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Key Diligence Issues for the Durable Medical Equipment and Supply Industry



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The durable medical equipment and supply industry has seen renewed interest from both financial and strategic investors. Durable medical equipment suppliers encompass a wide range of suppliers to end users of medical equipment and technology. This can include the distribution of both “durable” equipment such as wheel chairs, crutches and home aids, as well as disposable equipment including catheters, ostomy bags and similar disposable medical supplies. This ar-

ticle addresses a number of key issues that any investor in durable medical equipment and supply companies should consider prior to making an investment. This article will primarily address due diligence issues of durable medical equipment, prosthetics and orthotic supplies (“DMEPOS”) suppliers that actually distribute their products to end-user patients and bill Medicare, state Medicaid and commercial payors or individual patients for such products. This article does not address medical equipment wholesalers which typically do not bill third-party payors or patients for the products, but instead simply act as distributors between manufacturers and DMEPOS suppliers.

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1. *DMEPOS Supplier Standards.* In November of 2008, the Centers for Medicare and Medicaid Services (“CMS”) promulgated new supplier standards that apply to all DMEPOS suppliers. These supplier standards signaled a dramatic shift in an industry that historically had a relatively low level of CMS oversight.¹ CMS has continued to revise and evolve the supplier standards in

¹ 42 C.F.R. § 424.57

the ensuing years.² Meeting the supplier standards is a pre-condition for a DMEPOS supplier to receive payment for a Medicare-covered item. The supplier standards initially imposed twenty-six requirements on suppliers that wish to participate in the Medicare program. The most significant requirement in the supplier standards is that all DMEPOS suppliers must become accredited by a recognized independent accreditation organization. The remaining standards range from a requirement that each DMEPOS supplier maintain or post a significant surety bond of \$50,000, to the requirement that all suppliers maintain a physical facility with an appropriate site. Additionally, the supplier standards include various marketing restrictions which prohibit affirmative outreach to Medicare beneficiaries via phone without a previously existing relationship.

It is important that any acquirer of a DMEPOS business review the supplier's compliance with all applicable supplier standards. Many of the standards are new to DMEPOS suppliers, and suppliers have been undergoing the process of obtaining and maintaining accreditation and meeting the surety bond requirements. The failure to meet supplier standards results in any claim that is submitted to Medicare and Medicaid by such supplier being deemed invalid and may constitute a "false claim" as discussed further below.

2. Billing and Coding Documentation. Federal and state governments are placing renewed scrutiny on the billing and coding activities of DMEPOS suppliers as well as all other players in the healthcare industry. This is most evidenced by the Recovery Audit Contractor ("RAC") program.³ Recovery Audit Contractors are private, third-private individuals that are deputized by the Medicare Program to audit providers and suppliers. The auditors are permitted to keep a portion of all claims that they recover through the auditing process. Although generally DMEPOS billing and coding is more simplistic than certain complex providers such as hospitals and ambulatory surgical facilities, it is vitally important that the DMEPOS supplier maintain appropriate documentation to demonstrate that claims were validly submitted.

A key component of billing and coding for DMEPOS suppliers is the Certificate of Medical Necessity ("CMN") or DME Information Form ("DIF"). This form collects certain beneficiary information and includes the supplier certification. Depending upon the type of DMEPOS for which the supplier is billing, either a CMN or DIF is required by CMS.⁴ Additionally, all suppliers must maintain proof of delivery to demonstrate that the equipment or supplies were appropriately delivered to the patient. It is always recommended that in the context of a potential acquisition that any acquirer retain an expert billing and coding auditor with experience in the targets niche to review a sample of Medicare and Medicaid claims to confirm that all documentation, billing and coding has been done accurately. This exercise can both confirm compliance with applicable laws and validate the target's historical earnings.

² See, e.g., 75 Fed. Reg. 52629 (Aug. 27, 2010).

³ 42 U.S.C. § 1395ddd(h)

⁴ A list of the types of DMEPOS that require either a CMN or DIF can be found at Chapter 5, Section 3 of the Medicare Program Integrity Manual.

3. False Claims. The recent Patient Protection and Affordable Care Act⁵ and the Health Care and Education Reconciliation Act⁶ which modified the Patient Protection and Affordable Care Act, included a variety of revisions to the False Claims Act which encouraged and further simplified the process for prosecuting providers and suppliers for making false claims to the Medicare and Medicaid programs. There are a myriad of examples of False Claims Act cases in the DME world. For example, in August of 2008, a DMEPOS supplier paid \$2 million to the United States to resolve allegations it submitted false claims to Medicare. The plaintiff-whistleblower, a former executive of the supplier, filed a complaint which stated that the supplier routinely billed and was reimbursed by Medicare for oxygen equipment without any documentation of certificates of medical need.⁷

More recently, on May 10, 2010, a federal district court sentenced the owner of a Los Angeles durable medical equipment company to 55 months in prison and ordered him to repay \$508,134 in restitution for his part in a wheelchair fraud conspiracy.⁸ The defendant admitted to using a patient recruiter to obtain fraudulent prescriptions and medical documents from fraudulent medical clinics. As discussed above, conducting a billing and coding audit prior to closing a transaction should help to determine whether the target is engaged in improper claims. An important question to ask of the billing and coding auditor is whether the claims appear to be consistent with those made by similarly situated DMEPOS providers. For example, if frequency of use per patient or numbers of products per patient or other statistics appear to be high in comparison to similarly situated providers, this may be indicative of fraudulently submitted claims.

