbers). However, subject to patient choice, ABC can refer its Medicare CB patients to XYZ. Because ABC and XYZ will be “commonly owned,” XYZ can ask the CBIC to add ABC’s PTAN to XYZ’s CB contract.

Because this is a stock purchase and not an asset purchase, the “60 day notice” does not have to be given to the CBIC. A Novation Agreement is not required. XYZ will need to update its 855S with the NSC to show that ABC is XYZ’s new owner. After the 855S is processed, XYZ will need to submit the Contract Supplier Location Update Form to the CBIC to have ABC’s PTAN added to the CB contract.

Partial Stock Purchase

If ABC purchases 5% or more of XYZ’s stock, or vice versa, then under CB rules, ABC and XYZ will be “commonly owned.”

Assume that ABC purchases exactly 10% of XYZ’s stock. XYZ will update its 855S to show that ABC is a 10% owner of XYZ. Once the NSC records reflect that ABC is a 10% stockholder of XYZ, then XYZ will ask the CBIC to add ABC’s PTAN to XYZ’s CB contract. This is accomplished by XYZ filing a Contract Supplier Location Update Form with the CBIC. XYZ can request that ABC’s PTAN be added to a specific CBA/product category combination. For example, XYZ can ask that ABC’s PTAN be added only to that portion of the CB contract associated with the Phoenix CBA/oxygen product category. If the CBIC grants XYZ’s request and adds ABC’s PTAN to XYZ’s CB contract, ABC will be able to bill and collect under its own PTAN. ABC will not have to “bill through” XYZ.

In the future, if ABC and XYZ desire to bid for the same product category in the same CBA, then they will have to submit one bid for both companies. This is because they are “commonly owned.”
“Carve Out” of a Competitive Bid Contract

On July 11, 2014, CMS published a proposed rule entitled “Revision to Change of Ownership Rules to Allow Contract Suppliers to Sell Specific Lines of Business.” The rule was finalized on November 6, 2014. Interestingly, only one comment from the DME industry was filed. The new rule, found at 42 CFR§ 414.422 (d) (4), states:

For contracts issued in the Round 2 Recompete and subsequent rounds in the case of a CHOW where a contract supplier sells a distinct company, (e.g., an affiliate, subsidiary, sole proprietor, corporation, or partnership) that furnishes a specific product category or services a specific CBA, CMS may transfer the portion of the contract performed by that company to a new qualified entity, if the following conditions are met:

(i) Every CBA, product category, and location of the company being sold must be transferred to the new qualified owner who meets all competitive bidding requirements; i.e. financial, accreditation and licensure;

(iii) All CBAs and product categories in the original contract that are not explicitly transferred by CMS remain unchanged in that original contract for the duration of the contract period unless transferred by CMS pursuant to a subsequent CHOW;

(iv) All requirements of paragraph (d)(2) of this section are met; and

(v) The sale of the distinct company includes all of the contract supplier's assets associated with the CBA and/or product category(s); and

(vi) CMS determines that transfer of part of the original contract will not result in disruption of service or harm to beneficiaries.

What Has Been Occurring Up To Now

Up to now, a competitive bid (“CB”) contract could be transferred by one of the following ways:

- ABC, Inc. is awarded a CB contract that covers multiple product categories in three CBAs. ABC sells all of its assets to JKL, Inc. Through the novation process, the CBIC transfers ABC’s entire CB contract to JKL.

- ABC only sells its assets that are associated with ABC’s CB contract. This is a partial asset sale. Through the novation process, the CBIC transfers ABC’s entire contract to JKL.
• In other words, up to now, ABC’s CB contract could not be “carved up”....or “split up”.....or “subdivided.” The entire CB contract would stay with ABC or the entire CB contract would go over to JKL.

What The Final Rule Appears To Be Saying

• Assume that ABC, Inc. is awarded a CB contract that covers multiple product categories in multiple CBAs. Assume that ABC has “common ownership” with XYZ, Inc., DEF, Inc. and GHI, Inc. As “commonly-owned” entities, XYZ, DEF and GHI are added to ABC’s CB contract.

• Assume that ABC’s CB contract includes Negative Pressure Wound Therapy (“NPWT”) in CBA #1. Assume that XYZ is handling the NPWT in CBA #1. The final rule allows XYZ to sell all or a portion of its assets to JKL, Inc. Pursuant to the novation process, that portion of ABC’s CB contract (pertaining to NPWT in CBA #1) will be transferred to JKL.....and ABC will retain the balance of the CB contract. In other words, the rule allows for a “carve out” of ABC’s CB contract.

• There are ambiguities associated with the final rule. (i) First ambiguity – The rule indicates that XYZ must be a separate legal entity (e.g., a corporation or LLC). This is exemplified by the fact that “distinct company” is used two times. But then the rule lists examples of “distinct companies.” One example is a “sole proprietor.” A “sole proprietor” is not a legal entity (i.e., it is not a corporation or LLC). A sole proprietor is simply an assumed name (a “dba”). For example, if Fred Jones owns Fred’s Taco Stand, and if Fred has not set up a legal entity for Fred’s Taco Stand, then “Fred’s Taco Stand” is simply a “dba” of Fred Jones. I mention this ambiguity because of a variation of the hypothetical set out in the preceding bullet. Assume that XYZ is not a separate legal entity; rather it is a “division” of (or “dba” of) ABC. In this situation, can ABC sell its “XYZ division” to JKL? I don’t think so, but you can see where there may be some confusion. (ii) Second Ambiguity – Assume the fact situation set out in the preceding bullet. Assume that in addition to providing NPWT in CBA #1, XYZ also (i) provides items not covered by Medicare and (ii) provides items covered by other payers. Assume that NPWT is only a small part of XYZ’s business. Can XYZ sell only that portion of its assets associated with NPWT in CBA #1, and keep the balance of its business? Or must XYZ sell all of its assets to JKL? On the one hand, by utilizing the phrase “sell a distinct company,” it appears that the rule contemplates that all of the assets of XYZ must be sold. On the other hand, the rule states that the “sale of the distinct company includes all of the contract supplier’s assets associated with the CBA and/or product category(s).” This indicates that XYZ can sell only those assets associated with NPWT in CBA #1.

Effect on Bidders

The rule may affect (i) how some bidders submit bids and/or (ii) their actions after the competitive bid (“CB”) contracts are awarded. For example, in the past it has been common for ABC, Inc. to submit a bid for multiple product categories in multiple CBAs. ABC would be
awarded one CB contract. ABC would be stuck with the entire contract. It would have to keep the entire contract or ask the CBIC to transfer the entire contract. In other words, ABC was either “totally in” competitive bidding or “totally out of” competitive bidding. In light of the rule, as a Round 2 Recompete bidder, ABC may want to do one or more of the following:

• Before it submits its bid, ABC may want to form several “commonly owned” legal entities. When ABC submits its bid, it will include the commonly owned entities. If ABC is awarded a CB contract, then “Commonly Owned Entity #1” can handle one product category/CBA combination, “Commonly Owned Entity #2” can handle a different product category/CBA combination, and so on and so forth. Then ABC can “spin off” the commonly owned entities, along with that portion of the CB contract associated with each entity’s product category/CBA combination.

• Alternatively, ABC may want to wait to form “commonly owned” legal entities until after ABC is awarded the CB contract. ABC can ask the CBIC to add the commonly owned entities to ABC’s CB contract. Each commonly owned entity will be limited to a specific product category/CBA combination. Then ABC can “spin off” the commonly owned entities, along with that portion of the CB contract associated with each entity’s product category/CBA combination.

When a CB Contract Supplier “Meets Capacity”

A number of CB contract suppliers are facing the same challenge. Their volume has increased substantially and they have quickly met the capacity set out in their bid submission. For example, in its bid submission, ABC Medical may have listed its capacity for walkers as 2000. However, ABC has quickly sold more than 2000 walkers. ABC’s bank will not provide any additional working capital to ABC in order for ABC to purchase additional walkers. This is a dilemma for ABC. How can ABC continue to sell walkers when it does not have the financial capacity to purchase additional inventory? Can ABC cease providing walkers?

The competitive bid regulations – as well as the terms of the competitive bid contract – require that “[a] contract supplier must agree to furnish items under its contract to any beneficiary who maintains a permanent residence in, or who visits, the CBA and who requests those items from that contract supplier.” 42 CFR 414.422(e)(1). This regulatory language requires a contract supplier to service any beneficiary who requests the covered items, and it does not make an exception for suppliers that have reached the capacity stated in their bid submission.

In addition to the language in the competitive bid regulations and contracts, this issue was briefly addressed in the commentary in the preamble to the final rule that promulgated the competitive bid regulations. The following comments and responses are contained there:

Comment: One commenter requested that CMS clarify that a contract supplier can limit the number of items it provides in each category to its contracted capacity.
Response: As part of a supplier's response to the RFB, a supplier will be expected to state its projected capacity to furnish the items in each product category for which it is submitting a bid. The projected capacity submitted by a supplier would not become a binding term of the contract because contract suppliers will be required to furnish the items in their contract to all beneficiaries who maintain a permanent residence in the CBA, or who visit the CBA, and who request the items from them unless one of the exceptions discussed in this final rule applies.

72 FR 17992, 18025-26 (Apr. 10, 2007)

Comment: One commenter urged CMS not to prohibit contract suppliers from turning away beneficiaries, since there will be more than one contract supplier per CBA. The commenter stated that there may be circumstances in which a contract supplier is already operating beyond capacity and would not be able to furnish items to additional beneficiaries. In addition, the commenter noted that a contract supplier may not believe that a requested item is appropriate for the beneficiary.

Response: We continue to believe that contract suppliers should not be able to turn away beneficiaries because we do not want to create an opportunity for contract suppliers to turn away beneficiaries who have the most difficult medical conditions or are otherwise difficult to serve. We note that we proposed that there would be a limited exception to this requirement if there is a particular item that a physician or treating practitioner has ordered to avoid an adverse medical outcome, but is an item that the contract supplier does not normally furnish. In this case, if the contract supplier could not furnish the item, the requirements at Sec. 414.420(b) of this final rule would apply.

72 FR 17992, 18050-51 (Apr. 10, 2007)

Termination of Competitive Bid Contract for Failure to Provide Products

There are a number of valid complaints levied against competitive bidding. One complaint is that a DME supplier is awarded a CB contract in multiple CBAs, but refuses to provide products to beneficiaries who reside out of the supplier’s traditional service area. The complaint is that when the contract supplier receives an order for a beneficiary residing out of the supplier’s traditional service area, then the supplier will either (i) refer the beneficiary to another contract supplier or (ii) simply refuse to serve the beneficiary.

A number of House Representatives recognize this problem. On July 25, 2014, Congressman Tom Price, M.D. (GA-06) and 137 other Representatives (from both parties) sent a letter to the OIG requesting that it conduct a study of competitive bidding (including the National Mail Order Program for diabetic testing supplies) to determine what impact competitive bidding is having on the accessibility and quality of care for beneficiaries. The letter states:

At this point there is abundant and concerning evidence of arbitrary manipulation of the price-setting system that directly limits seniors’ access to care and
technology, an inattention to growing contractor non-compliance that is
significantly impacting the quality and choice of technologies and services, and
inadequate efforts to measure health impacts on beneficiaries. It would be a
grave error if the bidding structure developed by the Centers for Medicare &
Medicaid Services (CMS) severely reduces access to home support services just
as Congress seeks to enhance care quality through greater coordination of care,
especially for patients with complex and multiple chronic conditions. CMS directs
bidders be very clear that all suppliers must supply all products in every category
in every CBA that supplier won. Moreover, failure to supply is a breach of
contract. [I]f suppliers don’t provide products and services as required by their
contracts, then seniors’ access to the products prescribed by their physicians is
compromised, especially for products that are among the more expensive in any
given HCPCS code. Not making available to beneficiaries all products in a
category is a breach of contract according to CMS’ own explanation of the
program. In fact, CMS argues that binding bids are not needed in the program
because of this requirement. We note, however, that CMS is not enforcing the
requirement. For example, upon hearing that beneficiaries were having problems
with access to TENS from winning suppliers for the new General Home
Equipment category used in the Round 1 Recompete, a manufacturer of the
devices contacted each of the winning suppliers in this category and found that
only 44 percent of the suppliers were offering TENS to beneficiaries.

In a December 22, 2014 letter to Representative Price, the OIG agreed to conduct a study.
The letter states: “OIG will commence a study to determine the effects of the CB program on
Medicare beneficiaries’ access to durable medical equipment subject to competitive bidding. We
plan to review documents from providers and Medicare claims data for a nationally
representative sample of beneficiaries to determine and compare the rates at which beneficiaries
successfully obtained needed items subject to competitive bidding. For a purposive sample of
cases when beneficiaries appear not to have received needed items, we plan to explore why they
did not receive the items.”

The preceding two letters indicate that House Representatives and the OIG recognize the
existence of an access problem. The CBIC also recognizes the problem. In a January 2, 2015
letter to a contract supplier, the CBIC stated: “This letter is to notify you that the Centers for
Medicare & Medicaid Services (CMS) is terminating ________’s entire Durable Medical
Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) competitive bidding program Round
2 contract for all competitively bid items in all competitive bidding areas (CBAs) for which
_______ has been awarded a contract. Through our monitoring and enforcement of the
DMEPOS competitive bidding program, we determined that ______ is in breach of.....the
DMEPOS competitive bidding contract for refusing to furnish all items in your contract
throughout the CBA.....” By conducting “secret shopper” telephone calls, the CBIC determined
that the contract supplier was not furnishing certain products. The CBIC letter goes on to say that
____ has the right to submit a corrective action plan.

There are two messages to be derived from the three letters discussed above:
• A large number of House Representatives and the OIG recognize that a number of contract suppliers are not providing products as required by their CB contracts.

• The CBIC also recognizes the existence of the “access” problem. It is identifying noncompliant contract suppliers by conducting “secret shopper” telephone calls.

**Subcontracting**

**Introduction**

Competitive bidding rules provide that contract suppliers may subcontract with non-contract suppliers as long as the subcontractor has not been “excluded from the Medicare program, any State health program or any other government executive branch procurement or nonprocurement activity.” To demonstrate that subcontractors meet this requirement, among others, the contract supplier must disclose the subcontract and related information within 10 business days after the parties execute the contract. Failure to meet the disclosure requirements and other rules concerning subcontracts may result in termination of the competitive bid contract. According to the competitive bidding rules, “[CMS] might conclude that a contract supplier breached its contract if [CMS] discover[s] that the contract supplier did not fully comply with disclosure requirements . . . or falls out of compliance with the Medicare program requirements.”

**Responsibilities That Can Be Subcontracted**

According to the CBIC, contract suppliers may subcontract for (1) the purchase of inventory, (2) the delivery and set-up of items, (3) patient and caregiver instruction, and (4) the repair of rented equipment. To further clarify the services that a supplier may provide through a subcontract, CBIC directs suppliers to consult the DMEPOS Quality Standards. By comparing the Quality Standards to CBIC’s information on subcontracts, it is apparent that the contract supplier cannot delegate the following responsibilities to a subcontractor:

• Intake and assessment;
• Communications with prescribing practitioners to confirm orders and to recommend any necessary modifications to orders;
• Coordination of care with physicians and other practitioners;
• Verification that the items (1) comply with the physician order and (2) meet the beneficiary’s needs;
• Maintenance of documentation in the beneficiary’s file, including physician orders, certificates of medical necessity, DME information forms, proofs of delivery, the make and model of the item provided, verification that the beneficiary received training and instructions, and, for wheelchairs and power mobility equipment, documentation that positioning, seating, and specialty assistive technology have been evaluated;
• Review and updates of beneficiaries’ records;
• Ownership and responsibility of equipment;
• Ensuring the safety of products; and
• Investigation of any incident involving beneficiary safety.

