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Clinical Research & Health Insurance

A New Model for Managing Medical Research Billing, Preventing Insurance Fraud, and Negotiating Budgets with Trial Sponsors

Pier 6 Institute
FOR HEALTH LAW & POLICY

This White Paper is the Introduction chapter from the book *Clinical Research & Health Insurance* by Ryan Meade and Chris Conway.

The Growing Complexity of Clinical Research Billing Processes

Most research institutions in the United States leverage health insurance to finance clinical research studies.[1] While the expansion of health insurance over the past twenty-five years was intended to ease financial burdens on providers and patients, institutions now face growing complexity in clinical research billing operations.[2] Tools originally designed to simplify clinical research billing, such as the Coverage Analysis, have ironically grown longer and more complex, even as clinical trial protocols have become more standardized and predictable. Concerns over legal liability have intensified, despite regulatory clarifications and Supreme Court cases that narrow the risks of institutions violating the False Claims Act.[3]

At many institutions, clinical research billing compliance efforts continue to expand, yet genuine risk management of health insurance fraud during clinical trials seems elusive. It is clear these compliance frameworks are no longer achieving their intended objectives. The complexity now embedded within clinical research billing calls for a fundamentally different approach.

> *We propose a reorientation of clinical research billing that prioritizes payment over coverage, sponsor accountability over research institutions subsidizing trial activities, and legal risk management over administrative compliance perfection.*

The new model for clinical research financing presented in this book directly addresses this complexity by refocusing institutions on the core principles of health insurance reimbursement and legal risk management. We propose a reorientation of clinical research billing that prioritizes payment over coverage, sponsor accountability over research institutions subsidizing trial activities, and legal risk management over administrative compliance perfection. We have no doubt the statements so far may be controversial, but this book seeks to explain what we mean and convince readers that there is a simpler way to manage clinical research billing, craft a sponsor budget, and assess compliance risk than the current conventional approaches.

Our goals with this publication are to advocate for streamlining Coverage Analyses and simplifying the clinical research billing processes. We also propose a new model which incorporates a Research Payment Analysis in place of the "draft" Coverage Analysis, which is typically currently used for sponsor budget negotiations. Adopting this model will reduce study activation timelines and yield stronger overall compliance outcomes.

From Coverage to Payment

Our new model directly challenges the flawed assumption that health insurance coverage during clinical trials guarantees insurance payment. When research institutions first adopted the Coverage Analysis to manage compliance risk following Medicare's clinical trial coverage expansion, "coverage" was essentially synonymous with "payment." This is not the case anymore. Many "covered" items and services are not "paid" by health insurance today.[4] The Coverage Analysis began as a straightforward tool for compliant billing and fraud prevention but gradually evolved into the foundational document for budget negotiations with research sponsors.[5]

Initially, this worked effectively, as coverage and payment remained closely aligned. However, over the past two decades, shifts in health insurance payment methodologies have progressively widened the gap between coverage and actual reimbursement.[6] Insurance payment today applies to only a narrow subset of covered services, particularly for hospitals under Medicare's outpatient reimbursement policies.[7] Research institutions relying primarily on health insurance coverage to build trial budgets inevitably fail to recover their actual clinical costs.

> *Many "covered" items and services are not "paid" by health insurance today. Research institutions relying primarily on health insurance coverage to build trial budgets inevitably fail to recover their actual clinical costs.*

Introducing the Research Payment Analysis

A Coverage Analysis remains the best tool for mitigating fraud risk at the point of determining which clinical charges for a research patient can be billed to the patient's insurance or need to be directed to the study. However, there needs to be a deeper look at the utility of a draft Coverage Analysis during budgeting versus the necessity of a final Coverage Analysis for directing charges. We argue in this book that while a final Coverage Analysis should be used for charge review, the current approach of using a draft Coverage Analysis for sponsor budget negotiations disadvantages

the research site because it masks the actual costs which the sponsor should pay.

