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Professional Perspective

Home Health Sector Due Diligence

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Editor's Note: Unique business and legal factors require a different and targeted approach when conducting due diligence for home health agencies. Stringent government oversight and scrutiny necessitate a comprehensive understanding of the operating requirements entitling a home health agency to payment.

For prospective investors and acquirers in the home health arena, it is critically important to assure thorough due diligence before a deal is finalized. This requires an understanding of the business and legal issues relevant to home health organizations, along with a recognition that there is wide variation in health organizations' discipline around billing, documentation, recordkeeping, and compliance program implementation. This article provides a detailed summary of key business and legal due diligence factors that should be evaluated as part of a potential investment or acquisition in the home health sector.

Please also consult our companion Checklist: Due Diligence of a Home Health Target.

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Industry Background

Home health is a $100 billion industry in the U.S., spanning more than 33,000 provider organizations. Medicare defines home health care as medically necessary, part-time or intermittent, skilled care (nursing, physical therapy, continuing occupational therapy, and speech-language therapy) that is provided under the care of a physician. Clinical care provided in the home is supported by home medical equipment (HME) service companies, which deliver, install, and assess appropriateness of equipment in the home, as well as personal care services which focus on routine daily activities.

The home health and related medical equipment service sector has seen dramatic growth in recent years, due to demographic factors such as the aging population of baby boomers and increasing chronic health conditions among the elderly. This upswing has been amplified by the trend in favor of value-based purchasing, along with consumer preferences for care in the home.

The domestic home health market is projected to outpace growth of all other health-care types, including hospital and physician care. According to projections issued by the Office of the Actuary in the Center for Medicare & Medicaid Services, this rise will average 7% annually through 2028. The U.S. Department of Labor is forecasting a 36% growth rate in home health employment by the year 2028, adding an estimated 1 million jobs in the process—a projection that could easily be outpaced, given demographic and coverage trends.

In this growth environment, it is not surprising that there has been significant merger and acquisition activity and investment interest in home health. While there is some concentration in the market, there is ample room for continued consolidation.

Against this dynamic backdrop, several additional factors weigh in favor of accelerated home health consolidation:

- Many home health organizations are experiencing significant operating and financial performance pressure, which is intensified by changes in reimbursement models. The Covid-19 pandemic has created true crisis conditions for some home health entities, which may serve to create financial and solvency pressures conducive to acquisition.
- The broader trend of value-based care reimbursement and providing care in the lowest cost setting is advantageous for home care, as it provides a lower-cost alternative to nursing home and hospital care. As such, the utilization of home health services has increased substantially in recent years, reflected in a 49% increase in Medicare spending for home health services from 2008 to 2018, according to Centers for Medicare and Medicaid Services Office of the Actuary health expenditure data.
- Medicare Advantage plans have doubled enrollment over the last decade and now cover about 36% of the total Medicare beneficiary population. In 2020, Medicare Advantage plans were permitted to expand coverage for patients with chronic diseases or conditions. With this coverage flexibility, traditional and non-traditional in-home care are expanding rapidly.

Business Factors

Workforce Management

Recruiting and retaining qualified staff to fill clinical positions is necessary, and from a diligence perspective, staff turnover should be assessed to understand how effective those human capital functions are. Likewise, recruiting efforts for homecare workers should be quantified and tracked by examining the number of applications, interviews, and offers made/declined/accepted.

An often-overlooked component of workforce planning is ensuring that a home health agency has a solid approach for managing productivity and staffing. Operational leaders must monitor and manage the productivity of clinical FTEs, as well as ensure that premium pay, including overtime, is minimized and is only triggered on a planned, pre-approved basis. Staffing and scheduling should be optimized to ensure workers are scheduled for maximum hours with a manageable caseload of patients and efficient routes between locations, to avoid burnout. Furthermore, the use of paraprofessionals (e.g., home health aides) should be maximized when clinically appropriate to contain labor costs and to free skilled staff for the most clinically complex visits.

