

# Clinical Researcher

March 2019

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PEER REVIEWED

## **The Training Challenges in Billing and Research Compliance**

Kelly M. Willenberg, DBA, RN, CCRP, CHRC, CHC



Clinical trial billing is the process of ensuring that, from the coverage analysis to a claim reimbursement, you have revenue integrity. From the negotiation of a budget and contract against the coverage analysis to the revenue charge review and adequately coding claims, a site must ensure teamwork and communication for all stakeholders.

However, billing compliance is sometimes an overlooked component at clinical operations sites. What are the challenges with the process of billing compliance, and how do you train team members adequately? This article focuses on how determining when training is necessary and when it is lacking is a successful component of a compliant research billing process.

### **Challenges Ahead**

A research billing compliance professional faces challenges every day, and sometimes they are insurmountable. Understanding why a coverage analysis is necessary, and its importance to the development of the contract, budget, and informed consent is key. Although some sites have this process designated to someone on the research team, the necessity for having the proper training cannot be overstated.

Asking study coordinators to perform this task is truly difficult without the proper training and clinical expertise. Analyzing a protocol's study procedures from the billing perspective is not an easy task for anyone, least of all someone who has no idea what a coverage analysis is. However, their knowledge base from the clinical side in evaluating a study calendar and protocol for the clinical services can be extremely valuable to the process. Can they make an adequate evaluation and perform the necessary steps?

In some ways, having little or no training can be riskier, because once you start documenting using a bad process, you open the door for mistakes to be recorded and replicated. To be successful in research billing compliance, all staff need to accomplish many things, including an investment of time into professional development activities around the billing process.

## **Validation and Evaluation**

How do you validate and evaluate your process of billing compliance? First, you must know all the types of clinical trials open at your site and whether they are considered “deemed and qualifying” under the National Coverage Decision of the Center for Medicare and Medicaid Services. Beyond the more familiar types of drug trials, understanding what types of device trials, if any, your site has open (including those carried out under Category A or B Investigational Device Exemptions [IDEs]) and if they have approval from Medicare is vital to your success in reimbursement.

Recognizing the types of studies and promoting awareness of them among all participants at every visit will set you up for success. Identifying each study with a coverage analysis is best practice, and should be implemented to procedurally process claims in a compliant manner. This does not occur without dedication and knowledge on many levels in the billing compliance spectrum.

While training is important, staff turnover for the billing compliance team can lead to big issues if there is not a hand off of information. The consequences can impact accrual and compliance with the protocol. There are many steps to ensure that ultimately, a claim is submitted correctly; the regulations are intense and cannot be learned overnight. Each state Medicaid plan varies, and all commercial payers have different medical management policies that can cover or not cover clinical trials. Accepting that Medicare is the payer that you should follow with intention from the beginning will make the process smoother.

## **Targeting Training Needs**

What training is necessary for success? The first part of the billing compliance process is the coverage analysis. Training on a coverage analysis is absolutely necessary for best practice with a review of the protocol services against National Guidelines, National Coverage, and Local Coverage Decisions. This justification is documented and serves as justification when a claim is processed for a study participant with billable services.

The coverage analysis is the basis for a solid budget, contract, and informed consent. Knowing that the patient should be told what services their insurance or payer is going to be covering for a trial is part of the consent process, as they may end up with outstanding balances. This is why the person doing the consent should be

trained on the coverage analysis so they can describe correctly to the participant what their expected cost will be in the consent form, and ensure that this description is understandable to a person with an 8th grade education.

Another area that is important to the billing compliance process is ensuring that all coordinators receive education on how the coverage analysis impacts the consent. Explaining that something is covered by a sponsor is easy, but when it is documented as a routine cost in the coverage analysis, the consent process is marred by disagreement with the financial documents. Participants will be confused when they receive an explanation of benefits that shows something itemized that they thought was provided by the study sponsor. By building appropriate infrastructure around this process, everyone is informed about what is expected to be paid by Medicare or insurance and what the sponsor is paying for or providing for free, and ultimately the transparency helps the participant to understand their financial responsibility.