When budget negotiations rely on a draft Coverage Analysis, there is a risk that many services which are "covered" by insurance but not "paid" by insurance will be missed in the negotiation process. The resulting final Coverage Analysis which develops out of a budget influenced by a draft Coverage Analysis over-manages billing risk and fails to function effectively as a budgeting tool for the research site, particularly hospitals, in recovering costs. Given the limitations of the Coverage Analysis, there is a clear need for an alternative tool specifically tailored to align budget negotiations with realistic insurance revenue outcomes.

Understanding the reality of what insurance pays versus doesn't pay, as opposed to merely what health insurance covers, is what we refer to in the book as *financial realism*. Financial realism requires clinical research administrators to keep up with the changing trends in insurance reimbursement. The first step in financial realism is to recognize the widening gap between health insurance coverage and health insurance payment. The trend is not easily reversible anytime soon, but it is possible to reframe shrinking insurance funds into a powerful data opportunity to demonstrate to a sponsor the actual amount the site needs to conduct the research study.

Our new model introduces the Research Payment Analysis, replacing the draft Coverage Analysis as the primary method for determining a clinical trial's true financial requirements. The Research Payment Analysis more accurately evaluates which clinical trial services generate actual insurer reimbursement, and which clinical trial services should be funded by sponsors. The Coverage Analysis, in turn, should be reserved solely as the billing compliance document reflecting agreed-upon financial responsibilities between the research institution and sponsor. In the new model, there is no need for a draft Coverage Analysis anymore, since the Coverage Analysis becomes simplified to just assembling how the study documents and financing mechanisms play out under the law.

> *It is possible to reframe shrinking insurance funds into a powerful data opportunity to demonstrate to a sponsor the actual amount the site needs to conduct the research study.*

Introducing the Research Payment Analysis does not add complexity or extend study start-up timelines. Rather, it streamlines negotiations by clearly identifying the institution's true financial needs earlier in the process, thereby reducing trial activation delays with upfront data the sponsor cannot refute during negotiations.

As health insurance payment methodologies evolved over the past two decades, research institutions now face significant financial losses by billing insurers for services considered covered but not separately reimbursed (such as routine laboratory tests and supportive care services, which Medicare's Outpatient Prospective Payment System covers but does not pay). Instead, we propose that hospitals submit claims to insurers only for services that meet coverage criteria and generate actual insurer reimbursement while all other services required by the study should be funded directly by the sponsor.[8] Institutions should proactively negotiate with sponsors to fund not only the study-required services which are for research purposes only, but also all protocol-driven services that insurers "cover" but do not reimburse.

This shift from a coverage-centric approach to a payment-centric approach not only stabilizes institutional finances but also better aligns stakeholder incentives: sponsors fund the services necessary for regulatory approval of their investigational products, physicians focus on clinical oversight rather than financial minutiae, hospitals avoid being accused of subsidizing a for-profit sponsor's research, and patients are shielded from unexpected and burdensome co-pays and coinsurance that could deter participation in research.

Refocusing on Genuine Legal Risk

Clinical research billing tools initially emerged from the need to manage genuine health insurance fraud risks,[9] but over time they have drifted away from their primary objective. We propose that research billing operations return to their foundational purpose of preventing overpayments from federal healthcare programs, and that doing so will naturally lead to improved compliance outcomes. Our new model ties compliance activities to actual legal exposure, rather than to rigid procedural adherence which has no bearing on whether an institution has complied with the law. Given the strain that complex regulatory environments place on compliance programs, institutions must triage risks by clearly prioritizing compliance activities based on genuine legal risk.[10]

> *Phantom risks involve internal processes that would be ideal to conform to for consistency but present no legal risk in not achieving perfection; in fact, for many phantom risks there may not be legal risk even when there is utter and complete procedural compliance failure.*

When we discuss "genuine" legal risks in this book we contrast it with "phantom" legal risks. Phantom risks involve internal processes that would be ideal to conform to for consistency but present no legal risk in not achieving perfection; in fact, for many phantom risks there may not be legal risk even when there is utter and complete procedural compliance failure. For example, many research organizations require the Principal Investigator to sign or approve a Coverage Analysis. The Principal Investigator's approval or disagreement with a Coverage Analysis is related to no law and we are not aware of any liability that could arise in not having the Principal Investigator approve a Coverage Analysis.