Reimbursement and Revenue Cycle Management

PDGM Reimbursement. Effective Jan. 1, 2020, CMS implemented the Patient Driven Groupings Model, which represents an overhaul to home health reimbursement. Under PDGM, home health reimbursement is now based on a 30-day payment model, contrasted with the previous 60-day payment model under the Home Health Prospective Payment System (HHPPS). PDGM adds complexities to the revenue cycle, based not only on the shorter billing cycle but also due to new admission source and physician order requirements. As part of diligence, it is important to understand how an agency prepared for and adapted to PDGM, and whether they were able to identify and address any gaps or bottlenecks in revenue cycle processes or reimbursement.

Revenue Cycle Management. The revenue cycle is the set of business processes that translate clinical care into billing, reimbursement and ultimately revenue and reimbursement. The home health revenue cycle requires a comprehensive approach that begins with the patient intake and admissions process. Breakdowns in processes or workflows upstream can lead to delays in billing and cash flow, as well as revenue leakage due to denials.

Intake. During the diligence phase, the intake function should be evaluated at minimum to confirm the capabilities of the intake department to understand and confirm patient eligibility for home health services, namely "homebound" status, existing plan of care signed by a physician, medical necessity documentation, and face-to-face (F2F) documentation. F2F documentation is a condition of payment that can be fulfilled during the intake process. Gaps with respect to F2F documentation will result in loss of reimbursement.

For non-Medicare fee-for-service admissions, verification of insurance eligibility, benefits, and authorization requirements must be captured during the intake process. Missed steps in these processes can lead to claim denials and re-work for business office staff. Authorization denials can be difficult to overturn, resulting in write-offs and loss of net revenue. Revenue cycle due diligence should evaluate these functions relative to industry best practices and real-time processes on technology platforms.

Admission Sources and Referrals. Under PDGM, reimbursement will vary depending on the referral sources. Institutional admissions are considered those for whom the patient completed an acute or post-acute stay within 14 days of the home health admission, and result in a higher payment. Community admissions are those that do not follow an institutional stay, and result in lower payment. As part of diligence, the agency's referral data (or lack thereof) should be analyzed to evaluate referral trends. Referral analytics can be used to determine whether the agency has a healthy mix of community and institutional-based admissions and whether they have the ability to locate new referral sources in their market.

Physician Orders. PDGM now requires that the physician signature be obtained (with dates on the order) prior to each 30-day claim submission. This is an important change from the HHPPS billing method, through which physician orders were required by the end of each 60-day episode. This increases pressure on orders management and the clinical documentation workflow; tardiness in obtaining signed orders from referral sources can hold up billing processes and hinder cash flow.

During diligence, physician order turnaround time should be evaluated and benchmarked. Any breakdowns in workflow or communication between the home health agency and the referral sources pose a risk to the completion of the signed order.

Billing and Pre-Billing Processes. The shift to PDGM not only doubles the volume of Medicare claims billed—its requirements will also increase a billing department's volume of pre-bill edits or "claim checks" that must occur prior to billing. Billing workflow and resource allocation should be examined during diligence to ensure that PDGM-related updates were translated into pre-bill edits and that the billing staff was right-sized to accommodate additional volumes and prevent backlogs. A billing backlog could suggest workflow and/or technology challenges, resource issues, or lack of training related to PDGM.

As communicated in the 2020 Home Health Final Rule, CMS is phasing out requests for anticipate payment (RAPs) beginning with a decrease in the pre-payment amount in 2020 (20% instead of 50% to 60%). By 2021, all pre-payments will be eliminated. During the transitional period, existing agencies will continue to receive the split payment amount, however newly certified agencies (those obtaining certification after Jan. 1, 2019) will be required to submit no-pay RAPs.

Consequences of these changes include increased workload and decreased efficiency of billing staff, and disruptions to cash flow as agencies have been accustomed to receiving pre-payments early on in a patient's episode. Diligence exercises should evaluate how well business offices are equipped to handle fluctuations in billing volume during the transition, and how well they are prepared to address disruption in cash flow.

RCM Metrics. Revenue cycle performance should always be assessed as part of diligence. A common pitfall of many diligence exercises is an overemphasis on the singular indicator of DSO (days sales outstanding, an equivalent of AR days). Rather, the entire breadth of the revenue cycle should be viewed to understand not only receivables, but billing, denials, and bad debt. A standard set of revenue cycle performance metrics should be evaluated to gauge overall RCM performance. For example, Medicare and non-Medicare DSO, AR aging greater than 120 days from discharge, write-offs as a percent of net revenue, days to bill RAPs, days to bill final claims and LUPA percentage, should be evaluated during diligence.