Another problematic area for billing compliance is claims processing, when the research coordinator is contacted to help segregate charges on a participant claim. If the coordinator does not understand how the coverage analysis directly impacts submission of the claim, they can direct charges to the wrong payer. When they are not trained adequately, they may not order the services correctly. Asking one if something is “standard of care” might get an incorrect answer, thus a wrong claim is processed.

If the services are set as billable under the rules to a payer as a “routine” costs, the claim should be processed in that matter. Without the ability to track these visits, some sites find themselves overwhelmed and coordinators are relied on to make decisions on segregating charges with no knowledge or training of the billing compliance process. Making the wrong decision can separate hospital and physician billing into two different methods for one visit. Research staff must understand that how a service is ordered and documented can be the reason for a denial.

These types of services can be just as important in an inpatient device study and an outpatient drug trial. The government wants to know that you are billing both drug and IDE device studies correctly; both have unique challenges that must be understood. Anyone who deals with the claim at the patient care level needs information on the coverage analysis regardless the type of study you are dealing with when there is treatment. The communication flow is sometimes the biggest challenge for billing compliance teams, and often a lack of training can cause many discrepancies.

### **Considering the Three C’s**

The “three C’s” of billing compliance can be described as meeting the Challenges, fostering Collaboration, and accepting a spirit of Compromise.<sup>{1}</sup> Once you decide to meet the challenges of billing compliance, collaborating with colleagues will help in answering questions that arise. Keeping training on the agenda for all

team members and encouraging them to attend conferences that have billing compliance, revenue cycle, and reimbursement on the agenda is key. There are many conferences that have sessions on these topics.

There also are many opportunities for training. Finding opportunities where all staff—including coders, study coordinators, billing compliance managers, regulatory compliance experts, and accounting team members—can learn together is recommended. Having everyone work together and collaborate on how to face the challenges in billing is gratifying for billing compliance personnel.

Compromise involves reaching an understanding of how each department's procedures can impact others. Working together to face simple process issues with compromise for who is responsible can make the difference within a compliant billing process.

## **Conclusion**

Put training on your team's calendar and you will reap the benefits! Delving into networking opportunities, mentoring programs, and training will help staff to achieve career goals and make research billing compliance programs stellar. Attending clinical trial billing compliance conferences will strengthen your team members' abilities to meet the challenges that come with this important aspect of clinical trial management.

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PEER REVIEWED

## **Paying Subjects to Take Part in Research: A New Perspective on Coercion and Undue Influence**

David Borasky, MPH, CIP; Jeffrey A. Cooper, MD, MMM; Kelly FitzGerald, PhD



Under U.S. Department of Health and Human Services (HHS) and Food and Drug Administration (FDA) regulations and the International Council on Harmonization guidelines for Good Clinical Practice, for an institutional review board (IRB) to approve research with human subjects, it must determine that investigators will obtain informed consent from each prospective subject or the subject's legally authorized representative, under circumstances that minimize the possibility of coercion or undue influence. {1–4}

Payment for participation in research represents a mechanism to induce subjects to take part in research when they otherwise might not take part. Therefore, payment is part of the consent process and any payment provided to subjects must take place under circumstances that minimize the possibility of coercion or undue influence. However, how should IRB members determine that this is, in fact, the case in the studies they review?

### **Defining Undue Influence**

To determine whether any payments to participants minimize the possibility of coercion or undue influence, IRBs should apply the definitions of “coercion” and “undue influence.” The Belmont Report defines “coercion” as an overt threat of harm that is intentionally presented by one person to another to obtain compliance, where compliance in this case refers to agreeing to take part in research. {5} The Belmont Report further defines “undue influence” as an offer of excessive, unwarranted, inappropriate, or improper reward or other overture to obtain compliance. In this context, “compliance” refers to agreeing to take part in research or to continue participation in research. “Influence” means to impact, determine, guide, shape, alter, change, or transform and

“undue influence” is influence that is excessive, unwarranted, inappropriate, or improper. {6–8} Under the regulations and guidance, undue influence is ethically unacceptable, whereas influence that is not undue is allowable.