4. Competitive Bidding. Congress has passed⁹ and CMS is in the process of implementing a competitive bidding program that will have a significant impact on many DMEPOS suppliers. The competitive bidding program will essentially require suppliers of certain types of products to submit bids to the federal government in various selected regions. Winning bidders will be permitted to provide products to Medicare beneficiaries and those that are excluded will be excluded from participating. Medicare recently announced the initial competitive bidding awards to suppliers that submitted bids to supply items at competitive prices, meet Medicare's

⁵ H.R. 3590

⁶ H.R. 4872

⁷ *United States ex rel. Bell-Messier v. Rotech Healthcare Inc.*, E.D. Tex., No. 5:04CV0075, settlement announced 8/26/08. This also highlights an important characteristic of many false claim cases – the person initiating the suit or investigation is often a private-party such as a disgruntled former employee or another insider "whistleblower." The False Claims Act allows these private-parties to file suit and then if the United States Attorney finds the case meritorious, the United States can join the suit. This is called a "qui tam" suit. In many instances, the accused party begins with a private civil suit that grows into a serious government investigation. For this reason, all false claims actions should be handled with the utmost caution and care.

⁸ *United States v. Sadiqr*, C.D. Cal., No. 2:09-cr-00978-JFW, sentenced 5/10/10.

⁹ See, Section 302, Medicare Modernization Act of 2003 (MMA).

eligibility, quality and financial standards and are accredited by an independent accrediting organization.¹⁰

Starting on January 1, 2011, nine selected metropolitan areas will begin the competitive bidding programs where Medicare beneficiaries may only use the Medicare-contract suppliers to obtain the DMEPOS covered under the program.¹¹ The 2011 program will only include the following items: (i) oxygen supplies and equipment, (ii) standard power wheelchairs, scooters and related accessories, (iii) complex rehabilitative power wheelchairs and related accessories (Group 2), (iv) mail-order diabetic supplies, (v) enteral nutrients, equipment and supplies, (vi) continuous positive airway pressure devices and respiratory assist devices and related supplies and accessories, (vii) hospital beds and accessories, (viii) walkers and related accessories and (ix) support surfaces (certain mattresses and overlays) in the Miami, Fort Lauderdale and Miami Beach area only. An acquirer of a DMEPOS company should be acutely aware of the impact of competitive bidding on not only the supplier's ability to participate in the Medicare program and sell products to Medicare beneficiaries, but also on the future gross margins of the target.

5. *Commercial Payer Relationships.* Although Medicare and Medicaid typically account for a large percentage of sales of any DMEPOS supplier, commercial payers are increasingly playing a significant part in the revenue of these companies. Aside from reviewing the financial implications of a DMEPOS supplier's commercial payer agreements, it is important to note the legal terms and the supplier's compliance with a variety of state legal requirements that apply to companies that submit claims to commercial insurers. One of the hot button issues for health care providers (i.e., physicians and surgical facilities) and DMEPOS suppliers is the waiver and discount of co-payments and deductibles. Here, suppliers may routinely waive or discount the patient's payment in connection with the insurance. In certain states such as Florida, this practice is illegal.¹² Even in states where the practice is not expressly prohibited or illegal, private commercial payers are also taking their own steps to combat perceived abuses of out-of-network benefits, including provider reductions of the patient's financial responsibility for goods or services provided. For example, payers in many states are initiating their own recoupment actions against providers and suppliers based on the theory that the party

seeking payment is misrepresenting their usual and customary charges or engaging in fraud by submitting claims for payment in full by the payer while at the same time waiving or discounting the patient's portion. Finally, state's attorney generals are also increasingly involved with these types of investigations and enforcement actions. An acquirer of a DMEPOS supplier should be aware of the supplier's approach to waiver and discount of co-payments and whether the supplier is actually collecting the patient's portion.

6. *Referral Source Relationships.* Historically, one of the primary areas of fraud in the DMEPOS business has been the presence of financial relationships with referral sources. This has been seen in the form of kickbacks that are paid in exchange for referrals. These kickbacks may take the form of "closet programs" where a DMEPOS supplier pays a referral source such as a physician office an above fair market value rental rate in exchange for the use of a small storage closet which essentially is payment in exchange for referrals. There also may be non-cash consideration that benefits a referral source. This may include the use of DMEPOS staff by a physician or hospital (e.g., discharge planners) that should really be paid by the physician or hospital. There should be no benefits or other "remuneration" flowing from the DMEPOS supplier to the hospital, physician or other referral source.