**Accreditation**

Subcontractors that set up equipment and instruct beneficiaries must be accredited. By comparing CBIC’s information to the Quality Standards, it is apparent that subcontractors must be accredited before they:

- Instruct beneficiaries and their caregivers on the features, set up, routine use, cleaning, and maintenance of equipment and on any infection control practices;
- Adjust equipment to meet the needs of a beneficiary;
- Ensure that the beneficiary’s home allows for safe and effective use of the item; and
- Evaluate and document the positioning, seating, and special assistive technology of wheelchairs and power mobility devices.

On the other hand, a subcontractor may provide the following services without accreditation:

- The sale of inventory to the supplier;
- Delivery of items along with necessary contact information to beneficiaries;
- Delivery of the supplier’s written and pictorial instructions to beneficiaries; and
- Repair services for rental equipment.

**Avoiding Kickback Problems**

An example of a subcontractor arrangement is where a supplier (that was not awarded a competitive bid 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). Risk can further be reduced by
obtaining a fair market value analysis, from an independent third party, of the compensation paid to the subcontractor.

Important Provisions in a Subcontract Agreement

A Subcontract Agreement needs to contain a number of important provisions, including the following:

- The subcontract should represent and warrant that:
  - The subcontractor, 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 payer policy or rule (collectively, “Qualification”) to fully perform the subcontract services on behalf of the contract supplier, and the subcontractor will notify the supplier immediately upon notice of a threatened loss of Qualification as well as immediately upon notice of an actual loss or limitation of a Qualification.
  - Neither the subcontractor nor any of its officers, directors, owners, employees has ever been and will not be during the term of the Subcontract Agreement (1) convicted of a criminal offense, including any 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. The subcontractor will immediately notify the supplier if any person or entity associated with the subcontractor becomes the subject of an investigation that could threaten the subcontractor’s ability to continue to accurately represent and warrant the statements in the Subcontract Agreement, and the subcontractor will immediately notify the supplier if and when it can no longer represent and warrant the statements in the Subcontract Agreement and such notice to the supplier will explain why such representations and warranties can no longer be made by the subcontractor.
- The subcontract should covenant that:
  - The subcontractor 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.
  - The subcontractor acknowledges that, in the course of performing its duties hereunder, the supplier will disclose to the subcontractor confidential information having a special and unique nature and value relating to the supplier. As a material inducement to the supplier to enter into the Subcontract Agreement, the subcontractor agrees that, unless the supplier provides prior written consent, the subcontractor will not, at any time during or following the term of the Subcontract Agreement, directly or indirectly, disclose, publish,
or divulge, except in connection with the provision of the subcontractor’s services, any confidential information which has been obtained by or disclosed to the subcontractor through or in the course of its relationship with the supplier. As an exception, the subcontractor may disclose confidential information as required to comply with the binding order of a governmental entity that has jurisdiction over it, provided that the subcontractor (a) gives the supplier reasonable written notice to allow the 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.

- The subcontractor will maintain all Qualifications for the duration of the Subcontract Agreement.

- All subcontract services will be provided in accordance with (1) all applicable laws and regulations; (2) the 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 the supplier; and (4) any standards or procedures imposed by the accreditation organization by which the supplier is accredited. The supplier will provide a copy of the supplier’s applicable clinical protocols, policies and procedures to the subcontractor, and may modify any protocol, policy or procedure by providing 10 days notice to the subcontractor.

- The subcontractor will cooperate with the supplier in the conduct of quality improvement activities.

- The subcontractor will cooperate with the supplier in the supplier’s efforts to comply with the supplier’s contracts with third party payers.

- The subcontractor will produce any document or information in its possession that the supplier reasonably requires in order to comply with a request from any third party payer, state or federal agency, or accreditation organization.

- The subcontractor will maintain all documents and records necessary for it to provide its service.

- The subcontractor will indemnify and hold harmless the supplier from and against all damages, claims, liabilities and losses (including reasonable attorney's fees) resulting from the subcontractor’s negligence or willful misconduct committed in connection with the performance of the subcontractor’s duties hereunder. Likewise, the supplier will indemnify and hold harmless the subcontractor from and against all damages, claims, liabilities and losses (including reasonable attorney's fees) resulting from the supplier’s negligence or willful misconduct committed in connection with the performance of the supplier’s duties hereunder.
In providing services under the Subcontract Agreement, the subcontractor will be acting as a business associate of the 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. In compliance with the HIPAA standards, the parties will execute a Business Associate Addendum to the Subcontract Agreement.

The subcontract’s services might include the following:

- The supplier will arrange for a limited supply of DME to be shipped to the subcontractor, and the subcontractor will segregate and store the DME (“Consignment Inventory”). The supplier will retain title to the Consignment Inventory until it is furnished to a patient as directed by the supplier. The supplier will replenish Consignment Inventory as-needed. In the event of termination of the Subcontract Agreement, the subcontractor will promptly return any Consignment Inventory in the subcontractor’s possession to the supplier.

- If a patient chooses to obtain DME from the supplier, the supplier will notify the subcontractor that the patient requires an item of DME. After the supplier has performed the intake and assessment on the patient, and after the supplier instructs the subcontractor to furnish an item of Consignment Inventory to the patient, the subcontractor will promptly:
  - Deliver DME to the patient, as ordered by patient’s physician, at the subcontractor’s location, the patient’s residence, or at the hospital at which the patient is about to be discharged. The subcontractor will provide initial education and training to the patient or patient’s caregiver on operation and use of DME required by the patient, as ordered by the patient’s physician;
  - Provide the 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 the supplier directly regarding any complaint; and
  - Transmit to the supplier relevant patient information and documents in the form and manner required by the supplier, including, without limitation, proof of delivery.

- Should the subcontractor receive any patient complaints regarding use of the supplier’s DME, the subcontractor will immediately forward to the supplier such complaints. The subcontractor 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 the supplier. The subcontractor will make the log available to the supplier upon the supplier’s request.
The subcontractor will document its services on an invoice which it will submit to the supplier on a monthly basis.

The subcontractor will assist the supplier, as reasonably requested, in obtaining the necessary forms and documentation for billing and reimbursement for items and services provided by the supplier. The subcontractor will submit these forms to the supplier on a weekly basis. The supplier may withhold payment for services until the subcontractor submits such forms and documentation to the supplier.

The fees to be paid by the supplier to the subcontractor might look like the following:

<table>
<thead>
<tr>
<th>Service</th>
<th>Fee</th>
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<tbody>
<tr>
<td><strong>BEDS</strong></td>
<td></td>
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<tr>
<td>• Delivery of Bed</td>
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<tr>
<td>• Instructions Regarding Use of Bed</td>
<td>$____</td>
</tr>
<tr>
<td>• Set-up of Bed</td>
<td>$____</td>
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<tr>
<td>• In-Home Repair of Bed</td>
<td>$____</td>
</tr>
<tr>
<td>• Delivery of “Loaner”</td>
<td>$____</td>
</tr>
<tr>
<td>• Pick-up of “Loaner”</td>
<td>$____</td>
</tr>
<tr>
<td>• Pick-up and Cleaning of Bed After Use by Patient</td>
<td>$____</td>
</tr>
<tr>
<td><strong>MATTRESSES</strong></td>
<td></td>
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<tr>
<td>• Delivery of Mattress</td>
<td>$____</td>
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<tr>
<td>• Instructions Regarding Use of Mattress</td>
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<tr>
<td>• Set-up of Mattress</td>
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<td>• In-Home Repair of Mattress</td>
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<td>• Delivery of “Loaner”</td>
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<td>• Pick-up of “Loaner”</td>
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<tr>
<td>• Pick-up and Cleaning of Mattress After Use by Patient</td>
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<tr>
<td><strong>OXYGEN</strong></td>
<td></td>
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National Supplier Clearinghouse, Accrediting Organizations, and ZPICs

The DME industry is facing a “perfect storm” of changes: competitive bidding; decreased reimbursement; more stringent documentation requirements; an increasingly aggressive NSC; active accrediting organizations; and aggressive audits by ZPICs.

National Supplier Clearinghouse

There are a number of reasons why the DME supplier must take the NSC seriously, one of which is that the NSC can revoke (or suspend or deactivate) a supplier number with a “flip of the switch.” Compare this to a typical Department of Justice/OIG investigation that takes two to three years to resolve.

The NSC is routinely conducting unannounced site inspections, which frankly is a good thing. The compliant suppliers have nothing to fear while the fraudsters have a great deal to fear. However, even the compliant players need to be careful. The NSC inspectors have become more sophisticated and aggressive. They are interviewing patients and referring physicians. They are asking probing questions that were never asked in the past. For example, an inspector may ask if the supplier is marketing through W2 employees or 1099 independent contractors. The inspector may inquire if the supplier has the requisite written permission before it calls a prospective customer. In short, the NSC is looking at the supplier’s operations to determine if the supplier is complying with the supplier standards. What is scary is that if the NSC concludes that a supplier is not adhering to the standards, then the NSC can immediately bring the supplier to its knees by revoking (or suspending or deactivating) the supplier’s Part B number.

A physician should never diagnose and treat himself. Likewise, an attorney who represents himself has a fool for a client. The supplier should not be the sole judge of whether it is in compliance with the supplier standards. On a periodic basis, the supplier should bring in an outsider (attorney or consultant) to conduct a review of whether the supplier is in compliance with the supplier standards.

Accrediting Organizations

The accrediting organization exists by virtue of the good grace of CMS. CMS is becoming increasingly demanding of the accrediting organizations. CMS expects the accrediting organization to look at many facets of the supplier’s operation and to insist on changes that the accrediting organization (and CMS) deem to be necessary. If the supplier refuses to make the changes, then its accreditation will be revoked. This causes a domino effect that leads to the revocation of the supplier’s Part B number. Increasingly, when CMS receives complaints about a supplier, CMS will refer the complaints to the accrediting organization with the instruction to investigate and resolve the complaints. If the supplier proves to be uncooperative with its accrediting organization, then the supplier’s accreditation can be revoked.
In short, over the past couple of years, the accrediting organizations have become more sophisticated and aggressive. As with its relationship with the NSC, the supplier needs to do what is necessary to stay in the good grace of its accrediting organization. In particular, the supplier must understand and follow the policies and procedures that it previously submitted to, and that have been approved by, the accrediting organization. If the supplier hires an outsider to conduct a review of whether the supplier is complying with the supplier standards, the supplier should also direct the attorney/consultant to review whether the supplier is complying with the policies and procedures approved by the accrediting organization.

ZPICs

Prior to the 1996 enactment of HIPAA, Medicare program safeguard activities (i.e., activities aimed at detecting fraud and abuse) were funded from the contracted fiscal intermediary’s general program management budget. HIPAA revised the Social Security Act and established the Medicare Integrity Program. The MIP’s primary purpose is to deter fraud and abuse in the Medicare program by giving CMS authority to enter into contracts with outside entities and ensure the “integrity” of the Medicare program. In 1999, CMS developed the Program Safeguard Contractor program to support the MIP, stop Medicare fraud, and facilitate provider adherence to codified CMS Payment Criteria, Conditions of Participation, and applicable judicial rulings. PSCs are now transitioning to Zone Program Integrity Contractors. At the highest level, CMS considers a ZPIC as being responsible for directing, deterring, and preventing Medicare fraud and abuse.

ZPICs are divided into seven zones across the country. They have a contracted Statement of Work that encompasses all of the fundamental activities required for CMS program safeguard activities. ZPICs are responsible for post-payment audits, prepayment reviews, data analysis, benefit integrity and/or fraud detection, cost report audits, and provider education. The ZPIC will refer an identified overpayment to the DME MAC and may refer identified fraudulent activities to the OIG.

When a DME supplier receives notice that it is being subjected to a post-payment audit from a DME MAC, then the supplier must take the matter seriously but there is no reason to panic. The DME MAC is conducting a “medical review” audit - that is - does the supplier’s documentation support the product that was delivered to the patient? On the other hand, when the supplier receives notice that a ZPIC is conducting a post-payment audit or prepayment review, then while panic may not be necessary, a healthy dose of paranoia may be in order. The fact that a ZPIC is involved tells the supplier that CMS believes that the supplier may be engaging in fraudulent activities.

In conducting its investigation, the ZPIC will engage in one or more of the following: post-payment audit, prepayment review, and telephonic and in-person interviews of patients and physicians. A ZPIC investigator may ask the same type of probing questions that the NSC inspector may ask (see above). For example, the investigator may call Mrs. Smith and ask her: “Now Mrs. Smith, do you really need the diabetic testing suppliers that ABC Medical Equipment sold to you?” Or the investigator may ask Mrs. Smith: “Did you give ABC Medical Equipment...
written permission to call you?” Or the investigator may ask Dr. Jones: “Dr. Jones, you signed the order for diabetic testing supplies. Is this something that you came up with or did you receive an order from ABC Medical Equipment in which ABC told you that Mrs. Smith wants diabetic testing suppliers from ABC?”

A ZPIC post-payment audit is serious, but it is not “life threatening.” At least the supplier has been paid……so the supplier can pay its light bill. The supplier and the ZPIC are arguing over whether the supplier should keep the money that it had previously been paid. On the other hand, a pre-payment review can be “life threatening,” particularly if it is a 100% prepayment review. In a pre-payment review, the supplier has provided the equipment and subsequently submitted a claim. However, the ZPIC will not authorize payment of the claim unless it determines that the supplier’s documentation is in order. If the pre-payment review is large, then it can seriously hurt the supplier’s cash flow. The ZPICs are slow in processing prepayment reviews and, too often, act arbitrarily and in contravention of LCDs and other guidance. In short, it can be a painful process to get off of a prepayment review.

There are several factors that can make a supplier vulnerable to an aggressive prepayment review: (i) patient and physician complaints; (ii) the supplier primarily sells only one product; (iii) the supplier sells the type of product that has come under the government’s scrutiny; (iv) in the eyes of a DME MAC, the supplier’s billing patterns are noticeably different from the billing patterns of similarly-situated suppliers; (v) a sudden aberration from how the supplier has billed in the past; and (vi) the supplier’s error rate, resulting from previous post-payment audits and prepayment reviews, is high. Let us focus on the first and last points. When a patient or physician complains about a supplier to CMS, there will be an investigation. Investigations have been started within a week after CMS receives a complaint. When a supplier is subjected to a post-payment audit or a prepayment review, no matter how small, the supplier needs to do whatever is necessary to successfully respond to the audit/review. Too often, suppliers will respond in a cavalier fashion to small audits/reviews because “they are too small to mess with.” This results in a high error rate which, in turn, sets the supplier up for much larger audit/review.

There are several preventive steps that the supplier can take to reduce the risk of a post-payment audit/prepayment review. First, the supplier should implement a corporate compliance program. One of the most important aspects of such a program is that there is a person (corporate compliance officer) who is focusing on avoiding fraud. For a small supplier, the compliance officer can “wear several hats.” The compliance officer is normally not an attorney. What is important is that the compliance officer serves as the “canary in the mine shaft.” He/she is trained to determine if something may be wrong, thereby giving the supplier the opportunity to fix a problem before it gets out of hand. Second, the supplier needs to engage in regular self-audits of its patient files. Third, the supplier should have an outside consultant conduct a patient chart audit at least once a year. Fourth, the supplier should have a health care attorney conduct a periodic legal compliance audit. This will allow the supplier to determine if it is violating any of the federal or state anti-fraud laws (e.g., Medicare anti-kickback statute, Stark physician self-referral statute, telephone solicitation statute). Fifth, the supplier should seriously consider obtaining all documentation (including physician progress notes) before providing a product or
submitting a claim. Doing so will drive away some referral source physicians, but doing so may pay big dividends in the end as the supplier responds to audits/reviews.

**Compliance Program**

A Corporate Compliance Manual should be designed to follow guidance from the Office of Inspector General (OIG) and the Federal Sentencing Guidelines. The Federal Sentencing Guidelines, published by the United States Sentencing Commission, while designed to help judges determine the degree of fault in sentencing decisions, set forth the elements that a compliance program should meet. Similarly, the OIG has published guidance for compliance programs implemented by DME suppliers.