Electronic Visit Verification. As part of the 21st Century Cures Act, in an effort to reduce fraudulent billing, state Medicaid agencies are required to implement a system of electronic visit verification for personal care services and home health-care services provided and reimbursed under Medicaid. While the implementation deadline for home health EVV has been delayed to Jan. 1, 2023, it is nevertheless an important due diligence element.

EVV is to be managed in each state by a vendor with technology that captures key data elements for each encounter. States have broad flexibility in choosing their method of implementation for EVV. During due diligence, it is important to understand the home health organization's Medicaid payor mix and, especially for a multi-state or national entity, the type of EVV system chosen by each relevant state and the progress towards EVV implementation there.

Some states have chosen "closed" EVV systems that require provider agencies to use handheld devices. In this case, since integration with an EHR is not possible, workflow around the entry of EVV-required data elements needs to be understood from an efficiency and cost perspective. Other states have chosen "open" EVV systems in which one or more vendors must allow integration with existing technologies. In these instances, the administrative burden on the agency staff or clinicians will be less, but it is important to understand if the integration of EVV data capture was seamless to the billing process or whether the agency experienced any billing delays or issues with data mismatches.

Legal and Risk Factors

Enforcement/Investigatory Trends

Home health has been on the enforcement hot seat for many years. As described below, federal enforcement and administrative agencies have been steadily increasing scrutiny of home health billing, marketing, and business practices for well over a decade, with no end in sight. With the June 2020 issuance by the Department of Justice of updated guidelines for prosecutor evaluation of corporate compliance programs, it is likely we will see focused attention on the effectiveness of these compliance programs in the context of home health mergers and acquisitions.

In 2007, the DOJ and the Department of Health and Human Services created a Medicare Strike Force comprised of state and federal resources with the goal to "prevent and combat health care fraud, waste, and abuse." The majority of the strike force offices are located in areas that the government has identified as high fraud areas, and many of those locations have an extensive history of home health fraud and concurrent enforcement activities. Home health providers, particularly in certain areas of the country, such as Florida, Texas, and select areas in Southern California and in the Midwest, continue to be high on the list of governmental targets for audits, investigation, oversight, and enforcement.

In 2019, as in prior years, DOJ criminal and civil complaints involving millions of dollars were filed against multiple home health agencies. The complaints primarily involved False Claims Act (FCA) allegations due to illegal marketing and kickback activities. Also in 2019, the Office of Inspector General (OIG) for HHS issued multiple reports noting that home health agencies it had audited had billed for home health services that did not comply with Medicare requirements, with resulting overpayments that were due to the government. Additional similar reports are expected to be issued in 2020.

The Review Choice Demonstration project is yet another tool in the arsenal to monitor home health agencies. CMS instituted the RCD project for all home health claims submitted in Illinois, Ohio, Texas, North Carolina, and Florida. These five states are served by Palmetto GBA as the Medicare Administrative Contractor. Home health agencies in the RCD states have the option to choose pre-claim reviews, post-payment reviews, and minimal claim reviews with a 25% payment reduction, and, with certain options and meeting certain metrics, providers can modify their choices at six month intervals. CMS paused RCD activities due to the Covid-19 pandemic, but have fully resumed.

With the new PDGM payment model implemented in 2020, the government added a new compliance element and risk for home health agencies, which will be subject to ever-increasing scrutiny. In light of the sustained enforcement attention on home health, it is advisable for home health providers and their prospective investors to initiate focused compliance attention to PDGM.

Finally, as noted above, DOJ issued updated compliance guidelines in June 2020. These tools are used by prosecutors in assessing the effectiveness of compliance programs in the course of DOJ investigations, prosecutions, and related settlement negotiations. Overall, the compliance guidelines have long examined whether a compliance program is effective across a number of metrics such as adequacy of risk assessment and compliance resources, continuing compliance improvement processes, internal training, reporting structure, and internal investigation processes, the commitment of senior management, sufficient incentives and disciplinary measures, and management of third-party relationships.

The 2020 updates to the compliance guidelines now emphasize the importance of compliance due diligence of acquisition targets, and of a process for orderly integration of an acquired target into the compliance structure of the acquiring enterprise. Overall, DOJ makes clear its expectation that a party acquiring a home health business will conduct robust compliance due diligence pre-acquisition or merger and will be accountable for the effectiveness of the acquired party's due diligence post-transaction.