7. *Privacy and Security Laws.* One area that has traditionally not received enough attention in the DME industry is federal and state privacy and security laws. In particular, the Health Insurance Portability and Accountability Act¹³ ("HIPAA") and state privacy laws govern how and when certain information may be disclosed by a health care provider or other entity involved in the health care business. Traditionally the focus has been on health care providers that provide services directly to patients such as hospitals, physicians, etc. However, this may also potentially apply to DME suppliers if they handle patient information or what is known as protected health information ("PHI"). For example, HIPAA requires that a DMEPOS supplier must have in place certain privacy and security measures if dealing with PHI. This may extend to policies and procedures as well as information technology infrastructure and security. Recent amendments to HIPAA by the Health Information Technology for Economic and Clinical Health Act have imposed higher civil penalties and potential liability for companies who misuse PHI, causing compliance with privacy and security laws to become an area of increased importance. In addition, state laws may also impact how and when this information may be disclosed.

8. *State Licenses and Permits.* In addition to increased federal requirements requiring DMEPOS suppliers to meet certain standards, many states are beginning to license or otherwise issue permits to DMEPOS suppliers. The new supplier standards require that any Medicare-enrolled DMEPOS supplier comply with applicable state license requirements. If the target is operating in a state that has a state license process, it is important to review the status of state licenses. For example, the California Department of Public Health implemented the Home Medical Device Retailer (HMDR) Licensing Program which licenses and regulates all California and out-of-state facilities and busi-

¹⁰ See <https://www.cms.gov/apps/media/press/release.asp?Counter=3861&intNumPerPage=10&checkDate=&checkKey=&srchType=1&numDays=3500&srchOpt=0&srchData=&keywordType=All&chkNewsType=1%2C+2%2C+3%2C+4%2C+5&intPage=&showAll=&pYear=&year=&desc=&cboOrder=date>

¹¹ The initial nine metropolitan areas are: (i) California - Riverside, San Bernardino, Ontario; (ii) Florida - Miami, Fort Lauderdale, Miami Beach; (iii) Florida - Orlando; (iv) Missouri and Kansas - Kansas City; (v) North and South Carolina - Charlotte, Gastonia, Concord; (vi) Ohio - Cleveland, Elyria, Mentor; (vii) Ohio, Kentucky and Indiana - Cincinnati, Middletown; (viii) Pennsylvania - Pittsburgh; (ix) Texas - Dallas-Fort Worth, Arlington.

¹² Fla. Stat. § 817.234(7)(a) ("It shall constitute a material omission and insurance fraud for any physician or other provider, other than a hospital, to engage in a general business practice of billing amounts as its usual and customary charge, if such provider has agreed with the patient and intends to waive deductibles or copayments, or does not for any other reasons intend to collect the total amount of such charge.").

¹³ P.L. 104 -191 (1996).

nesses who supply medical devices or durable medical equipment for use in the home.¹⁴

Some suppliers include in their businesses certain activities related to medical devices and supplies which arguably may categorize them as manufacturers within the eyes of the FDA.

9. *State Medicaid Programs.* It has been widely publicized that many state treasuries are nearly bankrupt and states are looking for ways to limit the flow of funds out of state coffers. Many states have looked to cost cutting in their Medicaid programs to attempt to achieve this goal. An alternative approach that some states have implemented, aside from cutting reimbursement rates, is to limit or prohibit enrollment of new suppliers in the state Medicaid Program. These moratoriums also take the form of limiting changes of ownership of existing suppliers in their state. For example, California has had a moratorium in place since July 31, 2009, which prohibits the enrollment of new suppliers in certain counties and also restricts changes of ownership.¹⁵ Prior to

¹⁴ See, <http://www.cdph.ca.gov//programs/Pages/HMDRLicensingProgramHomePage.aspx>

¹⁵ The moratorium is set to expire Feb. 7, 2011.

investing in any DMEPOS supplier, it will be important to conduct a careful analysis of the target's Medicaid participation and whether a change of ownership might trigger or disallow further participation in certain State Medicaid programs.

10. *FDA Regulation.* Under the Federal Food, Drug and Cosmetic Act, the Food and Drug Administration ("FDA") primarily regulates manufacturers of medical devices. The FDA does not typically have regulatory authority over distributors or suppliers such as DMEPOS suppliers. However, some suppliers include in their businesses certain activities related to medical devices and supplies which arguably may categorize them as manufacturers within the eyes of the FDA. These activities can include the creation of kits of supplies and repackaging of medical supplies. Furthermore, the FDA has recently changed regulation of reprocessing of single use devices. DMEPOS suppliers that are on the cutting edge of kitting, repackaging or other activities related to the reuse of medical devices should be carefully reviewed to ensure FDA compliance.

Conclusion

The aforementioned ten points are the tip of the iceberg for diligence on a DMEPOS investment. As with any industry that has very little consolidation, there is a wide variety of industry practices that should be reviewed from not only a business diligence standpoint but also from a legal diligence standpoint.