The “Code of Conduct” section of the Corporate Compliance Manual should include a number of provisions, including the following:

- **Relationships with Physicians and Others in a Position to Influence Business**

  The Stark Law prohibits a physician from referring a Medicare patient to a provider with which the physician (or immediate family member of the physician) has a financial relationship – either an ownership interest or a compensation arrangement – for the furnishing of “designated health services” unless an exception applies. Designated health services include durable medical equipment, orthotics and prosthetics, outpatient prescription drugs and parental and enteral nutrition, among others.

  The Medicare anti-kickback statute prohibits knowingly and willfully offering, paying, soliciting, or receiving, directly or indirectly, anything of value if the purpose is to induce the recipient to (i) refer, order, recommend, or purchase an item or service for which payment may be made under a federal health care program such as Medicare or Medicaid; or (ii) arrange for someone else to do so.

  The anti-kickback statute contains certain exceptions. In addition, an arrangement does not violate the anti-kickback statute if the arrangement falls within a “safe harbor.”

  The False Claims Act prohibits submitting a bill or other information to Medicare or Medicaid that is false or misleading. Specific knowledge of violations is not required. Failing to repay an overpayment within 60 days after it is identified can lead to false claims liability.

  Federal law establishes Civil Monetary Penalties for certain actions, including violation of the Stark Law, violation of the anti-kickback statute, violation of the False Claims Act, violation of HIPAA privacy rules, and offering financial inducements to beneficiaries.

- **Conflicts of Interest**

  The employees should carry out their job responsibilities on the basis of what is in the company’s best interest and independent of personal considerations.
• Receipt of Improper Payments

An improper payment includes cash or anything of value, such as goods and services, received or used for any unlawful or improper purpose or payment.

• Use of Company Funds for Improper Payments or Gifts

The use of company funds for any improper payment should be prohibited. Any payment that is falsified or not reported in company books and records will be deemed to be an improper payment.

• Confidentiality

Employees and agents should keep all patient records confidential. Access should be restricted to authorized persons. No confidential information will be disclosed without proper consent.

• Reporting Abuse

All incidents of suspected child or elder abuse, including physical and emotional abuse and financial exploitation, should be reported as required by applicable state law. In addition to reporting required by law, employees and agents should immediately report the matter to the Compliance Officer.

• Physician Orders and Certificates of Medical Necessity

Only the attending/referring practitioner may provide a written order for goods or services provided by the DME supplier. The Affordable Care Act requires that a practitioner must conduct a face-to-face examination of the patient within six months prior to the date of a physician order for DME. Intake personnel must obtain physician orders and, when required, Certificates of Medical Necessity (“CMN”), from the attending/referring practitioner.

• Billing Practices

Before a claim is submitted to a third-party payer, employees should verify that all applicable policies and procedures of the company and the third-party payer have been followed. Employees should review the payer’s coverage requirements and ensure that the company has received the necessary documentation.

• Medical Records Documentation

Medical records documentation should meet the requirements of all applicable laws, regulations, accreditation standards, and Medicare quality standards. When payment is made by a third-party payer, medical records documentation should reflect the standards or requirements of the third-party payer or its outside review agents.
• **Company Property**

Company property should be used to conduct legitimate company business and other company activities. Employees and agents should not use company property for personal reasons except as permitted by company policies and procedures or otherwise approved in advance by the employee’s supervisor.

• **Marketing**

Advertising, marketing and promotional materials should not contain any unfair, inaccurate, or deceptive statements or any exaggerated or unwarranted representations. Employees and agents should not use any advertising, promotional, or other tactics or materials that unfairly undermine the products or services of a competitor.

• **Education and Training**

Training for employees should be conducted on a regular basis.

• **Investigations and Corrective Action**

The Compliance Officer will investigate complaints and other information (including audit results) that suggest violation of law, regulation, or policy, in order to (i) identify the individuals involved, (ii) determine appropriate corrective action, (iii) implement those procedures necessary to ensure future compliance, (iv) protect the company in the event of civil or criminal enforcement actions, and (v) preserve and protect the company’s assets.

The “Enforcement and Discipline” section of the Corporate Compliance Manual should include the following provisions:

• **Persons Subject to Action**

Disciplinary action, including suspension and termination, may be taken against any person who: authorizes or participates, directly or indirectly, in any action that constitutes a violation of applicable laws, regulations, or company policies; fails to promptly report any violation of company policy or applicable laws and any situations where conduct may constitute such a violation (collectively, a “Compliance Incident”), or withholds information concerning a Compliance Incident of which the employee or agent becomes aware; supervises a person involved in a Compliance Incident to the extent that the circumstances reflect inadequate supervision or lack of appropriate diligence by the supervisor; attempts to retaliate or participates in retaliation, directly or indirectly, against a person who in good faith reports a Compliance Incident or a person who encourages others to report a Compliance Incident; makes a report of a Compliance Incident which he or she knows (or should know) is false or misleading; or fails to cooperate fully with company efforts to investigate or otherwise address a Compliance Incident.
• Consideration

Imposition of disciplinary action is at the sole discretion of the company and will be made based on consideration of all of the relevant facts and circumstances of a particular situation, including whether a person involved in a Compliance Incident promptly reported the matter, the degree of the person’s cooperation and the nature of the person’s conduct. However, employees and agents are required to promptly report Compliance Incidents and to cooperate with the company in addressing such matters, and the fact that a person fulfills these obligations will not insulate the person from disciplinary action.

• Criminal Activity

If criminal activity or possible criminal activity is undertaken by any employee or agent, the Compliance Officer will undertake the following steps: (i) immediately stop the conduct forming the basis of the problem until such time as the offending practices are corrected; (ii) initiate appropriate disciplinary action against the person or persons whose conduct appears to have been intentional, willfully indifferent or with reckless disregard for legal requirements; appropriate disciplinary action includes, at a minimum, the removal of the person from any position with the oversight for or impact upon the claims submission or billing process and may include suspension, demotion, and termination; (iii) in consultation with legal counsel, the company will make appropriate notifications to the proper government officials; and (iv) promptly undertake a program of education at the appropriate department level, division level or facility to prevent similar problems.

The “Compliance Program Operations” section of the Corporate Compliance Manual should include the following provisions:

• Corporate Compliance Officer

The Compliance Officer is a member of the Corporate Compliance Department. He/she reports to both the CEO and to the Chairman of the Board of Directors.

• Corporate Compliance Department

The Corporate Compliance Department consists of the Compliance Officer, Director of Corporate Compliance and the Chief Operating Officer. The duties of the Corporate Compliance Department include: updating this manual; developing and modifying policies and procedures; ensuring that the company personnel receive appropriate training regarding the compliance plan and other policies and procedures; monitoring the regulatory environment within which the company operates; evaluating practices, policies and procedures of current risk areas and identification of new risk areas and appropriate new policies and procedures; recommending and monitoring internal systems of controls; monitoring internal and external investigations and overseeing corrective and preventive actions; evaluating appropriate activities that are designed to promote awareness of the corporate compliance program with particular emphasis on detecting and reporting
potential problems and violations; receiving evaluation and responding to complaints and problems with the Corporate Compliance Program; and other duties as delegated by the Compliance Officer.

- **Officer Reports**

  The Compliance Officer will report to the Board of Directors as appropriate, but not less than quarterly, on the activity and effectiveness of the Corporate Compliance Program. The Compliance Officer will also submit a written annual report on the status of compliance within the company that addresses any recommendations resulting from the prior year’s audit work and any other information requested by the Board of Directors.

The “Policies” section of the Corporate Compliance Manual should include the following (note that these are only brief descriptions of the policies; the actual policies are much longer):

1) **Auditing**

   To assure compliance with law and policy, the corporate compliance department will perform regularly scheduled audits on a quarterly basis, as well as periodic targeted audits as directed by the Compliance Officer.

2) **Background Screening**

   The Human Resource Officer, through the use of a third party vendor ("Background Check Company") will make reasonable inquiry into the background of prospective employees and agents who exercise substantial supervisory authority or who exercise substantial discretion within or on behalf of the company.

3) **CMNs and DIFs**

   A Certificate of Medical Necessity ("CMN") must be completed by the patient’s physician, the physician’s staff, or other authorized clinician in order to obtain Medicare reimbursement.

   The DME Information Form ("DIF") may be completed by the company. Employees should contact the patient’s physician or authorized person if there is any question regarding the information requested on the DIF.

4) **Claim Review**

   The company will not submit a claim to any payer until it has been reviewed and approved for completeness and accuracy. In addition, supporting documentation should be reviewed to assure that the items or services have been provided to the patient.
5) **Conflict of Interest**

Employees are required to properly report any actual or potential Conflict of Interest to the Compliance Officer. When reporting an actual or potential conflict, employees must truthfully disclose all relevant facts and circumstances.

6) **Electronic Surveillance**

The company will not use any electronic, mechanical or other device to intercept the contents of any telegraphic, telephonic, facsimile, modem-transmitted or other electronic communication, unless both of the parties to the communication consent to the interception.

7) **Enforcement**

Imposition of disciplinary action is at the sole discretion of the company and will be made based on consideration of all of the relevant facts and circumstances of a particular situation, including whether a person involved in a Compliance Incident promptly reported the matter, the degree of the person’s cooperation and the nature of the person’s conduct.

8) **False Statements**

It is improper for an employee or agent to make false statements or conceal material facts in any communication with company representatives in connection with the conduct of company business or other activities, including employment or employee benefit applications and any other reports or filings.

9) **HCPCS Coding**

The HCPCS code that most accurately describes the item provided or service rendered will be used on all bills. Intentional up coding is a violation of the law and will not be tolerated.

10) **Improper Payments**

An Improper Payment is defined as cash or anything of value, including goods and services received or used for any unlawful or improper purpose of payment, including bribes, kickbacks, payoffs or any other payment made in violation of applicable laws or regulations for any other improper purpose.

11) **Internal Reporting**

All employees and agents are required to report any information that leads them to suspect any violation of company policy or applicable laws and any situations where
proposed conduct may constitute such a violation (collectively, a “Compliance Incident”). Failure to report a Compliance Incident is a violation of company policy and will subject an employee or agent to disciplinary action, up to and including termination.

12) **Investigations**

All Compliance Incident reports received by any employee or agent will be forwarded to the Compliance Officer. The Compliance Officer will prepare a Compliance Report Form to be submitted to the Executive Team. The Compliance Officer will direct the initial investigation of the alleged problem or incident as soon as reasonably possible and in any event within ten days following the receipt of the complaint or report.

13) **Marketing**

A number of laws and regulations directly address marketing by Medicare providers and suppliers, including the Medicare anti-kickback statute, the Stark physician self-referral statute, the telephone solicitation statute, and the beneficiary inducement statute. Additionally, the OIG has published fraud alerts, advisory bulletins, and advisory opinions that address marketing. Vigilance with regard to marketing activities in all areas of the business is important to the company.

14) **Medical Necessity**

Payers will only pay for items and services that are: 1) medically necessary; 2) ordered by the patient’s treating physician or other authorized person; 3) covered items or services; 4) provided to the patient; and 5) meet criteria established by appropriate payer policy.

15) **Medicare Assignment**

For those items for which the company accepts Medicare assignment, Medicare patients will not be charged more than the amount allowed under the Medicare fee schedule, including patient coinsurance and deductibles.

16) **Payment Likely to be Denied**

If the company believes that payment for items or services will be denied by Medicare, the patient will be informed (prior to providing an item or service) that the item may be denied and that he/she may be responsible for the charges. The company will issue an Advance Beneficiary Notice (“ABN”) each time it makes the determination that Medicare payment will likely not be made because the item or service is not medically necessary.
17) **Physician Orders**

The company will not bill for any item or service unless it has been ordered by the patient’s physician or other authorized person. Such physician orders must be in writing. Verbal orders must be documented and confirmed in writing prior to billing for the item or service.

18) **Purchase Contracts**

The company actively pursues contracts with manufacturers and distributors that will enable it to meet its customers' individual and collective needs in the most efficient and affordable manner. The fulfillment of any obligations that may be placed on the company requires a complete understanding of what is required. Therefore, the Corporate Compliance Committee, or its designee, will investigate and obtain a thorough understanding of all of its obligations under each such contact it enters into. In addition, the company will fully comply with the terms of the contract and will take reasonable actions to assure itself that the contract does not violate any law or regulation.

19) **Record Retention**

The Corporate Compliance Department will ensure that records are retained in accordance with the Record Retention Guidelines set forth in this policy. In addition to the designated period under the Record Retention Guidelines, all records will be retained until any pending federal or state audits are completed.

20) **Training**

The Human Resource Officer will document the training provided to each employee. The documentation will include the name and position of the employee and agent, the date and duration of the educational activity or program, and a brief description of the subject matter of the education. New employees will be required by the Human Resource Officer to sign a statement certifying that they have received, read, understood, and will abide by the standards of conduct.

**The CEO Should Not Serve as the DME Supplier’s Compliance Officer**

There is not a great deal of formal guidance concerning the choice of a compliance officer. The Federal Sentencing Guidelines Manual states that "high-level personnel" should have overall responsibility for the compliance program, but makes no recommendations about what positions may appropriately be combined with the compliance officer role.

The Office of Inspector General, in its Compliance Program Guidance for Home Health Agencies, states, "Designating a compliance officer with the appropriate authority is critical to the success of the program, necessitating the appointment of a high-level official in the home health agency with direct access to the home health agency’s president or CEO, governing body, all other senior management, and legal counsel." Almost identical language appears in OIG
Compliance Program Guidance documents for other kinds of health care providers. In a footnote (which also appears in other CPG documents), the OIG states:

The OIG believes that it is not advisable for the compliance function to be subordinate to the home health agency’s general counsel, or comptroller or similar home health agency financial officer. Free standing compliance functions help to ensure independent and objective legal reviews and financial analyses of the institution’s compliance efforts and activities. By separating the compliance function from the key management positions of general counsel or chief financial officer (where the size and structure of the home health agency make this a feasible option), a system of checks and balances is established to more effectively achieve the goals of the compliance program.

The OIG adds, "When a compliance officer has other duties, the other duties should not be in conflict with the compliance goals ... E.g., companies should not choose a sales manager who may be pressured to achieve high sales, which might result in a conflict with compliance goals."

The CEO has the advantages of freedom of action and full access to company records and personnel, and has the authority to require conformity with compliance policies. However, there are at least two substantial arguments against assigning the compliance officer role to the CEO. The first is simply that the CEO may not be able to commit sufficient time to the role to be really effective as a compliance officer. The provider may not necessarily need a full-time compliance officer. However, it does need someone who can spend a large part of his or her time on compliance and, equally important, who can give compliance matters precedence over his or her other responsibilities when necessary. The CEO cannot have compliance at the top of his or her priority list all the time.

The more important reason why the roles of CEO and compliance officer should not be combined is that there are inherent conflicts between the two roles. The compliance officer is required to be independent and objective, acting in some ways as an outsider with respect to the company. The CEO, as the insider who oversees the activities of all of the other insiders, is unsuited for this role. The CEO is responsible for the financial performance of the company, and in that respect is somewhat like the sales manager mentioned in the OIG compliance guidance. Vigorous compliance enforcement may have a negative effect on financial performance in the short term. It may also reveal problems of which the CEO should have been aware. Any compliance issue that comes to light involving activities that took place on the CEO's watch may call the CEO's performance into question. The compliance officer may be required to report to the board that the CEO has failed to exercise adequate oversight of his or her subordinates, or even that the CEO has been complicit in improper activities. It is not realistic to expect the CEO to be objective in investigating and reporting on his or her own performance.