Compliance auditing of processes such as this add nothing to the compliance controls that manage genuine legal risk.

We will occasionally refer to making the distinction between genuine legal risks and phantom legal risks as *compliance realism*. Compliance realism is critical for efficiently deploying resources in a compliance program. While it is a good idea that Principal Investigators have familiarity with how health insurance works during clinical trials, particularly for their own professional fee billing, Principal Investigators actually bill very little to health insurance. The primary actor billing health insurance during a clinical trial is the hospital. Whether a Principal Investigator signs or approves a Coverage Analysis is of no consequence to a hospital submitting a claim to Medicare or Medicaid since the hospital is responsible legally for the accuracy of its hospital service claims.

A phantom compliance risk, in a sense, is one that is not a legal risk. Risk triaging is a significant challenge compliance programs face in the U.S. today. Our new model hopes to dissolve the fogginess in how to focus compliance program resources in one sector of the health care regulatory arena, clinical research billing.

Our new model operationalizes this refocus by establishing practical criteria for distinguishing genuine legal risk from phantom risks. Issues that do not materially impact health insurance payments or cannot result in actual overpayments should not be the attention of compliance programs. By clearly defining and deprioritizing these phantom risks, institutions are freed from unnecessary operational burdens, allowing them to reallocate compliance resources toward materially significant issues. Compliance teams will gain greater flexibility and capacity to proactively address overpayment risks, reducing their exposure to regulatory enforcement.

Three Principles of the New Clinical Research Billing Model

To fundamentally reset clinical research billing practices, our new model rests on three interrelated principles designed to realign institutional incentives, clarify stakeholder roles, and streamline compliance.

1. Insurance Payment-Driven Billing Analysis

Institutions must utilize insurance reimbursement data to accurately determine services that generate payment. Relying on the concept of health insurance “coverage” provides very little insight into which services will be paid by insurance. Research institutions should require sponsors to fund all protocol-driven services that insurers do not reimburse. This would close the gap between nominal coverage and actual payment so that research sites are not underwriting unreimbursed costs related to the sponsor’s study schedule. This approach prevents sponsors from shifting financial responsibilities onto research institutions by exploiting the ambiguity in health insurance “coverage” frameworks.

Stakeholders in clinical trials need to recognize that financial realism means deferring to the organizational people best capable of handling the varied technical aspects of a research portfolio.

2. Stakeholder Role Clarity

People and parties with interests in the success of a research study are many and varied. They rarely work with each other or have cross-competencies in the many tasks that go into starting up and running a trial. Stakeholders in clinical trials need to recognize that financial realism means deferring to the organizational people best capable of handling the varied technical aspects of a research portfolio. Financial specialists should manage negotiations with sponsors. This approach mirrors established practices hospitals employ during managed care negotiations with insurance companies. Physicians should generally not participate in financial rate negotiations because they lack familiarity with hospital revenue cycle intricacies.

3. Material Compliance Focus

Compliance programs should prioritize auditing instances of material non-compliance with Medicare and Medicaid regulations that directly risk overpayments from government insurers.[11] This prioritization reduces unnecessary focus on minor technical or procedure problems. A provider faces False Claims Act liability when it knowingly—that is, with actual knowledge, deliberate ignorance, or reckless disregard—submits false information that is material to the government’s payment decision. When a claim error is neither knowing (foreclosing scienter under *SuperValu*) nor material to reimbursement (foreclosing liability under *Escobar*), the False Claims Act does not impose liability for technical inaccuracies.[12]

By focusing explicitly on identifying and rectifying material compliance issues that could cause overpayments, institutions conserve resources otherwise wasted on addressing non-essential tasks. This targeted compliance approach addresses the primary causes of enforcement actions: payment from government insurers for services sponsors are contractually obligated to fund, payment from government insurers for services promised free in the ICF, and payment from government insurers for services performed solely for research purposes without clinical benefit to patients. This approach aligns with the Supreme Court’s *Escobar* decision, which holds that actionable False Claims Act liability under an implied false certification theory requires that the noncompliance be material to the government’s payment decision.