As parts of the HHS, the Office for Human Research Protections (OHRP) and FDA have released guidances regarding subject incentives that state, “Paying research subjects in exchange for their participation in research is a common and, in general, acceptable practice.” {9,10} The FDA guidance goes on to state that payments made to offset or reimburse out-of-pocket expenses do not raise issues of coercion or undue influence. This guidance also informs IRBs to look carefully at payments to ensure that they are neither coercive nor unduly influential.

### **Proposing a Different Approach**

Most IRBs are cautious about payments and reject those that are out of the norm as coercive or unduly influential. However, two recent papers cast doubt on this approach, and suggest that IRBs need to take a different approach to evaluating whether the circumstances of payments to subjects minimize the possibility of coercion or undue influence. {11,12}

The first issue noted by the authors of these papers is that studies of IRB members indicate that they commonly reject the use of monetary incentives because they categorize such incentives as coercive. {7,8} However, these authors note that IRBs should abandon the idea that incentive payments can be coercive. {11,12}

As noted in the Belmont Report, coercion involves the intentional threat of harm. {5} Although a threat to withdraw a payment to which a subject is entitled can represent an intentional threat of harm, subjects taking part in research are not entitled to incentive payments. Therefore, the offer of an incentive payment is a benefit and cannot represent a harm, no matter how large the payment.

Offering an incentive payment for participation cannot meet the definition of “coercion.” Therefore, IRBs should stop using coercion as a basis for requiring investigators to reduce the amount of payment to subjects. Instead, IRBs should focus on whether the influence presented by incentive payments represent influence that is acceptable or influence that is undue.

### **Considering Payment Impact**

While coercion is relatively easy to recognize because subjects are threatened, distinguishing undue influence from mere influence is more difficult. Undue influence implies that individuals will agree to take part in

research without a rational consideration of the information provided in the informed consent process, such as the risks and procedures involved in the research.

IRBs cannot consider an incentive payment to be unduly influential solely because an individual would not take part in the research but for the payment; this is precisely the reason investigators use recruitment incentives. Moreover, this logic would compel IRBs to determine that many acceptable incentives are unduly influential, such as advertising or a physician telling a patient that they might want to talk to the investigator to learn about taking part in a clinical trial.

If an IRB has approved a study, the IRB has determined that the risks are acceptable in the absence of payment. Adding payment to a research study cannot affect the acceptability of the research risks. In both cases, reasonable individuals can use good judgement and decide to take part in research with incentive payments, where in the absence of those payments, they would have declined.

Undue influence must lead to poor judgement. The question is: How does an IRB determine whether a payment causes prospective subjects to make a decision that is against their interests?

### **Recognizing Context Plays a Part**

A problem with payments is that an offer of payments designed to incentivize participation in research will not affect all individuals the same way. Subjects will have different perceptions of the financial reward based on the burden of the research in terms of costs of transportation, length of study visits, and degree of risks and discomforts. The offer may result in poor judgement by some individuals, but may not affect the judgement of others.

More specifically, what is unduly influential to one subject might be merely influential to another. As OHRP guidance states, “because influence is contextual, and undue influence is likely to depend on an individual situation, it is often difficult for IRBs to draw a bright line delimiting undue influence.”<sup>{9}</sup> Meanwhile, the IRB must approve the research for all individuals who meet the selection criteria, even if an incentive payment may cause poor judgement in a minority of subjects.

Since the theoretical likelihood of undue influence goes down with a decreasing incentive, many IRBs minimize the possibility of undue influence by mandating payments low enough to prevent any possibility of an incentive payment affecting someone’s judgement. This is problematic for two reasons. First, there is no threshold of payment below which no person would ever be unduly influenced. If the goal is to protect against such outliers, no payment can ever be free of undue influence. Second, there are other influences on a subject’s participation in research, and if the same paradigm is applied to these influences, one reaches an illogical conclusion.

## **Acknowledging Influence of Potential Benefits**

Lee points out factors other than incentive payments that influence subjects, and notes that if payments can be unduly influential, so can these other factors. {11} For example, a common influence on subjects' decisions to enroll in research would be potential benefit.

The potential benefit may be a therapeutic misconception or may be reasonably expected, based on reality. For example, early trials may have shown a high rate of complete remission in a lethal cancer that otherwise had no effective treatment, such as seen with early trials of imatinib and ipilimumab. This potential benefit, or the incorrectly perceived potential benefit, may be enough

to cause an individual to make a decision contrary to his or her own best interest. Research staff who run active Phase I oncology units see this not infrequently.