If the CEO is also a significant shareholder in the company, discovery and disclosure of compliance problems may have a direct negative impact on his or her financial status.
Finally, when a compliance issue is discovered, the CEO is usually the person who must decide how the company will respond. Especially if the issue is not black-and-white, this responsibility often requires a balancing of legal and business risks that is foreign to the role of the compliance officer. A CEO who is also a compliance officer would have to ignore other business considerations while investigating potential issues, but would have to take those issues into account in making a decision about responding.

On balance, these considerations weigh strongly against combining the roles of CEO and compliance officer.

**Administrative Appeals Process**

Post-payment audits (by DME MACs, ZPICs, and RACs) are a permanent part of the DME industry. Regardless of how thorough the DME supplier’s patient files are, the chances of winning at the audit stage are small. This is because the auditor is looking for a reason to deny a claim and demand a repayment. As a result, if subjected to an audit, the DME supplier can expect to traverse the various administrative appeal stages.

**Part One – Redetermination – First Level of Appeal**

The first level of appeal is the redetermination level. A redetermination is an independent review of the claim by someone who was not involved in the initial review. It is an “on the record” review, so you will need to present your argument on paper. It is important that your appeal be organized and succinct. The reviewer has a limited amount of time to spend on each claim. A supplier must submit everything necessary to prove medical necessity but be careful about submitting documentation that is not relevant, as it will distract the reviewer, making it harder for the reviewer to locate the relevant information. In addition to relevant documentation, a supplier should provide a summary of the medical necessity, noting specific documentation that supports medical necessity. If the supplier has a clinician on staff, it is recommended that the clinician be involved in writing the patient summary.

A supplier has 120 days from the date it received the initial determination to file a request for redetermination. CMS presumes that the notice is received five days from the date of notice, unless there is evidence to the contrary. All suppliers need to have some sort of tickler system in place to ensure that a request is filed in a timely manner. If the request is not received timely, it will not be heard and the overpayment demand will stand. A supplier should calendar the deadline to be 120 days from the date of the letter. This will create a little bit of a grace period in the case of some problem in getting the appeal filed.

It is strongly suggested that a supplier not wait until the last minute to file an appeal. This is even more important in the case of a post-payment demand if the supplier wants to avoid recoupment. Filing of the appeal will stop the DME MAC from recouping through the second level of appeal or the reconsideration decision. However, to stop recoupment, a redetermination request should be filed within 30 days or offsets will begin taking place on the 41st day. If a
request is filed between days 30 and 120 once the request is processed, offsets will cease, but any amounts already collected will not be returned.

The request for redetermination must be in writing and filed with the DME MAC. CMS states the preferred method for filing a request for redetermination is on a standard CMS form (Form CMS-20027), but other written requests will be accepted if they contain all of the following:

- The beneficiary’s name.
- The Medicare health insurance claim number.
- Specific item(s) and/or service(s) and the applicable date(s) of service.
- The name and signature of the supplier or the supplier’s representative.

If even one required element is missing, the appeal will be dismissed.

The redetermination is an independent, critical examination of a claim by contractor personnel who was not involved in the initial determination. The reviewer must obtain and review all available, relevant information needed to make a determination. Such information must be included in the case file, and the case file must be made available for inspection by an appellant (i.e., the supplier who is appealing) or party upon request.

The redetermination decision must be mailed to the supplier within 60 days of the date the DME MAC received the request for redetermination. This 60-day period is extended by 14 days each time the supplier submits additional evidence after filing the request for redetermination, even if the evidence is submitted at the request of the reviewer.

The DME MAC may dismiss a request for redetermination for a number of reasons, including, if:

- The supplier gives written notice withdrawing the request for redetermination;
- The party requesting the redetermination is not a proper party or is not entitled to a redetermination;
- The request for redetermination was not timely filed and the contractor did not find good cause for such failure;
- The request for redetermination was submitted by a representative, but the representative has not been properly appointed; or
- The redetermination request was not valid (i.e., did not have the required elements).

A supplier may appeal a dismissal of a redetermination to the Qualified Independent Contractor (QIC) by filing a request for reconsideration by the QIC within 60 days of the dismissal. A supplier may also request the contractor vacate its dismissal within six months of the date of mailing of the dismissal notice if the supplier can show good and sufficient cause.
Part Two – Reconsideration – Second Level of Appeal

If a supplier disagrees with the redetermination decision, it has 180 days from the date the supplier received the redetermination decision to file a request for reconsideration. The QIC reconsideration consists of an independent review. Like the redetermination review, a reconsideration review is based solely on the written record. QICs must follow national coverage determinations, CMS rulings, and applicable laws and regulations.

The request for reconsideration must be received by the QIC within the 180-day period. If the request is even one day late, it will not be considered and the overpayment demand will stand. To stay recoupment, a request for reconsideration should be filed within 60 days of the date of the redetermination decision.

The request for reconsideration must be in writing and filed with the QIC. The request may be on a standard CMS form (CMS-20033), the form included with the redetermination decision, or another writing (e.g., a letter). If the request is made in a letter, the letter must contain all of the following:

• Beneficiary’s name;
• Beneficiary’s Medicare health insurance claim number;
• The specific service and item and date of service for which reconsideration is requested;
• The name and signature of the party making the request or the party’s representative; and
• The name of the contractor who made the redetermination.

Also, the supplier should explain why it disagrees with the initial determination and redetermination and present any additional evidence and arguments of fact or law.

When the QIC receives a request for reconsideration, it will request the case file from the DME MAC. It is very important to know that evidence not submitted to the QIC will not be considered at an ALJ hearing or further appeal unless good cause is shown as to why the evidence was not previously provided. Therefore, all relevant information proving the supplier’s case should be submitted to the QIC. Every level of review is what is considered a de novo review, meaning it is a new and independent review of the claim. So, even if a specific requirement was not questioned at a lower level, you should provide all information that supports the medical necessity of the claim. You never know what will catch the eye of the reviewer.

Within 60 days of receiving a request for reconsideration, the QIC must:

• Issue a written decision; or
• Provide the supplier with a statement advising that it is unable to complete its review within the 60-day time frame and provide reasons why it could not complete the review during that time frame in accordance with the rule.
If a supplier files a timely request for reconsideration to the QIC and the QIC has not made a decision within the 60-day period, then the supplier may send a written request to the QIC to escalate the appeal to the ALJ. Within five days of receiving a request for escalation, the QIC must either issue the reconsideration decision and notify all of the parties of its decision or acknowledge the escalation notice in writing and forward the case file to the ALJ hearing office.

Part Three – ALJ Hearing – Third Level of Appeal

A supplier that disagrees with the QIC’s reconsideration decision may request an ALJ hearing. This is the first time a supplier actually gets to talk to an individual and present its case on the claim. The supplier must file a written request for an ALJ hearing within 60 days after receipt of the QIC’s reconsideration decision. The supplier must also send a copy of the request to all other parties.

Recoupment is allowed during the ALJ process. If the overpayment demand is large and the DME supplier cannot afford to have the overpayment recouped, then the supplier should enter into a payment arrangement with the DME MAC while the supplier proceeds through the ALJ stage.

To qualify for an ALJ appeal, the amount in controversy must be greater than or equal to $120. The request must be made in writing and include all of the following:

- The name, address, and Medicare health insurance claim number of the beneficiary whose claim is being appealed;
- The name and address of the appellant, when the appellant is not the beneficiary;
- The name and address of the designated representative, if any;
- The document control number assigned to the appeal by the QIC, if any;
- The dates of service;
- The reasons the appellant disagrees with the QIC’s reconsideration or other determination being appealed; and
- A statement of any additional evidence to be submitted and the date it will be submitted.

The ALJ may conduct an oral hearing by video-teleconferencing, if such technology is available, or by telephone (which is often the case) if the request for hearing shows that a telephone hearing may be more convenient for one or more parties. An in-person hearing will be conducted if video-teleconferencing technology is not available or other special or extraordinary circumstances exist.

The ALJ sends a notice of hearing. The notice will contain a proposed time and place of hearing, and require all parties to reply to the notice by (1) acknowledging whether they plan to attend the hearing at the time and place proposed in the notice of hearing or (2) objecting to the proposed time or place of the hearing.

Any evidence that was not submitted prior to the issuance of the QIC’s reconsideration decision must be accompanied by a statement explaining why the evidence was not previously
submitted. The ALJ will examine the new evidence and determine whether the supplier had good cause for submitting the evidence for the first time at the ALJ level. If good cause does not exist, the ALJ will exclude the evidence from the proceeding and will not consider the evidence in reaching his or her decision.

Part Four – Review by the Medicare Appeals Council (MAC)/Judicial Review

Medicare Appeal Council

A supplier dissatisfied with an ALJ decision may file a written request for a MAC review within 60 days after receiving the ALJ decision (or dismissal). The final level of administrative appeal is a review by the MAC. The MAC may also decide on its own to review an ALJ decision or dismissal. CMS may also refer a case to the MAC for the MAC to consider reviewing it on its own within 60 days of the ALJ decision. A supplier may file objections to CMS’s referral to the MAC within 20 days of the referral notice.

For most cases, suppliers should pursue all appeals at least though the ALJ level. A determination of medical necessity can be very subjective and different reviewers may see the documentation more favorable and allow the claim. Whether or not to pursue a MAC appeal should be decided based on the facts of the claim at issue, and not all claims are appropriate for appeal at this level.

A request for MAC review must be filed in writing to the MAC and be made either on a standard form or other writing. Such other writing must include the following to be accepted:

- Beneficiary’s name;
- Medicare health insurance claim number;
- The specific service(s) or item(s) for which the review is requested;
- The specific date(s) of service;
- The date of the ALJ’s decision or dismissal order, if any;
- If the party is requesting escalation from the ALJ to the MAC, the hearing office in which the appellant's request for hearing is pending;
- The name and signature of the party or the representative of the party;
- And any other information CMS may decide.

The request for MAC review must identify the parts of the ALJ decision with which the appellant disagrees and explain why it disagrees with the ALJ decision. The MAC will limit its review to those exceptions raised by the request for review, unless the appellant is an unrepresented beneficiary. The MAC will give, upon request, a reasonable opportunity to file briefs or other written statements about the facts and law relevant to the case. The MAC will only consider the evidence contained in the ALJ’s record, unless the ALJ decision contained new issues that the parties did not have a chance to address. If the MAC determines that additional evidence is needed to resolve the issues in the case and the hearing record indicates that the previous decision-makers (QIC, ALJ, etc.) have not attempted to obtain the evidence, the MAC may remand the case to an ALJ to obtain the evidence and issue a new decision.
If new evidence related to issues previously considered by the QIC is submitted to the MAC by a supplier, the MAC must determine if the supplier had good cause for submitting it for the first time at the MAC level. If not, the MAC will exclude the evidence. When the MAC excludes evidence, it must give notice thereof to all parties. The MAC may, either on its own or upon request, issue a subpoena for evidence that is material to an issue at the hearing, but may not issue such subpoena to CMS or its contractors. The MAC generally decides a case from the record. However, the MAC may grant a party’s request to present oral arguments if it decides that the case raises an important question of law, policy, or fact that cannot be readily decided based on written submissions alone. If the MAC decides on its own that oral argument is necessary, it will give the parties notice of the time and place for oral argument at least 10 days prior to the scheduled date.

Judicial Review

A supplier may request court review of the MAC decision by filing a complaint (i.e., lawsuit) with the U.S. District Court. The complaint must be filed within 60 days after the date the supplier receives notice of the MAC’s decision. To qualify for judicial review, the amount in controversy must be greater than or equal to $1,220. This is typically a very expensive process and few cases are actually filed in federal court for this reason.

How a Federal Prosecutor Thinks

Qui Tam Lawsuits

Many investigations are a result of a qui tam (whistleblower) lawsuit. This is when a disgruntled ex-employee, or disgruntled current employee, files a federal lawsuit against the DME supplier. The lawsuit will be in the name of the current/ex employee ("relator") and in the name of the U.S. The qui tam lawsuit will be based on the federal False Claims Act ("FCA"). It is the position of the DOJ that if the DME supplier commits an act that violates any law (civil or criminal), and if the supplier eventually submits a claim to a government health care program (in which the claim directly or indirectly is related to the acts), then the claim is a "false claim."

Under the FCA the DME supplier (and its individual owner) can be liable for actual damages, treble damages, and between $5500 to $11,000 per claim. The qui tam lawsuit will go "under seal," meaning that nobody (except for the DOJ) will know about it. An Assistant U.S. Attorney (in the jurisdiction in which the qui tam is filed) will review the lawsuit and will ask investigative agents (FBI, OIG) to investigate the allegations set out in the qui tam suit.

The agents may talk to other current or ex-employees. The agents may talk to patients and referring physicians. The agents may talk to others who may have information regarding the allegations set out in the qui tam. After they conduct their investigation (which may take up to a year), then the AUSA will decide whether or not to "intervene." By "intervening," the AUSA will take the lawsuit over and the relator's attorney can sit on the sidelines.
Assume that the AUSA intervenes. When this happens, then the DME supplier will be made aware of the existence of the qui tam. A qui tam is a civil lawsuit. If the DME supplier is found to be liable, then it can be required to pay money and enter into a Corporate Integrity Agreement. An owner or officer of the DME supplier may be "excluded" from participating in a government health care program.

Here is where things can get to be a bit scary. The AUSA may open up a "parallel criminal file." The purpose of the criminal file is to determine if any of the DME supplier's acts constitute a crime. This is when a person can end up serving some time in "Club Fed." In fact, many criminal cases brought against DME suppliers result from qui tam lawsuits. The reason for this is because the DOJ has limited the resources to "look for" fraud. There are only approximately 93 U.S. Attorney's Offices throughout the U.S. Each office has a politically-appointed U.S. Attorney and then has multiple AUSAs. Some AUSAs handle drug cases; others handle violent crime; others handle human trafficking; others handle financial institution crime; others handle health care fraud; and so on and so forth. In short, the DOJ does not have limited resources to go "seek out" health care fraud.

And so this is where qui tams come in. Essentially, the DOJ has "outsourced" or "subcontracted out" the "seeking out" of health care fraud to private citizens: disgruntled ex and current employees. The take-away is that the DME supplier lives in a glass house. The DME supplier cannot hide anything. Truth will always bubble to the surface. If the DME supplier is doing something it should not be doing, then an employee knows about it.

If the DME supplier ends up settling with the DOJ, and paying a great deal of money, then the qui tam relator will end up receiving between 15% to 20% of the proceeds. Considering the large amount of money that can be collected under the FCA, this provides a large incentive for disgruntled ex or current employees to bring qui tams.

Prosecutorial Discretion

Federal anti-fraud laws are broad and somewhat vague. An Assistant United States Attorney ("AUSA") can compare acts of a DME supplier to a law and conclude that the law has been violated. Conversely, a defense attorney can look at the same set of facts, and the same law, and conclude otherwise. Unfortunately, the AUSA has unlimited resources and time and can make life miserable for a DME supplier if the AUSA chooses to do so. The take-away is that the AUSA has a great deal of "prosecutorial discretion."

Even if a target of a federal investigation (civil or criminal) believes that it has done nothing wrong, then it will nevertheless likely choose to reach a settlement (civil case) or plea (criminal case) because the risk of going to trial is too high. The vast majority of criminal cases that go to trial result in a conviction. The reason for this is because the statute is so broadly worded, it is easy to violate it. Plus, a typical indictment will include everything but the kitchen sink. For example, the indictment may contain 75 separate "counts," any one of which can result in a prison term of five years. A common approach of an AUSA is to threaten to bring a multi-count indictment (e.g., 75 counts) but offer to drop all but one count if the target will plead to the
one count. Even though the target may not want to do so, it may not want to run the risk of going to trial. The same approach holds true with civil False Claims Act ("FCA") cases. The target may believe that it owes no money, but will be inclined to pay money in order to avoid the catastrophic damages under the FCA.