Avoiding the Complexity Trap and Technological Overreach

The increasing complexity of Coverage Analyses and misguided investments in clinical research management technology represent significant challenges to effective compliance and financial management in clinical research billing. When Coverage Analyses try to manage phantom risks or anticipate all charge scenarios a research patient may encounter the research institution is on a road to nowhere, an impossible destination to reach. Coverage Analyses, as we will explain, simply cannot anticipate all the possible charge capture scenarios prior to a patient encounter. There is no technology that can accomplish this because no technology can predict the future or anticipate a patient's clinical presentation.

> *A physician encounters a research patient as a whole person, a complex phenomenon which must be treated as a whole person. This is why a Coverage Analysis as a billing tool is a guide, but not an algorithm, for what can or cannot be billed to insurance.*

The Coverage Analysis is widely recognized as the central compliance tool in clinical research billing. Initially developed as a straightforward guide to mitigate overpayment risks, at many research institutions it has since evolved into an overly complex, cumbersome, and largely ineffective document. This complexity has obscured the original purpose of the Coverage Analysis, significantly diminishing its effectiveness for risk mitigation.

Coverage Analyses can no longer reliably inform sponsor budget negotiations, as they are not designed to reflect evolving health insurance payment methodologies. A Coverage Analysis presents, as its name suggests, the services that are covered and not covered by health insurance during the clinical trial. When something is not covered by an insurance plan, then billing the health insurer risks allegations of insurance fraud. Coverage, however, today tells us absolutely nothing about what health insurance pays for covered services. Coverage Analyses are critical for legal risk management during research studies but that is what they should be focused on and not confused with a financial analysis of the unreimbursed costs of a clinical trial.

A Coverage Analysis also cannot list all of the possible services a research patient will receive during the patient's study visit. When a physician treats a research patient, the physician cannot focus only on a narrow set of data points prescribed by the protocol while ignoring the patient's clinical state. A physician encounters a research patient as a whole person, a complex phenomenon which must be treated as a whole person. This is why a Coverage Analysis as a billing tool is a guide, but not an algorithm, for what can or cannot be billed to insurance. This guide tool needs to be utilized by a human being who can apply the direction and principles represented on the Coverage Analysis to the charges for all the services that occurred during a patient encounter.

This complexity is further exacerbated by substantial institutional investments in technology platforms intended to streamline research billing processes. Yet, rather than simplifying billing processes, these platforms frequently impose cumbersome workflows and intricate data-entry requirements that introduce additional layers of complication, escalating costs, and prolong time-to-activation. These systems have diverted institutional focus away from substantive compliance obligations and obscured critical health insurance reimbursement trends that directly impact trial finances.

To be sure, we believe that clinical research portfolios are best managed with technology platforms that at a minimum track study status, identify research patients, and serve as a document warehouse. We have nothing whatsoever against technology platforms that establish electronic calendars for managing trial performance and easy capture of patient data—we encourage them—but trying to merge an electronic study calendar that tracks data results and serves other trial management goals with health insurance revenue cycle principles is a categorical misalignment.

A Cultural and Operational Reset

Successfully addressing the dysfunction in clinical research billing requires moving beyond incremental adjustments toward a fundamental shift in institutional culture and operational practices. The new model described in this book is not merely a billing strategy; it is a cultural and operational reset. Institutions must confront the financial realities of health insurance reimbursement, abandon outdated assumptions that coverage equates to payment, and hold sponsors financially accountable based on empirical payment data or research institutions will face the need to find other resources to backfill the losses in conducting clinical research.

