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Representations and Warranties Health Care Due Diligence—for Insurers and Insureds

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It's not a secret. Health care is a heavily regulated industry. The most mundane-looking arrangements could pose significant risks in the form of penalties, overpayment liabilities, criminal prosecution, and/or civil damages; all of which present unique due diligence considerations for those looking to invest in or acquire a health care or health care-related business.

This poses a challenge for all parties involved, but particularly for representations and warranty insurance (RWI) underwriters. With more and more buyers seeking RWI for health care transactions—and with more and more underwriters willing to underwrite health care transactions—RWI coverage (or exclusions therefrom) often drives the regulatory diligence process, impacting not only underwriters and buyers, but also sellers who may be asked to issue special indemnities for issues not covered by RWI. Typically, health care transactions will contain robust representations and warranties relating to health care regulatory compliance, and even if not, there typically are compliance-with-all-laws representations that RWI would be asked to cover, putting health care regulatory diligence at the forefront of the transaction process overall.

The RWI process hinges primarily on assessing a buyer's due diligence, which should be commensurate with the materiality and significance of the various issues at hand, with the buyers relying on regulatory expertise to carefully conduct fact-finding and to analyze such facts against the legal constructs of health care. Underwriters will then rely on such analyses with their own counsel, who conduct diligence on the buyer's diligence to come up with a reasonable and agreeable RWI policy.

Keeping in mind all of the complexities and nuances of health care and health care law, this Briefing attempts to lay out some of the general and basic topics that would be prudent to assess as part of regulatory due diligence in a health care transaction, both for underwriters to feel comfortable underwriting and for buyers to obtain fair and appropriate coverage. The following are certain substantive areas of health care and health care law that buyers and RWI underwriters alike should be aware of in conducting, and evaluating, buy-side regulatory diligence. Note that these are illustrative, not exhaustive; there are myriad other regulatory issues that may be applicable to a specific transaction.

- **Licenses/Permits/Enrollment.** Health care diligence should start with the most basic and fundamental question: is the target licensed and permitted to be able to lawfully conduct its business? This seemingly basic question requires a buyer to understand the business that the target conducts so that it can analyze under federal and state law whether the target has all its required licenses and permits. This diligence should involve more than simply asking the target whether it has any material licenses; it requires an understanding of how health care is regulated based on jurisdiction. For example, a target that manages a

provider network could be considered a third-party administrator, a managed care organization, or even potentially a payer, depending on specific fee structures, functions, risks assumed, and jurisdiction. As another example, many seemingly ordinary goods technically could qualify as a "medical device"—it is not limited to just pacemakers or other implants. Items such as bandages and even software (yes, software) could be regulated by states and federal agencies as medical devices; targets that manufacture, distribute, or dispense such items could be subject to state and federal licensure and permitting requirements. Similarly, diligence should be conducted to ensure that the target company, at each of its locations and for all business lines, as applicable, is properly enrolled with payers to provide, bill for, and ultimately be paid for, such services. In particular, buyers should confirm that the target is properly enrolled to be able to appropriately bill any federal health care programs given that the failure to do so could result in overpayment liability and other potential penalties and fines.

- **Exclusion Checks.** Ensuring that the target regularly checks all personnel, including employees, contractors, etc., against national exclusion/debarment lists—including those maintained by the Department of Health and Human Services Office of Inspector General (OIG) and the U.S. General Services Administration—should be a basic part of health care regulatory due diligence. Depending on the target, the gold standard is to conduct such checks at hire and on a monthly basis. For example, exclusions from federal health care programs have a broader impact than may be intuitive; even if the excluded individual's services are not directly reimbursable by a federal health care program (including, for example, administrative services that may be reported as a cost for cost-reporting entities), the exclusion may lead to civil monetary penalties. Even if a target does not directly participate in federal health care programs, employing or contracting with excluded individuals could lead to contractual issues with payers, customers, and other drivers of revenue, as it has become more or less industry standard to contractually require all health care or health care-related entities to not engage any excluded individuals, even if no federal health care programs are involved or implicated. If a target does not regularly (or ever) conduct exclusion checks, it may be prudent for the buyer to conduct its own in connection with the transaction.
- **Fraud and Abuse—e.g., Stark/Anti-Kickback Statute.** Buyers should be prepared to talk fairly extensively about all fraud and abuse diligence conducted regarding the target's formal and informal relationships with other entities that could, even arguably, raise fraud and abuse concerns. Fraud and abuse law is often enforced through the federal False Claims Act, which could lead to treble damages and per-violation penalties that have the potential to add up to significant losses. For instance, simply stating that the buyers looked at an arrangement and found no fraud and abuse concerns is not sufficient; the analysis should involve explaining (1) whether the arrangement implicates (even arguably so) any fraud and abuse laws; (2) whether there are any applicable safe harbors or exceptions; (3) if not, the specific facts and circumstances that got the buyers comfortable with the arrangement. Buyers should be prepared to discuss relevant guidance (e.g. OIG alerts, advisory opinions, case law, etc.) and compare and contrast the facts at hand to explain the analysis. Additionally, given that the federal physician self-referral law (i.e. Stark Law) is a strict liability statute, buyers should be prepared to discuss how the target complies with the law, if applicable. If Stark is inapplicable, buyers should be prepared to discuss the diligence it conducted to ensure that Stark is *not* applicable—simple reliance on the seller's responses, particularly for entities that bill Medicare, may not be enough.
- **Compliance Program.** A general review and analysis of a target's compliance program, particularly of targets that participate, directly or indirectly, in federal health care programs generally provides a useful lens to review and understand the rest of the target's regulatory risk profile. While no compliance program is, or should be, the same, a comparison to the OIG's seven elements of an effective compliance program is often a helpful reference point for a buyer in assessing (and describing) a target's program. The presence of a compliance program isn't necessarily indicative of the lack of regulatory concerns, and the lack thereof also isn't automatically indicative of specific risks; however, it does help buyers (and underwriters) better understand other risks in context, relative to the target as an enterprise overall.