Medicare and Medicaid

For governmental payors, a fundamental component of payment eligibility is whether the services provided meet the required conditions for payment. Medicare home health guidelines differ from Medicaid coverage guidelines, however, both programs require that certain basic elements be met for the claim to be eligible for payment.

Parties conducting due diligence on a home health enterprise should complete a targeted but thorough billing and claims review. If any overpayment is identified, Medicare requires that the provider look back six years to conduct a review of claims and to establish any total overpayment that may be due. Failure to timely return overpayments can be considered a violation of the FCA. While sellers and buyers can contractually agree to the terms between the parties as to which party will be responsible for any Medicare or Medicaid liability if the buyer assumes the Medicare provider number (which occurs in the majority of transactions), there will be successor liability for the buyer under Medicare; Medicaid successor liability will depend on the relevant state's Medicaid program rules.

It is imperative that home health providers understand and comply with federal and state payor requirements to avoid regulatory and compliance pitfalls. Failure to comply with the requirements can lead to repayments, civil and criminal penalties, and exclusion from participation in federal and state health-care programs.

An eligible patient for home health services under Medicare is required to be homebound, in need of a skilled service (physical therapy, speech therapy, or continuing occupational therapy) on a part-time or intermittent basis and be under the care of a physician. Unlike Medicare, a state cannot require that a patient be homebound to be eligible under the state's Medicaid program but can set other guidelines for eligibility. Additional clinical and technical guidelines must also be met to be in compliance with billing guidelines.

Billing issues and concerns arise from both the clinical and technical components of the records, and certain conditions of participation (COPs) are also considered to be conditions of payment. Both the technical and clinical components must be met prior to submitting claims. Untimely, missing or incomplete documentation can be a basis for claims denials and recoupment and may require repayment to a payor.

The 36 Month Rule

For the uninitiated, it is imperative to appreciate a threshold limitation on changes of ownership under the Medicare program that is unique to home health agencies. By CMS rule, a Medicare provider agreement and related Medicare billing privileges ordinarily cannot be transferred through a change in majority ownership of a home health agency within 36 months after the effective date of the agency's initial enrollment, or the most recent change in majority ownership. Known as the "36 Month Rule," this limitation is intended to curtail frequent changes in ownership of home health agencies. A change in majority ownership is broadly defined to include asset sales, stock transfers, mergers, and consolidations.

If the 36 Month Rule applies, then the prospective new owner/acquiring party cannot accept assignment of the Medicare provider agreement, but instead must go through the very lengthy and complex process of initial Medicare enrollment and accompanying state survey or accreditation from an approved accrediting organization. This delay may negatively impact the feasibility of a potential home health agency acquisition and the projected revenue stream in the months following the change of ownership and should be evaluated early on in due diligence.

Due to the high level of fraud historically and the recognized increased potential for fraud in the home health segment of health-care, CMS has categorized newly enrolling home health providers as "high categorical risk." This designation means that there are additional screening requirements as compared to most other Part A providers, which must be completed prior to CMS issuing the home health agency a Medicare provider number.

In addition to meeting the enrollment requirements of providers at the lower limited and moderate categorical risk categories, an individual with a 5% or greater ownership interest in the newly enrolling home health agency will be subject to a fingerprint-based criminal history record check. While not required to complete a fingerprint-based background check, senior executives and managing employees must also pass background screening requirements. CMS requires that state Medicaid programs assign the same categorical designation for risk that has been assigned under the Medicare program.

Sellers should conduct due diligence on the buyers' owners and executives to ensure that the owners and executives meet the federal and state requirements for ownership of a home health agency. This process should include conducting criminal background checks, reviewing federal and state exclusion and debarment lists, and confirming that these individuals have not been subject to DOJ enforcement or a corporate integrity agreement, either individually or in their roles with respect to ownership or management of other health-care entities.

Failure to fully and timely meet Medicare enrollment and billing requirements could result in deactivation of the Medicare provider number and application of related sanctions and penalties.