> *The new model we present in this book is characterized by transparency, fairness, and realism in clinical research financing.*

This operational and cultural shift transforms clinical research from merely managing compliance risk into an ethically sound and financially stable enterprise. The new model we present in this book is characterized by transparency, fairness, and realism in clinical research financing. In doing so, it addresses systemic cost-shifting and stakeholder misalignment stemming from the Medicare policy decision in 2000 to expand coverage to certain services provided during clinical trials.[13]

Structure of This Book

In **Part One**, we explore how Coverage Analyses have drifted from their original compliance-focused function, becoming encumbered by an unrealistic pursuit of unattainable precision rather than addressing genuine compliance risks. We provide historical context on how health insurance coverage for clinical services originated, demonstrating how this history informs current compliance challenges.

In **Part Two**, we revisit fundamental clinical research billing rules, clarifying what institutions must evaluate when billing health insurance and how "coverage" for items and services is determined under the Medicare program. We focus on CMS's NCD 310.1 in this part of the book.

In **Part Three**, we describe how changes in health insurance payment methodologies began diverging significantly from health insurance coverage concepts. This divergence is particularly pronounced in hospital outpatient clinic services. At the core of this major shift in reimbursement is Medicare's Outpatient Prospective Payment System (OPPS).

In **Part Four**, we analyze the motivations of key stakeholders in clinical research, particularly as they intersect with research finances and health insurance. We frame these interactions within their strategic and financial contexts, clarifying each stakeholder's distinct objectives. Many clinical trials represent multi-million-dollar ventures for research institutions. They must be managed accordingly.

Finally, in **Part Five**, we present actionable steps for implementing the new model, detailing how the Research Payment Analysis can replace the draft Coverage Analysis during study start-up to improve sponsor negotiations. We describe specific strategies for leveraging health insurance payment data to accelerate sponsor negotiation. The book concludes where it begins, by proposing that Coverage Analyses be used for their principal purpose as a research patient charge review tool to manage health insurance fraud risk.

Returning to Simplicity and Clarity

It is time for research institutions to critically reevaluate long-standing assumptions regarding health insurance reimbursement and the effectiveness of existing compliance tools. Institutions must recognize that the excessive complexity embedded in research billing processes creates confusion, inefficiency, and errors, exposing them to increased financial and regulatory risk.

> *A fundamental shift is necessary: research institutions must restore simplicity and clarity in managing clinical research and health insurance.*

A fundamental shift is necessary: research institutions must restore simplicity and clarity in managing clinical research and health insurance. This involves returning to the basics of compliance risk management, with a clear focus on deploying resources that minimize risks of overpayments and legal liability. It involves understanding the interests of the stakeholders in clinical research financing. Most importantly, it involves fully understanding that health insurance payment methodologies have dramatically shifted over the past quarter century.

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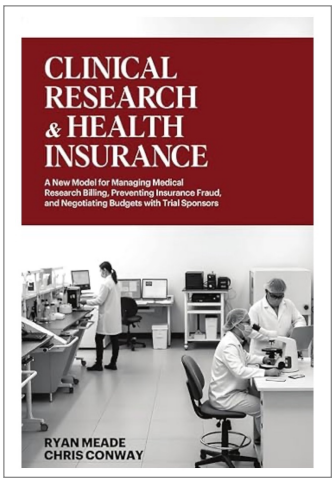

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Endnotes

1 "You may be wondering if clinical trials cost money and who pays for them. Many clinical trial costs are covered by the sponsor of the study, a patient's insurance plan if one is available, and sometimes there are out-of-pocket costs. Before you join a study, ask the study coordinator which costs are covered and which are not." "Who Pays for Clinical Trials?" National Cancer Institute: https://www.cancer.gov/research/participate/clinical-trials/paying (last accessed February 1, 2026). There are no data that provide a good estimate of how many clinical trials in the United States use health insurance to partially finance the research study, but the National Cancer Institute provides the above note to potential cancer clinical trial patients. We believe it is fair to say that most research sites leverage health insurance to fund clinical research to some degree, considering the enormous amount of time and effort that has been dedicated to the legal expansion of clinical trials health insurance coverage and the reality that developing Coverage Analyses has become its own profession.