How to Avoid Being a Target

The DME supplier needs to understand the principle that in fraud and abuse land, there is no such thing as a technical loophole. It is substance over form. If your head tells you one thing, and your stomach tells you something else, then ignore your head and trust your stomach. If it “looks like a duck, walks like a duck.....” You choose the metaphor. Understand the principle that the supplier “lives in a glass house.” Understand the principle that if the supplier is doing something wrong, then someone knows about it.

It is important that the DME supplier implement a functioning corporate compliance plan ("CCP"). A CCP is an approximate 50 page document that summarizes the most important anti-fraud laws and sets out procedures that will help the DME supplier avoid violating such laws. As part of the CCP, the supplier will need to continually train its employees regarding compliance with anti-fraud laws. The supplier needs to appoint a dedicated, and thick skinned, corporate compliance officer ("CCO"). For a large DME supplier, the CCO can be dedicated to only being the CCO. For a smaller DME supplier, the CCO can wear several hats. Normally, the CCO is not an attorney. The main job of the CCO is to be the “canary in the mine shaft.” The CCO does not have to know all of the nuances of the anti-fraud laws, but needs to know enough to have a Pavlovian reaction when he sees something that he does not like.

The principle benefit of having a CCO is that there is a person in the organization who is focusing on the various anti-fraud laws. As mentioned earlier, the CCO needs to have “thick skin.” By that we mean that he/she needs to be able to go “nose to nose” with the supplier’s CEO and say: “No, we cannot do what you want to do.” In addition, the CCO needs to be a “safe person” for employees to go to if they believe that the supplier is doing things it should not be doing. Often, fraudulent activities are discovered by rank and file employees. The DME supplier would much rather have the employee go to the CCO than go to a qui tam attorney. The DME supplier needs to investigate the concern raised by the employee. If the employee’s concern is well founded, then the CCO needs to report back to the employee, thank him/her, and explain what corrective steps the supplier is taking. Conversely, if the facts show that the supplier has done nothing wrong, the CCO needs to report back to the employee, thank him/her, and explain why the supplier’s actions are proper.

Use an Experienced Health Care Attorney

While the DME supplier can use its local attorney for day-to-day business matters, the supplier needs to also have a relationship with an experienced health care attorney who has the ability to instantly recognize kickback, Stark, inducement, and false claims issues. By bouncing ideas off of a health care attorney, the DME supplier can avoid problems down the road.
Signs that the Supplier is a Target

The DOJ will normally not let the supplier know that it is a target until the investigation is substantially completed. The DOJ will likely have obtained records (e.g., claims submissions) from DME MACs and other CMS contractors. The investigative agents (FBI, OIG) will interview ex-employees, current employees, patients and physicians. Normally, one of these interviewees will tell the DME supplier of the interview.

Responsive Steps

When an employee tells the supplier that the employee has been interviewed, it is appropriate for the supplier to ask the employee about what the investigator said. It is appropriate for the supplier to ask the employee for the name and contact information for the interviewing agent. The employee has the right to disclose.....or not to disclose......this information to the supplier. Let's say that the DME supplier becomes aware that an employee will be interviewed. The only advice the supplier can tell the employee is to tell the truth. It is appropriate for the supplier to ask the employee to brief the supplier after the interview takes place. The employee has the right to agree....or not agree.....to the supplier's request.

The supplier should preserve all documents, e-mails etc. (electronic and hard copy). As a general rule (there are exceptions), the supplier should be transparent with its employees. The supplier can tell the employees about the existence of the investigation, that the supplier has hired an attorney to represent it, and that the supplier will cooperate with the investigation. The supplier can tell its employees that they may be interviewed and if they are, then simply tell the truth. The supplier can tell the employees that if they feel comfortable in briefing the supplier after the interview, then the supplier would appreciate it. However, the supplier should emphasize that the employees have no obligation to brief the supplier. As soon as the DME supplier finds out of the existence of an investigation, then the supplier should hire an experienced health care attorney.

Assume that the supplier obtains the names and contact information regarding the investigating agents. The attorney should contact the agents and ask for the name and contact information of the AUSA that is supervising the investigation. The attorney should then contact the AUSA, inform the AUSA that the attorney represents the supplier, and start a dialogue with the AUSA. Remember what I said about prosecutorial discretion. The AUSA has much more power than the defense attorney has. And so here is another take-away: do not anger the AUSA. It is important that the AUSA trust the DME supplier's attorney. Such trust can prevent a seizure action from occurring (more on this later). Such trust can result in an orderly "rolling" production of documents and information to the AUSA. If the AUSA believes that the supplier, and the supplier's attorney, are being honest and transparent, then the odds are that the AUSA will be open to a resolution that the supplier can live with.
Seizure Action

The DME supplier should back up its data system off-site. In the event of a seizure action, then the supplier will not be shut down. A seizure action is when the AUSA obtains a Search Warrant from a Federal Magistrate. Normally, the AUSA will ask for a Search Warrant if the AUSA is given information that the supplier may hide or destroy files. The seizure action is intended to "preserve the evidence" so that the DOJ and OIG can look at it.

In a typical seizure action, multiple agents (FBI, OIG, IRS) will enter the premises unannounced and instruct the employees to "move away from their keyboards." The agents will take the computers and hard copy documents. If the supplier does not have its documents backed up off-site then the supplier will be essentially shut down. The agents may attempt to talk to the employees. The employees have the right to talk, or not to talk, to the agents.

Normally, the DOJ will, at the supplier's expense, make copies of everything taken (electronic and hard copy) and give the copies to the supplier. However, this can take several weeks to accomplish. Hence, the importance of having documents backed up off-site. When the agents first walk through the door, the DME supplier should call its health care attorney so that the attorney can give proper guidance. Normally, the attorney will talk to the lead agent. The lead agent will give to the attorney the name and contact information of the supervising AUSA. The attorney can then call the AUSA, arrange to have copies (of the seized documents) made, and start a dialogue.

Resolution of Civil Proceeding

Assume that the AUSA proceeds against the DME supplier civilly. In other words, the AUSA does not want to put anybody in jail. The damages, fines and penalties under the FCA far exceed what the supplier can pay. And so the supplier's attorney and the AUSA will usually enter into an "ability to pay" settlement in which the supplier will pay as much money as it can without forcing it to close its doors. Payment of the money will be made to the DOJ. Separate from that, the supplier will likely be required to enter into a Corporate Integrity Agreement with the OIG. This is normally a five year contract between the supplier and the OIG. The CIA will impose a number of requirements on the supplier, including annual reports to the OIG, training employees, and having an Independent Review Organization audit the supplier's operations on an annual basis.

Resolution of Criminal Proceeding

Assume that the facts, unfortunately, support the AUSA's allegation that a crime has been committed. The case can go in a number of directions. The wisest course of action is for the supplier to work out a plea. In other words, it is normally not wise to go to trial. The supplier should attempt to work out a plea before there is an indictment. An indictment is a public statement by the government of the "bad things" that the supplier has done. It is hard for the government to be lenient after an indictment is issued. If a resolution is worked out before an indictment is issued, then it is worked out "pursuant to a criminal Complaint." This allows the
AUSA to have off-the-record discussions with the supplier's attorney. This, in turn, gives the AUSA substantial flexibility in working out a resolution. A resolution can take a number of paths: (i) plea by the corporation, with no plea by the owner of the corporation; (ii) deferred prosecution plea by the owner (no felony conviction); (iii) felony conviction of the owner with probation; (iv) felony conviction of the owner with home detention; (v) felony conviction of the owner with half-way house; and (vi) felony conviction of the owner in which the federal sentencing guidelines suggest a relatively short prison term (e.g., 11 to 18 months).

**Expanding Into the Retail Market**

There is a “perfect storm” of events that is pushing DME suppliers into the retail market. First, Medicare is limiting what it is willing to pay for health care. Second, there are 78 million “baby boomers” who are retiring at the rate of 10,000 per day. The “boomers” are accustomed to paying their own way and they understand that they will have to pay out-of-pocket for a chunk of their medical services. Third, “boomers” will want to live out their days in their homes…not in a long term care facility. And fourth, “boomers” are accustomed to shopping retail, whether in person or via the internet. This “perfect storm” opens up opportunities for the innovative DME supplier.

For purposes of this section, “retail market” is defined as any market that does not involve the federal or state government as the payer. In the retail market, the payer will be the consumer (out-of-pocket) and commercial insurers. This section will address the many statutory and regulatory issues that the DME supplier must address as it pushes into the retail market. Specifically:

- **Federal Anti-Fraud Statutes, Safe Harbors, OIG Advisory Bulletins, OIG Special Fraud Alerts, and Supplier Standards** – Most DME suppliers that venture into the retail market are also Part B suppliers and they bill Medicare and Medicaid for covered items. When the suppliers move into the cash and commercial insurance market, they nevertheless need to be aware of how federal statutes and regulations have an impact on their retail business. For example, let’s say that ABC Medical Equipment, Inc. enters into a 1099 independent contractor arrangement with John Smith, a marketing rep. Smith generates both commercial and Medicare business for ABC. However, ABC pays commissions to Smith only for the commercial business; ABC pays nothing to Smith for the Medicare business. At first blush, ABC may feel comfortable that it is not violating the Medicare anti-kickback statute. However, the OIG has stated that the commissions being paid for the commercial patients are also rewarding Smith for generating Medicare business……hence, a violation of the anti-kickback statute.

- **State Anti-Fraud Statutes** – All states have anti-fraud statutes. These are similar to their federal counterparts. Some state statutes come into play only when the payer is the state’s Medicaid program. Other state statutes apply even when the payer is a commercial insurer (or the consumer paying cash). Some states specifically incorporate the federal safe harbors while others do not. Look at the example set out in the preceding bullet. Assume that Smith only generates commercial business for ABC. The arrangement will
be acceptable in a state in which its anti-kickback statute only applies when the payer is the state’s Medicaid program. On the other hand, the arrangement will be prohibited in a state in which its anti-kickback statute applies even if the payer is a commercial insurer.

- **Selling Items to Cash-Paying Customers at a Discount off the Medicare Allowable** – Assume that ABC sells Medicare-covered items and takes assignment. Further assume that ABC sells the same items for cash at a discount off the Medicare allowable. In doing this, ABC needs to be aware of the federal statute that prohibits an DME supplier from charging Medicare substantially in excess of the supplier’s usual charges, unless there is good cause.

- **Purchase of Internet Leads** – This is a hot area in terms of enforcement actions brought by the Department of Justice, Office of Inspector General, the NSC and the ZPICs. When purchasing internet leads, it is critical that the DME supplier not violate the Medicare anti-kickback statute. When communicating with leads, it is equally as critical that the supplier not violate the telephone solicitation statute.

- **Tapping into Non-Traditional Payer Sources** – In order to survive, the DME supplier must lessen its dependence on Medicare fee-for-service. This is so for the obvious reasons: competitive bidding, lower reimbursement, stringent documentation requirements, post-payment audits, and prepayment reviews. It is important for the supplier to look for other sources of income: cash sales, long term care facilities, hospices, the V.A., TRICARE, workers compensation, and self-pay employers.

- **Collection of Co-Payments** – At the end of the day, the law requires the DME supplier to make a reasonable effort to collect co-payments, regardless of whether the payer is Medicare or a commercial insurer. Failure to make such a reasonable effort, can expose the supplier to liability under the Medicare anti-kickback statute, state anti-kickback statutes, federal and state inducement statutes, federal and state false claims acts, and state insurance fraud statutes. The same exposure to liability exists if the supplier routinely waives co-payments.

- **Bankruptcy, Estates, Divorce and Other Self-Pay Scenarios** – As the supplier makes a reasonable effort to collect co-payments, the supplier needs to understand the steps it can take in the event that the customer files bankruptcy, dies, becomes disabled, or goes through a divorce.

- **Sales Taxes** – If the DME supplier has a physical presence in a state, and sells products to customers located in that state, then the supplier will be responsible to pay sales taxes. On the other hand, what if the supplier mails products to customers in another state (and the supplier has no connection with that other state other than mailing products into it)? Is the supplier responsible for sales taxes in the state into which the supplier mails products? Will the answer change if the DME supplier has a marketing rep in the state into which the supplier mails products?
• Qualification as a Foreign Corporation – Let’s say that ABC is incorporated in Indiana and ABC mails products into Colorado. In fact, ABC’s only connection with Colorado is that it mails products to Colorado residents. Under the law, ABC is a “foreign” corporation to Colorado. Must ABC “qualify as a foreign corporation” in Colorado? Will the answer change if ABC has some other connection with Colorado, such as having a marketing rep in Colorado?

• Communications with Prospective Customers – Separate and apart from the telephone solicitation statute and Supplier Standard #11, the DME supplier must be aware of, and comply with, FTC and FCC regulations and with the federal “CAN-SPAM Act.” Equally as important, all states have statutes and regulations addressing communicating with potential customers; the supplier must be aware of the state statutes and regulations.

• State Licenses – Even if the DME supplier is selling products to commercial customers, the supplier needs to be aware of state licensure requirements. The NSC posts state licensure requirements on its website. However, the NSC website is not entirely accurate and it is the supplier’s responsibility to confirm each state’s licensure requirements. In many states, as to whether the supplier must obtain a license is determined by the type of product that the supplier will sell.

Waiver of Copayment

Assume that a DME supplier desires to implement a policy entitled, “Collection of Deductibles and Copayments and Economic Hardship Waivers” (“Policy”). Assume that under the proposed Policy, the supplier desires to waive a patient’s copayment if (i) the patient’s family income is less than 400% of the federal poverty guidelines (“FPG”) and (ii) the patient does not have secondary insurance. Assume that the supplier’s experience is that many patients who have family incomes between 200 and 400% of the FPG are unable to afford copayments. Lastly, assume that the supplier takes into consideration the fact that individuals at this income level may qualify for premium assistance under the Patient Protection and Affordable Care Act (“PPACA”).

Applicable Law

Under the Medicare anti-kickback statute, DME suppliers may not “knowingly and willfully offer or pay any remuneration . . . to any person to induce such person . . . to refer” business reimbursable by a federal health care program. The OIG has indicated that routine waivers or reductions of copayments implicate the federal anti-kickback statute. However, DME suppliers do not violate the anti-kickback statute if they waive cost-sharing obligations after the patient has proven a financial hardship.

The OIG has identified procedures that will reduce the risk that a supplier will violate a federal statute. The OIG recommends that suppliers adopt written criteria for determining a patient’s financial need. The OIG has indicated that “[t]he ‘financial need criterion’ is not limited to ‘indigence,’ but can include any reasonable measures of financial hardships . . . [such as] the
local cost of living; a patient’s income, assets, and expenses; a patient’s family size; and the scope and extent of the patient’s medical bills.”

PPACA extends financial assistance to individuals with incomes of 400% of the FPG. Similarly, this income level may be a reasonable measure of financial hardship for purposes of reduced copayments as long as the supplier evaluates the totality of the patient’s circumstances and implements other safeguards to avoid a practice of routinely waiving copayments.

**Premium Assistance under PPACA**

Individuals who meet the following conditions are eligible for premium assistance under PPACA: (1) the individual’s employer does not offer coverage, or coverage offered by the employer is underfunded; (2) the individual is not covered by a federal health care program; and (3) the individual’s modified adjusted income is between 100 and 400% of the FPG. Individuals eligible for premium assistance will receive a subsidy based on their income level.

For those eligible for premium assistance under PPACA, the law establishes the maximum percent of the individual’s modified adjusted income that the individual will have to pay toward the premium of the second lowest cost silver plan. If the cost of the premium for this plan exceeds the maximum percent of an individual’s income identified under PPACA, then the individual may receive financial assistance. For example, assume Mr. Smith’s income for 2014 is $28,735, which is 250% of the federal poverty line. The cost for the second lowest cost silver plan in his area is $5,733. Under PPACA, Mr. Smith may receive financial assistance if the cost of the premium is greater than 8.05% of his income (i.e. $2,313). Therefore, Mr. Smith will receive premium assistance in the amount of $3,420. This is the amount of the premium ($5,733) minus $2,313 (i.e., the limit established under PPACA for Mr. Smith’s income level).