State Licensure Requirements

As noted throughout this article, legal and regulatory oversight of home health agencies occurs at both the federal and state levels. While it may be obvious, a home health agency must not only meet CMS Conditions of Participation (COP) requirements (assuming Medicare/Medicaid participation), and other federal and state laws governing anti-fraud, personnel, and privacy, but must also be licensed as a home health agency in states in which it operates and which have a licensure requirement.

While these licensure standards may mirror or be similar to federal COP requirements, they also may be more stringent in certain cases. As discussed below, there likely will be criminal background check mandates, and there may be worker protections under state law. In addition, many states have Certificate of Need (CON) laws that require state regulatory approval before establishing or modifying certain health-care facilities. These CON laws may address the change of ownership of a home health agency. All of these state law considerations should be evaluated during due diligence.

Personnel Requirements

In every health-care merger and acquisition transaction, it is important to conduct targeted due diligence on clinical and non-clinical staff and enterprise practices. For home health-care transactions, this facet of due diligence should fully appreciate the inherent risks associated with a mobile workforce involving many skill levels and providing services to vulnerable individuals in their homes, along with certain laws and regulations unique to the home health workforce.

This due diligence should start by assessing the adequacy of a home health agency's staffing. Across the sector, home health aide shortages are becoming more acute. Insufficient staffing and high staff turnover rates can lead to federal and state regulatory deficiencies and other risks. It is also important to evaluate whether this staff is receiving continuing training to meet federal and state requirements and whether technology is being used effectively to extend and support workforce capacity.

At the federal level, CMS imposes certain requirements under its home health COPs that impact minimum staffing levels and staff competencies. These COP requirements, which were substantially revised effective 2018 for the first time in 30 years, focus on more robust care plan requirements that must be continuously updated. Each staff member, including home health aides, coming into contact with a patient becomes part of the interdisciplinary team, and must be able to participate in and document these updates electronically.

From a practical perspective, this means that staffing at all levels, including aides, must be competent in the assessments and documentation of health status and services provided. In addition, a licensed clinician must be responsible for all services provided to a home health patient. With the new PDGM payment structure, home health agencies should be very cautious with changes in staffing.

Due diligence also must examine state laws for compliance with staffing mandates and related patient care standards. In addition, while there is no federal law on point, most states require criminal background checks on home health employees and generally prohibit the employment of individuals with certain types of convictions from working with home health agency patients. There is wide variation in these laws, as to the type of background check required, the types of convictions that are disqualifying, and whether there is a waiver process that can be pursued by an individual with a disqualifying conviction. As a general matter, a home health agency should have a robust process in place for conducting background checks periodically on new and existing employees, and this should be documented as part of due diligence.

Many states also have enacted broadly-applied "ban the box" laws that limit the ability of a prospective employer to inquire about prior convictions in an initial job application, or to impose a flat prohibition on the hiring of workers with prior criminal convictions. While these laws do not invalidate the home health-specific disqualifying convictions under state law described in the previous paragraph, they may restrict the ability of a home health agency to impose across the board employment policies preventing the hiring of all persons with non-disqualifying convictions.

At both the federal and state levels, there are fair labor standards that apply to home health workers. Under the federal Fair Labor Standards Act and final rules that became effective in 2015, home health agencies must comply with minimum wage and overtime rules. The very nature of home health work creates challenges in calculating and documenting worked hours; this is particularly true for live-in workers. The FLSA is supplemented by emerging domestic workers' bill of rights laws, which have been enacted in eight states, including California, Massachusetts, New York, and Illinois, and are being considered in others.

While the particulars of these laws vary, they generally provide home health caregivers with overtime, paid time off, anti-discrimination and harassment protections, and the right to a written contract. The written agreements with staff should be clear as to classification, worked hours calculation and documentation. Moreover, the agency's compliance program should have a well-developed wage and hour documentation and audit component to it, which should give adequate consideration to live-in worker compliance.

Risk Management and Insurance Coverage

While due diligence in health care inevitably involves a risk management and insurance coverage review, this topic merits a few words of caution in the home health sector. This may be especially true if the acquisition target is a family-owned or smaller home health agency.

Throughout this article, we have discussed the changing standard of care and increasing scrutiny for home health service delivery. At the same time, staffing shortages are becoming more acute. In this climate, the risk of professional liability exposure for rapidly-expanding home health services can be significant.