2 Nigel Markey et al., *Clinical Trials Are Becoming More Complex: A Machine Learning Analysis of Data from over 16,000 Trials*, 14 Sci. Reps. 1 (2024). *See also* Brianna Krafcik, Gheorghe Doros & Marina A. Malikova, *A Single Center Analysis of Factors Influencing Study Start-up Timeline in Clinical Trials*, 3 Future Sci. OA 4 (2017); Akash Goyal et al., *Assessment of North American Clinical Research Site Performance During the Start-up of Large Cardiovascular Clinical Trials*, 4 JAMA Network Open 7 (2021). Much of the literature about the burden of complexity in clinical research billing tools and operations surfaces in discussion about research study time-to-activation rather than articles published directly on the burdens to an organization in conducting a Coverage Analysis.

3 *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176 (2016); *United States ex rel. Schutte v. SuperValu Inc.*, 598 U.S. 739 (2023). This case, hereafter referred to simply as *SuperValu*, clarifies the subjective scienter standard under the False Claims Act. *See also* Deborah Farringer, *From Guns That Do Not Shoot to Foreign Staplers: Has the Supreme Court's Materiality Standard Under Escobar Provided Clarity for the Health Care Industry About Fraud Under the False Claims Act?*, 83 Brook. L. Rev. 1227 (2018). We realize it is a controversial statement that the risks of health care institutions violating the False Claims Act have narrowed in light of the enormous volume of regulations governing the Medicare and Medicaid programs and the steady-drum beat of *qui tam* suits and prosecutions for federal healthcare program insurance fraud. However, the corpus of Medicare and Medicaid regulations which must be complied with is distinct from the legal standard that must be met in order to incur False Claims Act liability. The U.S. Supreme Court has issued two critical opinions that structure the standards for liability under the False Claims Act: *Escobar* and *SuperValu*. *See* 31 U.S.C. §3729(a)(1)(A)–(B). The progeny of *Escobar* is still in development even though the case is a decade old. In *United States ex rel. Campie v. Gilead Scis., Inc.*, 862 F.3d 890 (9th Cir. 2017) the court applied *Escobar*'s materiality standard in a pharmaceutical manufacturing context. In *United States ex rel. Harman v. Trinity Indus., Inc.*, 872 F.3d 645 (5th Cir. 2017) the court addressed the "government knowledge" defense to FCA materiality. The concept of materiality has deep roots in Western legal thought. Roman law distinguished between *dolus malus* (fraudulent intent material to a transaction) and *dolus bonus* (permissible exaggeration or puffery). Under the *Lex Aquilia*, liability for *damnum iniuria datum* required not mere error but culpable conduct material to the harm. *See* Justinian, *Digest*, 4.3.1.

4 As an example of how ubiquitous the notion of coverage equaling payment was, Ryan wrote the following in a textbook in 2014: "For the sake of describing the four principal health payment systems in this chapter, we generally will use the terms 'coverage and payment' interchangeably." Ryan D. Meade, *Health Care Payment Systems*, in *Problems in Health Care Law: Challenges for the 21st Century* (J. Steiner ed., Jones & Bartlett Learning 2014). The general interchangeability of the terms "coverage" and "payment" was a true statement in 2014 and for many decades prior to that. It is not true now. The distinction between coverage and payment has long roots in western law and commercial exchanges. It even parallels Aristotle's distinction between *potentia* (capacity, potentiality) and *actus* (realization, actuality) in *Metaphysics*, bk. IX, 1045b–1046a. A service that is "covered" has the capacity to be paid—in other words it qualifies for payment—but qualification alone does not necessitate that payment occur.