As long as the DME supplier assesses an individual’s ability to pay a copayment in a manner similar to that of PPACA and implements other safeguards against routine waivers, the supplier may consider income at 400% of the applicable FPG eligible for a copayment reduction. In a manner similar to the assessment under PPACA, the supplier should consider the amount of the copayment and all sources of income available to the patient when the supplier determines whether or not to waive or reduce the patient’s copayment. The supplier should also implement other safeguards discussed below to avoid a practice of routinely waiving patients’ cost-sharing obligations.

**Safeguards against Routine Waivers**

To avoid concerns that the supplier may be engaging in a routine business practice of waiving copayments, the supplier may want to implement the following safeguards:

1. The supplier should ensure that its waiver policy reflects the supplier’s actual practices.
2. The supplier should require patients who may qualify for a full or partial waiver to complete and sign the application required under the waiver policy. Furthermore, the supplier should keep the signed applications on file.

3. The supplier should request some form of documentation verifying the application (e.g., a pay stub or W-2) when possible. Moreover, the supplier should require such documentation in the event the supplier has any doubts regarding the validity of information provided on the application.

4. The amounts of the copayment reductions should be granted on a sliding scale that is based upon the patients’ resources. For example, patients with incomes at 100% of the FPG may be eligible for full waivers whereas patients with incomes between 200 and 400% of the FPG may only qualify for partial waivers. The amount of the actual waiver should depend on the particular patient’s resources, and the supplier should attempt to collect some copayment for patients with income levels above 100% of the applicable FPG.

5. The patient’s income level should not be the sole factor considered by the supplier. The supplier should evaluate the totality of the patient’s circumstances to determine whether the copayment is truly a financial hardship for the patient. Therefore, among other items, the supplier should consider the amount of the copayment, resources available to the individual, and the individual’s expenses.

6. The supplier should periodically assess the percentage of its patient population that receives reduced copayments. If the percentage is 10% or greater, then an enforcement authority may allege that the supplier is engaging in a routine business practice of waiving copayments. Accordingly, the supplier will need to take steps to reduce the qualifying percentages for full or partial waivers.

**Waiver of Copayments: Out-of-Network Patients**

An increasing number of commercial insurers are closing their provider panels, thereby not allowing the suppliers to bill the insurers as in-network suppliers. This relegates the out-of-network suppliers to one of two choices: (1) decline to serve the patient or (2) to serve the patient and bill the insurer as an out-of-network supplier. The challenge with billing as an out-of-network supplier is that the patient normally has to pay a higher copayment than if the DME supplier was an in-network supplier. This has led some out-of-network suppliers to offer to waive the patient’s copayment if the patient purchases from the out-of-network supplier. The problem with waiving such copayments is that the out-of-network supplier may be setting itself up for liability.

Insurers sometimes file lawsuits against out-of-network health care providers that routinely waive copayments and deductibles. For example, Aetna has brought suits against providers in California, New Jersey, New York, and Texas. Many of these suits allege breach of contract, unjust enrichment, and fraud. Claims of law fraud allege that providers that waive
copayments submit claims that do not reflect the actual discounted charge and, therefore, materially misrepresent the transaction. Some state regulatory authorities have issued guidance indicating that routine waivers of patients’ cost-sharing obligations constitute fraud.

A number of courts have addressed cases involving out-of-network providers that routinely waived copayments and deductibles. A common claim in these cases is that the provider submits a false or fraudulent claim and overcharges the insurer when the provider bills the insurer the full amount but does not intend to collect the copayment. Several legal scholars have concluded that the non-collection of the patient’s copayment or deductible may be lawful in and of itself, but the intentional or contractual waiver of the obligation to pay the deficiency prior to submitting a claim is, by contrast, unlawful.

In *Kennedy v. Connecticut General Life Insurance Co.*, 924 F.2d 698 (7th Cir. 1991), a chiropractor sued CIGNA because CIGNA refused to pay a claim submitted by the chiropractor who was an out-of-network provider. Under CIGNA’s insurance policy, CIGNA covered 80 percent of medical expenses and the beneficiary was required to pay the remaining 20 percent. When the chiropractor submitted a claim, CIGNA suspected that he did not collect the 20 percent copayment. Therefore, CIGNA requested proof that the claim represented 80 percent of the full amount charged. In the process, CIGNA received information that the chiropractor waived the patient’s copayment. As a result, CIGNA refused to pay the claim and the chiropractor sued. The court ruled in favor of CIGNA. According to the court, if the chiropractor “wishes to receive payment under a plan that requires co-payments, then he must collect those co-payments – or at least leave the patient legally responsible for them.”

In *Feiler v. New Jersey Dental Association*, 467 A.2d 276 (N.J. Super. Ct. Ch. Div. 1983, a dental association sought an injunction against the billing practices of Dr. Melvin Feiler who waived copayments for 97 percent of his patients. Moreover, Dr. Feiler advertised that he would waive copayments. The association claimed that Dr. Feiler’s activities were fraudulent and constituted unfair competition. The court agreed and ordered that Dr. Feiler either bill insurers for the amounts he actually collected or inform insurers of any waivers provided to patients.

A number of state insurance agencies have weighed in on this issue. For example, the New York Department of Insurance has taken the position that the practice of waiving copayments may constitute fraud in the state:

Depending on the circumstances, the waiver of otherwise applicable co-payments could constitute insurance fraud.

If a health care provider, as a general business practice, waives otherwise required co-insurance requirements, that provider may be guilty of insurance fraud... For example, if a health care provider indicates that the charge for a procedure is $100 and the insurer anticipates that the provider will collect a 20% co-payment amount, the insurer will reimburse the insured $80. If, however, the provider waives the co-payment, that provider’s actual charge becomes $80, which then
obligates the insurer, assuming payment at 80% of the usual charge, to reimburse the insured only $64.


In the event a DME supplier accepts the risks associated with waiving copayments for out-of-network patients, then it would be prudent for the out-of-network supplier to notify the insurer that the supplier waived the patient’s cost-sharing responsibility. Such notice may serve as a credible defense against any claim of fraud and deceptive trade practices. However, such notice may cause the insurer to deny the claim.

**HIPAA**

What the DME Supplier Should Know

Under HIPAA’s basic privacy requirement, *covered entities* and their *business associates* may not use or disclose an individual’s protected health information (“PHI”) except with the individual’s consent or as otherwise permitted by HIPAA. A Medicare-enrolled DME supplier that is required to submit claims electronically is a covered entity.

**Fines/Penalties.** Civil fines for HIPAA violations can range between $100 per violation (with an annual maximum of $25,000 for repeat violations) to $50,000 per violation (with an annual maximum of $1.5 million). Criminal liability may be imposed on covered entities and other individuals who “knowingly” obtain or disclose identifiable PHI in violation of privacy laws. Punishment for violation of criminal statutes include fines up to $50,000 and imprisonment up to one year. Offenses committed under false pretenses allow penalties to be increased up to a $100,000 fine and imprisonment up to five years. Offenses committed with the intent to sell, transfer, or use identifiable health information for commercial advantage, personal gain, or malicious harm permit fines of $250,000 and imprisonment for up to ten years. In addition, some covered entities may also be excluded from participation in Medicare.

**No Private Cause of Action.** HIPAA does not create a private cause of action for aggrieved individuals. In other words, an individual who is affected by a HIPAA violation cannot bring suit against the offender under HIPAA. Rather, HIPAA is enforced by the Office of Civil Rights (“OCR”) and CMS.

**Breach Notification.** HIPAA requires covered entities to notify individuals when their unsecured PHI has been *breached*. All breach notifications must be made without unreasonable delay, and in no circumstance more than 60 days after the breach is discovered, unless a law enforcement official determines that notification would impede a criminal investigation or damage national security. A breach is considered discovered on the first day such breach is known or reasonably should have been known to the covered entity, including any employees, officers, or agents.
**Risk Assessment.** HIPAA also requires covered entities to perform a risk assessment to determine if there is a significant risk of harm to the individual as a result of the impermissible use or disclosure of the individual’s PHI. Factors to be considered include: (i) the nature and extent of the PHI involved, including the types of identifiers and the likelihood of re-identification; (ii) the unauthorized person who used the PHI or to whom the disclosure was made; (iii) whether the PHI was actually acquired or viewed and; (iv) the extent to which the risk to the PHI has been mitigated.

If, after performing the risk assessment, a covered entity determines that there is a low probability that the PHI has been compromised, no notification is required. Otherwise, notification of individuals by the covered entity is required. Various methods of notification exist, depending on the number and location of individuals whose PHI has been breached.

**Actual Written Notice.** Actual written notification must be provided to the individuals affected by the breach by first class mail or email. Email is only permissible if the individual has agreed to receive electronic notice. If the affected individual is deceased, notification must be sent to the individual’s next of kin or personal representative if the covered entity knows that the individual is deceased and has the address of the next of kin or personal representative.

Written notifications must be written in plain language and must include the following:

1. A brief description of what happened, including the date of the breach and the date of discovery of the breach, if known;

2. A description of the types of unsecured PHI that were involved (i.e. full name, Social Security number, date of birth, etc.);

3. Any steps individuals should take to protect themselves from potential harm resulting from the breach;

4. A brief description of what the covered entity is doing to investigate the breach, mitigate harm to individuals, and protect against any further breaches; and

5. Contact procedures for individuals to ask questions and obtain additional information, which must include a toll-free telephone number, an email address, website, or postal address.

**Substitute Notice.** If the covered entity does not have sufficient contact information for some or all of the affected individuals or if some notifications are returned as undeliverable, the covered entity must provide substitute notice as soon as reasonably possible after the covered entity is aware that it does not have sufficient contact information. The type of substitute notice depends on the number of individuals the covered entity is unable to contact.
If fewer than 10 individuals cannot be reached through actual written notice, the covered entity must provide substitute notice through alternative forms of written communication, telephone, email, a posting of notice on the covered entity’s website, or other similar means.

If 10 or more individuals cannot be reached via actual written notice, the covered entity must provide substitute notice through either a conspicuous posting on the covered entity’s website home page for 90 days or conspicuous notice in major print or broadcast media in the geographic areas where the affected individuals likely reside. These substitute notices must be reasonably calculated to reach the affected individuals. Additionally, the covered entity must set up a toll-free telephone number, active for 90 days, where individuals can determine if his or her PHI was included in the breach. This toll-free number must be included in the substitute notice.

In cases where the covered entity determines there is imminent danger that the unsecured PHI will be misused, notice by telephone or other means may be made, in addition to the written notice required.

**Notification to the Media.** If 500 or more individuals in any one state or jurisdiction are affected by a breach, in addition to providing written notice as described above, a covered entity must notify prominent media outlets serving the state or jurisdiction without unreasonable delay and in no case more than 60 days after the breach was or reasonably could have been discovered. The notification to the media must include the same information as required in the actual written notice.

**Notification to DHHS.** If more than 500 individuals are affected by a breach, the covered entity must notify DHHS of the breach without unreasonable delay but in no case more than 60 days after the breach is discovered. The notification to DHHS must be provided if more than 500 individuals are affected, regardless of whether the individuals are residents of a particular state or jurisdiction (unlike the notification to the media standard). Information regarding the manner of reporting breaches may be found on the DHHS website. The DHHS website will maintain a list of covered entities that submit reports of breaches involving more than 500 individuals.

If fewer than 500 individuals are affected by a breach, immediate notification does not need to be made to DHHS. However, the covered entity must maintain a log or otherwise document the breach and submit the information annually. The information must be submitted to DHHS no more than 60 days after the end of a calendar year. Again, information on the manner of reporting breaches may be found on the DHHS website.

**Remedial Steps.** If the covered entity suspects a data breach, then it should take remedial steps to mitigate the effects of the suspected data breach and prevent future occurrences, as any breach discovery is also a HIPAA security incident that requires response and reporting. The covered entity’s analysis of its policies and procedures should include the following items:

1. Is there a system or procedure to discover breaches? Does this apply to both the covered entity and its business associates?
2. Has the entire workforce been trained on the need for prompt reporting of privacy and security breaches? Are meaningful sanctions or consequences applied for untimely reporting of breaches? Is documentation maintained of the training and the sanctions?

3. Is there a procedure in place to remediate the cause of the breach, if possible, and demonstrate that it is not likely to re-occur?

Additionally, the covered entity should review its HIPAA forms, policies and procedures to ensure that each satisfies current regulatory requirements and that employees receive initial and refresher HIPAA training as often as necessary to build a culture of compliance.

**HIPAA Marketing Guidelines**

Most suppliers are aware that when implementing a marketing program involving Medicare/Medicaid patients, they need to avoid violating the commonly-known federal anti-fraud statutes: Medicare anti-kickback statute, beneficiary inducement statute, telephone solicitation statute and the Stark physician self-referral statute. In implementing a marketing program, if the DME supplier either complies with the federal anti-fraud laws or avoids servicing patients covered by a federal or state health care program, then the supplier may feel that it is “home free” and can structure the program however the supplier wants to structure it. While it is certainly helpful if the DME supplier does not have to be concerned about federal anti-fraud statutes, the supplier is not entirely out of the woods. The DME supplier needs to be aware of the HIPAA marketing restrictions.

HIPAA requires “covered entities” to obtain a valid authorization from individuals before using or disclosing protected health information (“PHI”) to market a product or service to them. See 45 CFR § 164.508(a)(3). A DME supplier falls within the HIPAA definition of a “covered entity.” PHI is a subset of “individually identifiable health information,” which is defined as (i) information that is a subset of health information, including demographic information collected from an individual, and (ii) is created or received by a health care provider . . . ; and (iii) related to the past, present, or future physical or mental health or condition of any individual, the provision of health care to an individual; and (iv) that identifies the individual; or (v) with respect to which there is a reasonable basis to believe the information could be used to identify the individual. 45 CFR §160.103.

HIPAA broadly defines “use” of PHI to include the sharing, employment, application, utilization, examination, or analysis of such information. 42 CFR § 160.103. The new HIPAA definition of marketing states what is not marketing:

Marketing does not include a communication made: . . . [f]or the following treatment and health care operations purposes, except where the covered entity receives financial remuneration in exchange for making the communication[.] . . . to describe a health-related product or service (or payment for such product or service) that is provided by, or included in a plan of benefits of, the covered entity.
making the communication, including communications about: the entities participating in a health care provider network or health plan network; replacement of, or enhancements to, a health plan; and health-related products or services available only to a health plan enrollee that add value to, but are not part of, a plan of benefits.


Therefore, to avoid HIPAA’s requirement that the DME supplier obtain a valid authorization from the customer before making a marketing communication, the marketing communication must concern a health-related product or service (i) provided by the supplier and (ii) the supplier cannot receive financial remuneration in exchange for making the communication.

Earlier this year, when the Department of Health and Human Services revised the definition of marketing communication, it issued the following comments to the final rule:

We believe Congress intended that these provisions curtail a covered entity’s ability to use the exceptions to the definition of “marketing” in the Privacy Rule to send communications to the individual that are motivated more by commercial gain or other commercial purpose rather than for the purpose of the individual’s health care, despite the communication being about a health-related product or service.

78 Fed. Reg. 5592. HIPAA applies to any patient...no matter how old or how young...and whether the patient is covered by Medicare or commercial insurance. In other words, HIPAA is not limited to Medicare patients. These comments make it clear that a health care provider (including a DME supplier) can only use a patient’s PHI for the medical benefit of the patient. The DME supplier cannot disclose or use the PHI for purposes of marketing (i.e., for the purposes of making money) unless the patient gives a valid prior written authorization for such use or disclosure. In short, when the patient “walks into the provider’s facility,” the patient needs to feel secure that his PHI will only be used for the purpose that it was designed to be used.