It is incumbent on parties conducting home health due diligence to pay careful attention to the extent and effectiveness of the agency's risk management program. Is there a risk management officer with suitable credentials and resources? Is there a claims identification and reserving system in place, with appropriate oversight? Does this risk management system link to the quality assurance program?

Intertwined with risk management is the sufficiency of insurance coverage, for professional liability, general liability and directors' and officers' activity. Not only should the individual and aggregate limits be evaluated, but the self-insured retentions and reputation of the carrier must be considered as well. And, of course, the seller and buyer should continue coverage, both pre-and post-acquisition.

Marketing/Referrals

Marketing practices in the governmental payor world are unlike marketing practices in virtually any other industry. The majority of marketing activities that are standard in other industries are improper and illegal when performed by a health-care provider, when services are reimbursed by a governmental payor. In addition, many states have their own rules that impact marketing and referral activities.

Anti-Kickback Statute. Because marketing activities and resulting referrals are a significant focus of government audits and investigations, the due diligence review should include a review of the home health agency's marketing activities to ensure that the activities conducted and any items provided or payments made in connection with the marketing program are in compliance with the federal Anti-Kickback Statute.

The AKS prohibits providers from providing anything of value in exchange for referrals for which payment will be made by federal or state health-care programs. An individual or entity is at risk of violating the AKS if even one purpose of the activity is a payment for referrals, and both the giver and the receiver in such an arrangement have liability. Numerous federal and state governmental entities have taken criminal and civil actions against home health agency owners, operators, clinicians, marketers and recruiters, primarily due to illegal and improper recruitment and marketing activities.

There are many relationships between a home health agency and individuals or entities with which it conducts business that could potentially run afoul of the AKS. To address these common provider relationships, the OIG has identified safe harbors. For these types of relationships, if the relationship meets the specified requirements, the entities receive the benefit of a rebuttable presumption that the relationship does not violate the AKS. It is important to note that meeting a safe harbor does not automatically mean that a relationship does not violate the AKS. However, the starting point for the analysis of whether the relationship is in compliance is that the relationship does not violate the AKS, and the government would have to prove otherwise.

Parties to a transaction should pay close attention to any formal or informal relationships entered into between the home health agency and any other party where either party has the ability to refer patients to the other party, to ensure compliance with the AKS. Compliance with the safe harbor requirements will provide additional support that the relationship does not violate the AKS.

Beneficiary Inducement. An individual or entity is not permitted to provide remuneration to individuals so that those individuals will choose the giver to provide items or services that will be covered under Medicare or a state health-care program. Remuneration includes waivers of copayments and deductibles and transfers of items or services for free or for other than fair market value.

The OIG has provided guidance stating that items of nominal value would not be considered an inducement, and the dollar values considered "nominal" are $15 per item or $75 in the aggregate. This exception was intended to cover small promotional items that could not reasonably be interpreted as influencing an individual to choose a particular provider to provide an item or service. It is important to note that while there are these nominal value exceptions, the OIG has stated that if a provider frequently provides items or services with a nominal value, the frequent provision of those items or could preclude those items or services from being considered nominal.

Additionally, while there are certain exceptions that apply to all providers if specified requirements are met, it is never permissible for providers to provide cash or cash equivalents. Providers must be extremely careful when giving any item or providing any service for free or below market value to an individual whose services will be covered under a federal or state payor program.

When conducting due diligence, parties should include a review of the types of items that are or may be provided to beneficiaries, the value of those items, and how the provision of such items are tracked.

Physician Self-Referral Law a.k.a Stark Law

Paying physicians for legitimate medical services provided to a home health agency may be proper, but any home health agency that enters into an arrangement with a physician must also, in addition to the AKS, consider whether the arrangement is in compliance with the Stark Law.

Under the Stark Law, when an entity enters into an arrangement with a physician, if the physician or an immediate family member has an ownership, compensation or investment interest in the entity and the entity provides services that have been identified as "Designated Health Services," the physician is prohibited from referring patients to that entity. DHS services are the following: clinical laboratory services, physical therapy, occupational therapy, and outpatient speech-language pathology services; radiology and certain other imaging services; radiation therapy services and supplies; DME and supplies; parenteral and enteral nutrients, equipment, and supplies; prosthetics, orthotics, and prosthetic devices and supplies; home health services; outpatient prescription drugs; and inpatient and outpatient hospital services.