5 Cynthia E. Boyd & Ryan D. Meade, *Clinical Trial Billing Compliance at Academic Medical Centers*, 82 Acad. Med. 646 (2007).

6 Joshua D. Gottlieb et al., *The Complexity of Billing and Paying for Physician Care*, 37 Health Aff. 619 (2018); Medicare Payment Advisory Comm'n, *Report to the Congress: Medicare and the Health Care Delivery System* (2020). *See* 42 C.F.R. §§419.31–419.32 (APC payment methodology and packaging rules). *See also* Uwe E. Reinhardt, *The Pricing of U.S. Hospital Services: Chaos Behind a Veil of Secrecy*, 25 Health Aff. 57 (2006).

7 Ctrs. for Medicare & Medicaid Servs., *Medicare Claims Processing Manual*, CMS Pub. 100-04, ch. 4, §10 (2025); Laxmaiah Manchikanti et al., *Medicare's Hospital Outpatient Prospective Payment System: OPPS 101 (Part 2 of 2)*, 14 Pain Physician 11 (2011); Pam Kassing & Christina D. Berry, *Hospital Outpatient Prospective Payment System: A Maturing Prospective Payment System*, 17 J. Am. Coll. Radiology 534 (2020). *See* 42 U.S.C. §1395l(t).

8 This proposal for thinking through a budgeting strategy for research sites negotiating with sponsors follows a minimalist approach if a site wants to leverage health insurance to help finance a clinical trial. In our opinion, the ideal approach is for sponsors to pay for all services required by a study protocol since this would relieve research patients of co-pays and deductible responsibility during a research study. It would also minimize variability in the payments research sites receive for study services. However, we recognize that this may not work for all studies or all sites and so we present a negotiating strategy that allows for health insurance to partially finance the trial.

9 Boyd & Meade, *supra* at 646; *see also* F. Lisa Murtha, *Meet Dr. Cynthia Boyd & Ryan Meade and Learn Details of the Rush Clinical Trials Billing Settlement*, 8 Compliance Today (2006).

10 We are not stating that internal procedures have no value in managing compliance risks; indeed, having consistent processes and standard operating procedures are important tools in training operations staff. However, in this book we are focused on exploring the legal dynamics of how clinical research and health insurance interact with each other. *See* OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg. 8987 (Feb. 23, 1998). *See also* Melissa S. Baucus & Janet P. Near, *Can Illegal Corporate Behavior Be Predicted? An Event History Analysis*, 34 Acad. Mgmt. J. 9 (1991).

11 The materiality standard is of central importance to the *Escobar* holding. *See Universal Health Services, Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 192–93 (2016) (holding that FCA liability for implied false certification requires that the misrepresentation or omission be "material to the Government's payment decision").

12 The knowledge requirement for False Claims Act liability is the central importance of the *SuperValu* case. Although *SuperValu* cannot be read as merely *Escobar* Part II, *SuperValu* and *Escobar* nevertheless have a

sufficient family resemblance to serve as a continuum of cases emphasizing that the False Claims Act does not impose liability merely because a claim is inaccurate. It is also important to note that intentional fraud raises the stakes even if there is no payment. The False Claims Act does have a level of knowledge which treats "actual knowledge" the same as both "reckless disregard" and acting in "deliberate ignorance" from a civil fraud perspective (31 U.S.C. §3729(b)(1)(A)). However, when a provider has specific intent in "knowingly and willfully" attempting to defraud a federal healthcare program, then an even more serious criminal statute is triggered which does not need to be connected to overpayments or decisions about payment. 18 U.S.C. §1347.

13 Ctrs. for Medicare & Medicaid Servs., *Medicare National Coverage Determinations Manual*, CMS Pub. 100-03, ch. 1, §310.1 (2000).

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