- **Non-Traditional Health Care Companies.** Buyers should understand that even if the target is not a "traditional" health care company that provides health care items or services, many (if not all) health care-related laws could become applicable to the target and thus warrant diligence. For instance, just because a target does not provide health care services, it does not mean the Health Insurance Portability and Accountability Act (HIPAA) is inapplicable; if the target is a subcontractor of a covered entity and receives protected health information, it could be subject to HIPAA as a business associate. Moreover, even non-health care companies (including, for example, providers of administrative services) could be in the position to refer or recommend certain health care items, services, or providers, and thus implicate the Anti-Kickback Statute. These types of analysis should be a fundamental part of health care regulatory due diligence.

The above are examples of substantive areas of health care and health care law that buyers should be mindful of in conducting diligence and preparing to engage RWI underwriters; each target will implicate a unique set of health care laws that should be analyzed as appropriate for the transaction. In addition to these substantive areas, the below are a few additional concepts that buyers should take into account when conducting diligence and discussing the diligence conducted with RWI underwriters.

- **Reliance on Management Call.** A management call is often an important and efficient tool to cover many areas of diligence for buyers, particularly in the earlier part of the diligence process. However, while useful, it may not be sufficient to rely on statements on a management call when preparing diligence material for RWI purposes. For instance, if a physician group that bills Medicare makes a conclusory statement that it is not subject to Stark, buyers may wish to look at specific HCPCS/CPT codes billed to Medicare to ensure that the target does not bill any designated health services to understand why Stark is inapplicable. Or, if a HIPAA-covered entity states that it keeps breach logs for all security incidents, buyers may wish to be able to state that they have reviewed a sample of such logs to confirm that the company does indeed keep breach logs. Put succinctly, for certain areas of diligence, a simple reliance on a statement made on the management call may not be sufficient for RWI coverage.
- **Historical Risk vs. Go-Forward Risk.** Where there is a compliance/regulatory issue with a target, buyers should be aware that mitigation and remediation strategies for post-signing/closing typically does not provide comfort regarding historical risk. Recall that RWI generally insures representations and warranties about the *past*; fixing and mitigating issues on a go-forward basis may not be sufficient to guard against concerns about historical risks that the underwriter may not be willing to cover through RWI.
- **Assessing Risk Broadly.** Generally speaking, issues that are disclosed by sellers in a schedule are not covered by the corresponding representation and thus not covered by RWI. However, depending on the facts and circumstances, a narrow disclosure could give rise to concern that there could be broader risks associated. For instance, a dispute with a specific payer based on a target's billing practice could be a sign that other payers could also take issue with the billing practice; underwriters may be reluctant to cover such a risk and more broadly exclude an issue. Again, depending on the particular issues, it may be prudent for buyers to be prepared to explain why the issue is limited to the narrower disclosure and why a broader exclusion is not warranted.
- **Materiality.** Certain issues may truly be immaterial to the size and nature of the transaction. However, this is not a one-size-fits-all threshold for materiality; it always depends on the specific context of the issue. For example, if a target has a specific billing issue with a purely commercial payer (i.e. zero federal health care program dollars), but that payer only generates 1% of the target's revenue, it may be appropriate to limit diligence based on the materiality. However, if that same 1% of revenue comes from a federal health care program, a different level of diligence may be warranted given the implications of payer controversy involving federal funds. Buyers should be able to, at least at a high-level, quantify the materiality of an issue.

Ideally, all of the above items and principles should be addressed in the diligence memorandum that the underwriter and its counsel can review as part of the RWI underwriting process. How smoothly and efficiently the RWI process goes will depend primarily on the thoroughness of the diligence and the diligence memorandum, as well as the sophistication of both the buyer's and underwriter's health care regulatory counsel. While there certainly are market trends that drive the level of diligence warranted and acceptable for RWI, certain diligence areas and items are ubiquitous and fundamental in a health care transaction, which typically brings a heightened level of regulatory risk for buyers and underwriters alike given the highly regulated nature of health care. The above items and principles should, hopefully, provide some base level understanding for buyers and underwriters alike on the common regulatory issues that drive, or should drive health care regulatory due diligence and consequently, the RWI process.