Stark is a strict liability statute, which means that unless an exception applies to the arrangement, a provider is prohibited from submitting or causing the submission of claims for services provided pursuant to the arrangement. If a physician violates Stark, the physician is subject to fines and exclusion from Medicare, which will lead to an exclusion from Medicaid. If an entity discovers that it has entered into an arrangement in violation of Stark, the entity should consult with counsel and strongly consider reporting the violation to CMS utilizing the Voluntary Self-Referral Disclosure Protocol. If the arrangement also violates the AKS, then the report should be made to the OIG, not via the SRDP

Parties conducting due diligence should carefully review all home health relationships with physicians where the physician or an immediate family member has an ownership, investment, or compensation interest in the home health provider to ensure that the relationships are compliant with Stark.

The Health Insurance Portability and Accountability Act (HIPAA)

All health-care providers providing services to patients where payment is made by a federal or state payor are considered covered entities under HIPAA and are required to meet the HIPAA privacy and security requirements. Home health agencies obtain and use protected health information (PHI) to perform services for their patients, and that PHI is required to be kept private and must be maintained in a "secure" environment.

Home health agencies in particular face challenges that many other providers do not encounter because the home agency staff is traveling to patients' homes to provide services rather than being located in a physical building.

Home health agencies, like all other covered entities, are required to enter into a business associate agreement (BAA) with any individual or entity working on the agency's behalf, where the contracted individual or entity is, or might be, provided with PHI. Home health agencies should note that, depending on the activities being conducted, contracted individuals and entities who are covered entities could be considered business associates to other covered entities, and for the contract purposes, a BAA might be required.

Covered entities are required to ensure compliance with HIPAA security and privacy, and if a home health agency determines that there has been a HIPAA breach, or if there has been a breach by a business associate, the home health agency must ensure that it, or the business associate, as applicable, complies with the requirements in the HIPAA Breach Notification Rule.

In addition to public reporting and imposed remedial actions, a lack of compliance with HIPAA privacy and security requirements and breach reporting obligations can create a hefty financial liability for a home health agency. Therefore, due diligence should include a review of the home health agency's BAAs, HIPAA policies and procedures, logs and disclosures of any reported HIPAA breaches, remedial actions taken, and any governmental actions or penalties taken against the entity due to a HIPAA breach.

Telehealth in Home Care Delivery

As indicated throughout this article, the use of technology is becoming increasingly essential to home health agencies in their compliance with COPs and the PDGM reimbursement paradigm. We also see a broad sea change in the explosive growth of telehealth in the U.S., with the expectation that the use of telehealth in the home will continue to be used in some form in a post-Covid era.

The lifting of federal and state constraints on originating sites has allowed for telehealth in the home during the Covid-19 pandemic, in both urban and rural areas, with expanded asynchronous technology and by an expanded array of practitioners. At the time of this article, it is not yet clear how much of this expansion will remain in effect after the public health emergency subsides. However, there is a broad emerging consensus that federal and state law likely will accommodate the permanent expansion of telehealth and other similar technology-enabled care delivery tools in yet-to-be-defined ways. This trend will entail expanded use of technology in the care of home health agency patients.

At the same time, both DOJ and OIG are taking aggressive enforcement action against telehealth owners and operators who have been deemed to engage in fraud, some of which have involved interaction with individuals in their homes through telemarketing or similar activities. OIG representatives have recently expressed targeted concern about the potential for fraud in the delivery of telehealth in the home, and in the context of Covid-19. OIG intends to conduct a broad review of the program integrity risks associated with Covid-related telehealth delivery.

For parties conducting due diligence for a home health transaction, it is important to review not only the adequacy of current technology to meet the COPs, PDGM, and personnel requirements discussed above, but also to evaluate whether the home health agency currently engages in telehealth. If telehealth services are being provided, the review should include whether these services conform with current federal and state laws governing licensure and credentialing of these services and whether billing and reimbursement for these services and ancillary business arrangements pass muster under anti-fraud laws and enforcement standards.

Conclusion

Conducting due diligence of home health agencies requires specialized consideration of the factors and regulatory environment that are unique to the home health sector. Buyers of home health agencies should understand the nuances and familiarize themselves with the legal, compliance, regulatory, and operational elements of this burgeoning industry prior to completing any acquisition.