Other Hot Button Issues

“Renting Out” a Commercial Insurance Provider Contract

A challenge facing DME suppliers relates to commercial plans that have “closed panels.” For example, ABC Medical Equipment applies to be added to the provider panel for an Insurance Company. However, the Insurance Company informs ABC Medical that the Insurance Company has a sufficient number of DME suppliers on its provider panel. Unless a solution can be found, this places ABC Medical in the unenviable position of having to (i) decline to serve patients covered by the Insurance Company or (ii) serve the patients on an out-of-network basis.
To address this challenge, a number of DME suppliers are turning to the subcontract model. In its most simplistic form, here is how it works: Assume that XYZ Medical Equipment is on the Insurance Company’s provider panel. Assume that Mrs. Smith is covered by the Insurance Company. Under the subcontract model, XYZ Medical will subcontract out to ABC Medical specific responsibilities to take care of Mrs. Smith. XYZ Medical will bill and collect from the Insurance Company and XYZ Medical will, in turn, pay ABC Medical for its subcontract services. On the surface, this looks like a straightforward arrangement. However, as is often the case, the “devil is in the details” and if the subcontract arrangement is set up incorrectly, then ABC Medical and XYZ Medical are exposed to potential liability. Let me explain.

A Medicare Part B supplier number cannot be sold, transferred, or “rented.” Doing so can violate the Medicare anti-kickback statute, the federal False Claims Act, and the supplier standards.

There are similar legal concerns in the commercial insurance space. A commercial insurance contract cannot be “rented.” In other words, XYZ Medical cannot simply allow ABC Medical to “use” the contract that XYZ Medical has with the Insurance Company. If ABC Medical and XYZ Medical want to enter into a bona fide subcontract arrangement, then the issues they need to address are the following:

• Does the provider contract between XYZ Medical and the Insurance Company address whether or not XYZ Medical can subcontract out its services? If so, what does the contract say? Does it simply give the right, without any restrictions, to XYZ Medical to subcontract out its services? Or does the contract allow subcontracting… but only if certain conditions are met?

• If the provider contract says nothing about subcontracting, then do the Insurance Company’s provider guidelines address subcontracting? If the contract and the provider guidelines are silent regarding subcontracting, then it is likely permissible for ABC Medical and XYZ Medical to enter into a subcontract arrangement. However, out of an abundance of caution, it would be wise for XYZ Medical to call the Insurance Company and inquire about subcontracting.

• Assume that ABC Medical and XYZ Medical conclude that subcontracting is allowed. Does XYZ Medical have operational responsibilities and financial risk? Said another way, does XYZ Medical have “skin in the game?” When XYZ Medical submits a claim to the Insurance Company, then XYZ Medical is representing that it is the supplier. As the supplier, XYZ Medical needs to have at least a minimal level of operational responsibilities and financial risk. If ABC Medical completely takes care of Mrs. Smith, and if all that XYZ Medical does is bill and collect from the Insurance Company, then XYZ Medical is not really the supplier; rather, ABC Medical is the supplier. Hence, there is a risk that the Insurance Company will assert that XYZ Medical submitted a fraudulent claim, and that ABC Medical collaborated
in the submission of the fraudulent claim. Additionally, if ABC Medical is generating
the patient and is doing all the work, and if XYZ Medical is pocketing a percentage of
the payment by the Insurance Company, then there is a risk that the arrangement
violates a state anti-kickback statute. Almost all states have an anti-kickback statute
that is similar to the Medicare anti-kickback statute. Some state anti-kickback statutes
apply only if the payer is the state Medicaid program. Other state anti-kickback
statutes apply even if the payer is commercial insurance or is an individual patient
paying cash.

The “take-away” is this: Just because a subcontract arrangement does not involve patients
covered by government health care programs does not mean that the parties can set up a “sham”
subcontract arrangement. A subcontract arrangement requires two parties: a contractor (XYZ
Medical) and a subcontractor (ABC Medical). The contractor needs to have the minimum
operational responsibilities and financial risk necessary for it to credibly hold itself out as the
“supplier.”

Wrong Marketing Practices Can Lead to Payment Suspension

With a “flip of the switch,” a Medicare contractor can immediately bring a supplier to its
knees. For example, the NSC can suspend/revoke a DME Part B supplier number and/or a ZPIC
can instruct the DME MACs to cease paying a supplier. Of course, the DME supplier can appeal
these actions. But even if the supplier wins on appeal nine months later, the damage has been
done……the supplier’s doors are likely closed.

In the past, the question of whether a supplier’s marketing practices were legal fell into
the province of the DOJ/OIG. In the past, the contractors did not look at marketing practices. For
example, in the past, the NSC would look at hours posted and insurance coverage and the DME
MACs and ZPICs would look at documentation. This has changed. Now, the NSC is looking at
marketing practices. In its inspections (scheduled or unscheduled), the NSC may ask if the
supplier’s marketing reps are W2 employees or 1099 independent contractors. The NSC may
inquire if the DME supplier is calling prospective customers who are Medicare beneficiaries.
The ZPIC will ask the same types of questions. A ZPIC investigator may visit (over the phone or
face-to-face) with a DME supplier’s patients and ordering physicians. If the NSC does not like
what it hears, it may suspend/revoke the supplier’s Part B number; if the ZPIC does not like what
it hears, it may instruct the DME MACs to suspend payments.

Here is an example. Recently, a DME supplier received a letter from AdvanceMed that
said, in part: “The purpose of this letter is to notify you of our determination to suspend
Medicare payments to _______…pursuant to 42 C.F.R. 405.371(a)(2)……This suspension is
based on credible allegations of fraud. The suspension of your Medicare payments took effect on
_______……Prior notice of this suspension is not being provided because giving prior notice
would place additional Medicare funds at risk and hinder our ability to recover any determined
overpayment……[T]he suspension of your Medicare payments is based on, but not limited to,
evidence……which indicates that ______ has been engaged in soliciting and billing for
unnecessary and unwanted medical services. Since at least ______, ______ has been
submitting claims to Medicare for medical items whose orders were derived from prohibited solicitations in violation of 42 C.F.R. 424.57(11). Evidence developed during an OIG investigation alleges that ______ contracted with several telemarketing firms to sell ________ in violation of 42 C.F.R. 424.57(11) and that _____ paid these telemarketing firms based on the amount of referrals generated in violation of the Anti-kickback statute.”

The AdvanceMed letter is a “real world” example of what the government can do when it has a supplier in its “cross-hairs.” The recipient of the letter allegedly purchased leads in such a way that it violated the Medicare anti-kickback statute. Instead of waiting for two to three years for a DOJ/OIG investigation to wind its way to a conclusion, the ZPIC shut the supplier down “with a flip of the switch.”

Calling Medicare Beneficiaries

CMS does not like it when DME suppliers call Medicare beneficiaries. The concern is that an elderly person…who does not feel well…can be taken advantage of over the phone by an unscrupulous supplier.

The telephone solicitation statute and Supplier Standard #11 are limited to DME suppliers. They are meant to protect the elderly from being “cold called.” The statute and standard essentially say the same thing. Picture Mrs. Smith, a 78 year old Medicare beneficiary, sitting in her living room watching television. ABC Medical Equipment, Inc., directly or through an agent, may not call Mrs. Smith unless one of three conditions exist.

- First condition - ABC has provided a Medicare-covered item to Mrs. Smith any time in the past, and ABC is calling Mrs. Smith about that particular item.
- Second condition - ABC has provided a Medicare-covered item to Mrs. Smith within the past 15 months, and ABC is calling Mrs. Smith about other products that ABC can provide.
- Third condition - ABC has never provided a Medicare-covered item to Mrs. Smith. Mrs. Smith is a prospective customer of ABC. Mrs. Smith has given her consent (electronic or “blue ink”) to be called by ABC. Under the heading of “if it looks like a duck, walks like a duck, and sounds like a duck,” here is what cannot happen: (i) ABC cannot call Mrs. Smith and ask for permission to call her at a later time; (ii) a marketer cannot cold call Mrs. Smith and ask her if ABC can call her; (iii) a “final expense” life insurance company cannot call its beneficiaries, ask them a bunch of questions about their life insurance, and then ask them if they are interested in DME, and if the answer is “yes,” transfer their names to ABC; and (iv) a marketer cannot call Mrs. Smith under the guise of a “survey,” ask her questions about her house, her dog, her flowers, and then ask her if she is interested in DME…and if she says “yes,” then transfer her name to ABC. Conversely, ABC can call Mrs. Smith if it is a “solicited” call…that is…if Mrs. Smith has affirmatively taken action that reflects her consent to be called. For example, let’s say that Mrs. Smith watches a television...
commercial and calls ABC. Mrs. Smith reaches ABC’s voicemail. Mrs. Smith
leaves a message asking that ABC call her. In response, ABC calls Mrs. Smith. It is
unlikely that CMS will allege that the telephone solicitation statute and Supplier
Standard #11 are violated. Look at another example. Mrs. Smith goes to a web
landing page for ABC. She fills out the consent-to-be-called box and then hits
“submit.” In response, ABC calls Mrs. Smith. This is a proper electronic consent on
condition that (i) ABC is the only company listed on the web landing page, (ii) the
consent is specific to ABC, and (iii) the box that Mrs. Smith submits clearly states
that she is giving ABC permission to call her.

Unsolicited phone calls to Medicare beneficiaries are a big deal to two of the most
powerful Medicare contractors: the NSC and ZPICs. There have been occasions when a ZPIC
will instruct DME MACs to suspend payments to a DME supplier because the supplier is
allegedly violating the telephone solicitation statute. There have been occasions when the NSC
threatens to revoke a DME supplier’s Part B supplier number because the supplier is allegedly
violating Supplier Standard #11. For example, the NSC sent a letter to a client that stated the
following:

“Dear Supplier: This letter is official notice that the...National Supplier
Clearinghouse (NSC) has found the facility...to be in violation of...[Supplier
Standard #11]. Our office has received information that your company contacted
a patient in order to solicit their business...DMEPOS suppliers are prohibited
from making unsolicited telephone contacts. Please provide proof of your
compliance with this standard. Please be advised that you are allowed 21
calendar days from the date of this letter to provide the SACU with information
that may allow us to verify your full compliance with the DMEPOS supplier
standards. If you fail to comply with the 21-day deadline, the SACU may initiate
actions to revoke your Medicare DMEPOS supplier number.”

Consignment Arrangement with Hospital Emergency Room

In a typical consignment arrangement with a hospital ER, (i) the DME supplier will place
orthotic product (e.g., braces) in a “closet” in the hospital ER; (ii) the physician will order a
product, such as a brace, for the patient to wear home … and utilize in the home; (iii) the hospital
staff will pull the brace out of the consignment “closet” and place it on the patient; (iv) the
patient will be discharged from the ER and wear the brace home; and (v) the DME supplier will
collect the required documents and bill for the brace.

A consignment arrangement is legally acceptable so long as the following requirements
are met: (i) the consigned inventory is only for the convenience of the patient; (ii) the hospital
cannot directly or indirectly make money off the consigned inventory (e.g., the hospital cannot
use the consigned inventory for procedures); (iii) the patient must be given the right to choose to
purchase a product from the consigned inventory or from another DME supplier; and (iv) if the
DME supplier pays rent to the hospital, then the rental agreement must comply with the space
rental safe harbor to the Medicare anti-kickback statute. The safe harbor has a number of
requirements, including the following: (i) the rental agreement must be for a term of at least one year; (ii) the rent must be fixed one year in advance; and (iii) the rent must be at fair market value.

42 CFR § 411.15(m)(1), the outpatient bundling regulation, provides that “any service furnished to an inpatient of a hospital or to a hospital outpatient . . . during an encounter . . . by an entity other than the hospital” is excluded from Medicare coverage, subject to certain exceptions. Orthotic products are neither expressly included nor excluded from the outpatient bundling regulation. The same is true with DME. However, in an amendment to this regulation, CMS stated in the preamble to the Notice of Proposed Rulemaking the following:

Sometimes a hospital may furnish an item or services for which a patient will have a continuing need. For example, a hospital may furnish a DME item such as a wheelchair...DME is defined under section 1861(n) of the Act as equipment used in the patient’s home or in another institution used as his home other than a hospital or skilled nursing facility (SNF). By definition, DME is not something that is provided for use in the hospital setting. Therefore, we do not believe that the DME benefit provides for any item or service that is expected to be used by the patient while in the hospital as an inpatient or outpatient...The covered Part B benefit for DME as described under section 1861(n) of the Act is intended for equipment used in the home, so a hospital that furnishes DME to its patients is not providing a hospital service to its patients, but is acting in the capacity of a supplier of DME, not a provider of hospital services. For these reasons, we will not require bundling of DME for hospital patients.

In contrast, orthotic products provided to hospital inpatients are expressly included in the Part A prospective payment system (“PPS”) rate and are not separately billable.

Depending on the specific product dispensed, a credible argument may be made that (i) the outpatient facility patient will have a continuing need for the orthotic product once the patient returns home and (ii) it is permissible for the DME supplier to bill for an orthotic product dispensed to an outpatient facility patient. This argument is further supported by Chapter 20, Section 110.3 of the Medicare Claims Processing Manual, which allows a DME supplier to deliver durable medical equipment, prosthetics, and orthotics (but not supplies) to an inpatient up to two days before discharge if certain conditions are met. This provision indicates that orthotics are products that are used in the home.

Orthotic products are billable under HCPCS codes that describe (i) prefabricated orthotic products furnished off-the-shelf (“OTS”) and (ii) items that require expertise in customizing the product to fit the individual patient. In the case of the latter, the HCPCS code includes the fitting, adjustment or other similar services. Since the DME supplier is not providing the fitting or adjustment, it should not bill under the customized orthotic HCPCS code; rather, it should bill under the OTS orthotic HCPCS code.
The hospital cannot bill for the orthotic product because the supplier (seller) of the product is the DME supplier. Further, the hospital cannot bill for fitting, adjustment or similar services (collectively referred to as “fitting services”). The reason for this is two-fold. First, if the DME supplier provides an OTS product, then there are no fitting services associated with the product. Second, if the DME supplier provides a custom-fitted product, then the HCPCS code assigned to the product includes fitting services, meaning that the hospital cannot separately bill for the fitting services.

CMS explains that when hospital outpatient staff provide a prosthetic or orthotic device, and the HCPCS code that describes that device includes the fitting services, the hospital should not separately bill for the fitting services. There is no CMS guidance authorizing a hospital to bill for a visit or procedure HCPCS code for a product provided by a DME supplier.

Supplier Standards and Consignment Arrangements

Two supplier standards are applicable to consignment arrangements: (1) suppliers must enroll each physical location in Medicare and (2) suppliers may not share practice locations with other suppliers or providers.

Under the first standard, each physical location where a DME supplier meets with patients and sells/rents products to them, must enroll in Medicare. Warehouses and repair facilities are not subject to the enrollment requirement (i.e., the patient has no access to the warehouse and products are not sold at the repair facility).

Under the second standard, when a physical location is subject to the enrollment requirement, the DME supplier may not share that location with other suppliers or providers. Despite this prohibition, consignment arrangements are commonplace for suppliers. For example, National Government Services, a Medicare contractor, has published guidance regarding the use of consignment closets. Consignment arrangements are generally allowed because when a DME supplier places inventory at a hospital, the area where the inventory is placed does not constitute a physical location of the DME supplier (i.e., the supplier does not meet the patient at the hospital/physician office).

In 2009, CMS published a transmittal with the express purpose of prohibiting most consignment closet arrangements, but that transmittal was rescinded before it was scheduled to go into effect. CMS said that it was “rescinding this change request to consider other implementation dates,” but so far there has been no follow-up. It is possible, however, that at some point CMS will again issue instructions that restrict or prohibit consignment arrangements.

If the DME supplier decides to pay rent to the hospital, the rent should be at fair market value, be fixed at least one year in advance, and not take into account, directly or indirectly, the volume or value of referrals or other business generated between the parties. The OIG discussed the payments for rent for consignment closets in physicians’ offices in a Special Fraud Alert, noting that such payments are inherently suspect. The OIG observed that the following factors should be avoided when a DME supplier rents space from a physician:
1. rental amounts in excess of amounts paid for comparable property rented in arms-length transactions between persons not in a position to refer business;
2. rental amounts for subleases that exceed the rental amounts per square foot in the primary lease;
3. rental amounts that are subject to modification more often than annually;
4. rental amounts that vary with the number of patients or referrals;
5. rental arrangements that set a fixed rental fee per hour, but do not fix the number of hours or the schedule of usage in advance (i.e., “as needed” arrangements);
6. rental amounts that are only paid if there are a certain number of Federal health care program beneficiaries referred each month; and
7. rental amounts that are conditioned upon the supplier's receipt of payments from a Federal health care program.

The guidelines set out in the Special Fraud Alert apply to rent paid to a hospital under a consignment arrangement.

The DME supplier (not the hospital) is the supplier. The DME supplier bills and collects from Medicare. The DME supplier is responsible to collect the documentation necessary to support its claim to Medicare. Likewise, it is the DME supplier’s responsibility to collect co-payments.

The agreement between the DME supplier and the hospital should specify (i) the documents to be collected by the hospital before it dispenses an orthotic product (on behalf of the DME supplier) to the patient and (ii) the responsibility, if any, that the hospital has to the DME supplier in the event that a claim is not paid, or in the event that a previously-paid claim is recovered by a third-party payer because of deficient documentation.

It is the responsibility of the DME supplier to make reasonable efforts to collect co-payments. If a patient asserts an inability to pay co-payment, then the DME supplier can waive the co-payment only if the patient discloses credible information to the supplier that supports such inability to pay.

When a Medicare patient is being discharged from a hospital, and the physician has ordered DME, the hospital must give the patient the opportunity to choose a DME supplier.

**Oxygen: Restarting the 36 Month Cap**

The 36 month oxygen rental period can restart in the following situations:

- The supplier “abandons” its oxygen patients.
- The supplier files a Chapter 7 bankruptcy or a liquidating Chapter 11.
- If the beneficiary elects to obtain new oxygen equipment after the five year reasonable useful lifetime of the oxygen equipment has expired.
There is a specific incident of damage beyond repair (e.g., dropped and broken, fire, flood, etc.) or the item is stolen or lost.

During the 36-month rental payment period, if there is a break-in-need for at least 60 days plus the days remaining in the month of discontinuation and new medical necessity is established.

The reasonable useful lifetime (“RUL”) for oxygen equipment is five years. At any time after the end of the RUL, the beneficiary may elect to receive new equipment, thus beginning a new 36-month rental period. The five year period begins on the initial date of service and runs for five years from that date. It is not based on the actual age of the equipment. The five year period does not re-start if there has been a change in oxygen modality, change out of equipment, or change in supplier.

When the RUL of a beneficiary’s portable oxygen equipment differs from the RUL of the beneficiary’s stationary oxygen equipment, the RUL of the stationary oxygen equipment will govern for both types of oxygen equipment. If the RUL end date of the portable oxygen equipment is before the RUL end date of the stationary oxygen equipment, the RUL end date of the portable oxygen equipment is extended to coincide with the RUL end date of the stationary oxygen equipment. If the RUL end date of the portable oxygen equipment is after the RUL end date of the stationary oxygen equipment, the end date of the RUL of the portable oxygen equipment is shortened to coincide with the RUL end date of the stationary oxygen equipment. When the end date of the RUL of the stationary oxygen equipment occurs, the beneficiary may elect to obtain replacement of both the stationary and the portable oxygen equipment.

If the beneficiary elects to obtain replacement of the stationary and the portable oxygen equipment, both types of oxygen equipment must be replaced at the same time, and a new 36-month rental period and new RUL is started for both the replacement stationary oxygen equipment and the replacement portable oxygen equipment.

A Medicare beneficiary who resides in a DMEPOS competitive bidding area (“CBA”) may obtain replacement of both the stationary and portable oxygen systems only from a contract supplier having a competitive bidding contract for the CBA in which the beneficiary permanently resides.

If the beneficiary elects not to receive new equipment after the end of the five year RUL and if the supplier retains title to the equipment, all elements of the payment policy for months 37-60 remain in effect. There is no separate payment for accessories or repairs. If the beneficiary was using gaseous or liquid oxygen equipment during the 36th rental month, payment can continue to be made for oxygen contents. If the beneficiary elects not to receive new equipment after the end of the five year RUL and if the supplier transfers title of the equipment to the beneficiary, accessories, maintenance, and repairs are statutorily non-covered by Medicare. Contents are separately payable for beneficiary-owned gaseous or liquid systems.

A specific incident of damage to equipment is required such as equipment falling down a flight of stairs, as opposed to equipment that is worn out over time. A new 36 month cap rental
period cannot be started if equipment is replaced due to malfunction, wear and tear, routine maintenance or repair. A new 36-month rental period and new reasonable useful lifetime is started on the date that the replacement equipment is furnished to the beneficiary. Claims for the replacement of oxygen equipment for the first month of use only are billed using the HCPCS code for the new equipment and the RA modifier.

The supplier must include on the claim for the first month of use a narrative explanation of the reason why the equipment was replaced and supporting documentation must be maintained in the supplier’s files. For example, if equipment was stolen, the supplier should keep a copy of the police report in its files. For lost or irreparably damaged equipment, the supplier should maintain any documentation that supports the narrative account of the incident.

The requirements for the initial CMN and claim for replacement equipment are:

- The Initial Date should be the date of delivery of the replacement oxygen equipment.
- Claims for the initial rental month (and only the initial rental month) must have the RA modifier (Replacement of DME item) added to the HCPCS code for the equipment when there is replacement due to reasonable useful lifetime or replacement due to damage, theft, or loss.
- Claims for the initial rental month must include a narrative explanation of the reason why the equipment was replaced and supporting documentation must be maintained in the supplier's files.

With reference to the recert CMN for replacement equipment:

- Repeat testing is not required. The supplier should enter the most recent qualifying value and test date. This test does not have to be within 30 days prior to the Initial Date. It could be the test result reported on the most recent prior CMN.
- There is no requirement for a physician visit that is specifically related to the completion of the CMN for replacement equipment.

If the beneficiary enters a hospital or SNF or joins a Medicare HMO and continues to need/use oxygen, then when the beneficiary returns home or rejoins Medicare FFS, the payment resumes where it left off. If the need/use of oxygen ends for less than 60 days plus the remainder of the rental month of discontinuation and then resumes, then payment resumes where it left off. During the 36-month rental period, if the need/use of oxygen ends for more than 60 days plus the remainder of the rental month of discontinuation and new medical necessity is established, a new 36-month rental period will begin. For a new Initial CMN, the blood gas study must be the most recent study obtained within 30 days prior to the Initial Date. The beneficiary must be seen and evaluated by the treating physician within 30 days prior to the date of Initial Certification.

If there is an interruption in medical necessity of greater than 60 days plus the days remaining in the last paid rental month, once the need resumes, the supplier will collect supporting documentation (made available upon request) of the new medical need including, but not limited to: (i) new prescription (detailed written order, WOPD if required); (ii) new Initial
CMN (with new qualifying oxygen test results performed within 30 days of new initial date); (iii) documentation supporting new medical need; (iv) documentation explaining interruption of need; and (v) documentation supporting the length of interruption (e.g., pick up date, new delivery date). The claim for the **first month** of the new rentals meeting the above documentation should include: (i) new Initial CMN; and (ii) the following narrative statement: "Break in medical need greater than 60 days."

During months 37-60, if need/use of oxygen ends for more than 60 days plus the remainder of the rental month of discontinuation and new medical necessity is established, a new rental period does not begin. The supplier that provided the oxygen equipment during the 36th rental month must provide all necessary items and services for the duration of the reasonable useful lifetime.

**Charging Cash Customers Less Than What is Billed to State Medicaid**

Billing and collecting from state Medicaid programs is more expensive and time consuming for a DME supplier than collecting from a cash-paying customer. It is logical for suppliers to desire to charge a cash-paying customer less than what the supplier bills Medicaid. The question thus arises: Is it permissible for the supplier to do so?

Most state Medicaid programs require the supplier to bill the Medicaid program its usual and customary price. The following is a summary of the law in five states, as well as a discussion of federal law.

Cal. Code Regs. tit. 22, § 51480(a) states that “[n]o provider shall bill or submit a claim for reimbursement for the rendering of health care services to a Medi-Cal beneficiary in any amount greater or higher than the usual fee charged by the provider to the general public for the same service.” Cal. Code Regs. tit. 22, § 51501(a) clarifies that “[n]otwithstanding any other provisions of these regulations, no provider shall charge for any service or any article more than would have been charged for the same service or article to other purchasers of comparable services or articles under comparable circumstances.” In addition, Cal. Code Regs. tit. 22, § 51008.1, which establishes the upper billing limit for incontinence medical supplies, states, in relevant part, the following:

(a) Bills submitted . . . for durable medical equipment . . . , medical supplies . . . , or incontinence medical supplies . . . shall not exceed an amount that is the lesser of:

(1) The usual charges made to the general public, or

(2) The net purchase price of the item, which shall be documented in the provider’s books and records, plus no more than a 100 percent mark-up. Documentation shall include, but not be limited to, evidence of purchase such as invoices or receipts.
(A) Net purchase price is defined as the actual cost to the provider to purchase the item from the seller, including any rebates, refunds, discounts or any other price reducing allowances, known by the provider at the time of billing the Medi-Cal program for the item, that reduce the item’s invoice amount.

(B) The net purchase price shall reflect price reductions guaranteed by any contract to be applied to the item(s) billed to the Medi-Cal program.

(C) The net purchase price shall not include provider costs associated with late payment penalties, interest, inventory costs, taxes, or labor.

Ill. Admin. Code tit. 89, § 140.12(h) states that the provider agrees to “[m]ake charges for the provision of services and supplies to recipients in amounts not to exceed the provider’s usual and customary charges and in the same quality and mode of delivery as are provided to the general public.” Ill. Admin. Code tit. 89, § 140.481(a), which addresses reimbursement rates for medical equipment, supplies, and related products, clarifies that the term “usual and customary charge” means the provider’s usual and customary charge to the general public.

Minn. R. 9505.0450 states that “[a] provider shall bill the department for the provider’s usual and customary fee only after the provider has provided the health service to the recipient.” Minn. R. 9505.0175 defines “usual and customary” as follows:

“Usual and customary,” when used to refer to a fee billed by a provider, means the charge of the provider to the type of payer, other than recipients or persons eligible for payment on a sliding fee schedule, that constitutes the largest share of the provider’s business. For purposes of this subpart, “payer” means a third party or persons who pay for health service by cash, check, or charge account.

Ohio Admin. Code 5160-1-60(D) states that “[p]roviders are expected to report their usual and customary charge (the amount charged to the general public) on all claims.” Ohio Admin. Code 5160-1-17.2(A) states that Medicaid providers agree to “bill . . . for no more than the usual and customary fee charged other patients for the same service.” Furthermore, Ohio Admin. Code 5160-1-02(B) states that “[a] medical service is not reimbursable if . . . the service is charged at a rate greater than the provider’s usual and customary charge to other patients.”

Under 55 Pa. Code § 1101.75(a), a provider enrolled in the Pennsylvania Medicaid program “may not, either directly or indirectly . . . [s]ubmit a claim for a service or item at a fee that is greater than the provider’s charge to the general public.” 55 Pa. Code § 1101.62 further states the following:

The Department’s maximum fees or rates are the lowest of the upper limits set by Medicare or Medicaid, or the fees or rates listed in the separate provider chapters and fee schedules or the provider’s usual and customary charge to the general public. For the purpose of establishing the usual and customary charge to the
general public, the provider shall permit the Department access to payment records of non-MA patients without disclosing the identity of the patients.

Although Pennsylvania’s regulations do not define “usual and customary charge to the general public,” 55 Pa. Code § 1101.21 clarifies that the term “general public” means “[p]ayers other than Medicaid. The term includes other health insurance plans.” Furthermore, 55 Pa. Code § 1123.60, which addresses limitations on payment for medical supplies, states that “[u]nder no circumstances may the provider be paid an amount that exceeds the price the provider currently charges the self-paying public.”

Federal law prohibits a supplier from charging Medicare or Medicaid substantially in excess of the company’s usual charges, unless there is good cause. Specifically, 42 U.S.C. § 1320a-7(b)(6)(A) provides, in relevant part, as follows:

The Secretary may exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1320a–7b (f) of this title):

. . .

Any individual or entity that the Secretary determines—

(A) has submitted or caused to be submitted bills or requests for payment. . . under subchapter XVIII of this chapter or a State health care program containing charges . . . for items or services furnished substantially in excess of such individual’s or entity’s usual charges . . . for such items or services, unless the Secretary finds there is good cause for such bills or requests containing such charges or costs[.]

The key terms “substantially in excess” and “usual charges” are not defined in the statute. The current regulations issued under the statute, codified at 42 C.F.R. § 1001.701, simply repeat the language of the statute, without providing any guidance about the meaning of “substantially in excess” or “usual charges.” The Office of Inspector General (the “OIG”) has provided guidance through OIG Advisory Opinions and a guidance letter regarding the meaning of these terms on several occasions, but that guidance has been inconsistent.

The OIG’s most recent attempt to clarify the meaning of the statute came in 2003, when the agency published a proposed rule. 68 Fed. Reg. 53,939 (Sept. 15, 2003). In the proposed rule, a provider’s “usual charge” was defined as the average or the median of the provider’s charges for the same item or service during the previous year, excluding charges for services provided to uninsured patients free of charge or at a substantially reduced rate; charges under capitated contracts; charges under fee-for-service managed care contracts where the provider is at risk for more than 10% of its compensation; and charges to Medicare, Medicaid and other federal health care programs, except TriCare. In other words, the “usual charge” would be the average or median of (i) charges to cash purchasers, (ii) negotiated rates under commercial indemnity and
non-risk commercial managed care contracts, (iii) out-of-network payments from commercial payers, and (iv) charges under TriCare contracts.

It is also important to note that the proposed rule specifically addressed the issue of a separate legal entity being formed to handle non-federal health care program business. The proposed rule required that the charges of “any affiliated entities providing substantially the same items or services in the same or substantially the same markets” be included when calculating the usual charge of a provider. The term “affiliated entity” was defined as “any entity that directly or indirectly, through one or more intermediaries, controls, is controlled by, or is under common control with the provider.”

Under the proposed regulations, a supplier’s charge to Medicare would be considered “substantially in excess” of its usual charges if the fee schedule amount for an item (or the submitted charge, if the submitted charge was less than the fee schedule amount) was more than 120% of the supplier’s usual charge. Stated another way, the supplier would be considered to be in violation of the statute if its “usual charge” for an item was less than 83% of the Medicare fee schedule amount (i.e., in excess of a 17% discount from the Medicare fee schedule). The statute provides an exception for “good cause,” which could allow a supplier’s usual charges to be less than 83% of the Medicare fee schedule if the supplier can prove unusual circumstances requiring additional time, effort or expense, or increased costs of serving Medicare beneficiaries. However, CMS later withdrew the proposed rule. 72 Fed. Reg. 33,430, 33,432 (June 18, 2007). As a result, there is no definitive federal guidance on when a supplier’s charge to Medicare or Medicaid will be viewed as “substantially in excess” of its “usual charge.”

The states referenced above do not require a provider to bill Medicaid the lowest price it offers to any payer. Rather, the regulations generally require that a provider not bill Medicaid in excess of its “usual and customary” price. “Usual and customary” is typically defined as the price most commonly charged by the provider for items or services provided to non-Medicaid patients.

If the supplier’s cash sales are small in relation to what the supplier bills Medicaid, the small volume of such cash sales should not appreciably affect the supplier’s usual and customary charges.