## **Minimizing All Possible Sources of Influence**

Lee observes that the standard IRB approach to reducing the likelihood that payments will unduly influence subjects is to reduce them. {11} If IRBs were to apply their standard approach to payments to other research benefits, Lee notes that IRBs would have to reduce potential benefits to minimize undue influence. For example, the IRB would require protocols to randomize a greater percentage of subjects to placebo or require lower doses of drug in the treatment group to the point where individuals would be less motivated to take part.

Factors such as the possibility of closer follow-up, less expensive medical care, or access to medical care also influence subjects to join trials. IRBs could minimize the possibility of undue influence by reducing follow-up visits or requiring subjects to pay for the study drug; clearly, however, this is absurd. The IRB would be penalizing all subjects based on the behavior of a subset of individuals, and would be interfering with science that otherwise meets the criteria for approval.

## **Factoring in Fairness**

There is an issue of fairness at stake when denying a subject reasonable compensation because of the behavior of a minority. If an insufficient number of subjects enroll in a research study, the likelihood of gaining important knowledge is reduced.

One can argue that reducing payments to subjects is different from reducing benefits in research. However, that does not solve the problem that potential benefits may present undue influence and that, to approve research, the

IRB is obligated to ensure that such undue influence is minimized. Can IRBs use a single strategy to minimize undue influence related to incentive payments and potential benefits?

### **Obtaining Legally Effective Consent**

One solution to this issue is to go back to the definition of undue influence. Undue influence implies that individuals will agree to take part in research against their own best interest. The unduly influenced subject may have agreed to participate in the research without any consideration of the risks or the procedures that would take place.

The FDA and HHS regulations refer to “legally effective consent,” which generally means that an individual has been provided sufficient information about the research, understands that information, has considered that information, can understand the implications of a decision to take part, can make a decision, and can communicate that decision. {1,2,5} The unduly influenced subject fails these criteria, based on not considering the information and not understanding the implications of a decision to take part.

Essentially, unduly influenced subjects are in a state where they cannot provide legally effective consent. This applies not only to subjects who are unduly influenced by incentive payments, but also to subjects unduly influenced by actual or perceived potential benefits, advertisements, and recommendations of a treating physician that participation in a specific research trial would be in that patient’s best interests.

### **Determining Capacity to Consent**

Another situation in which individuals are unable to provide legally effective informed consent arises when subjects are cognitively impaired and lack the capacity to provide informed consent. Typically, protocols require subjects to be able to personally provide informed consent, or in some cases, require a legally authorized representative to provide consent on behalf of such subjects.

Although some protocols involve the expectation that prospective subjects may or may not lack capacity to consent, almost all protocols involving adults are based on the idea that the research team knows whether a subject taking part has the capacity to provide legally effective informed consent. If they do, subjects must personally provide informed consent and permission by a legally authorized representative for the subject to take part in the research is insufficient. If they don’t, the investigator cannot enroll the subject or must obtain the permission of a legally authorized representative, depending on the specifics of the protocol.

Many IRBs have dealt with situations that require the research team to evaluate during the consent discussion whether the prospective subject has the capacity to consent. This involves the research team listening to the

prospective subject's statements and questions to assess whether he or she understands the information being provided, is considering that information, understands the implications of a decision to take part, can make a decision, and can communicate that decision.

IRBs can apply the same process to undue influence, which like capacity to consent, is another factor that interferes with the ability of an individual to provide legally effective informed consent.

### **Recognizing Undue Influence**

Some IRBs may scoff at the idea that the research team can evaluate whether a subject is providing legally effective informed consent, but the fact is that IRBs often rely on research teams to make this decision. If the research team can determine whether a subject is providing legally effective informed consent based on capacity to consent, it can follow the same process to exclude subjects being unduly influenced by incentive payments or by perceived or actual prospect of benefit.

In our travels, we have met investigators from clinics that exclusively conduct Phase I oncology trials. They commonly run into patients who are looking for a cure and are not interested in learning about or considering the risks. These investigators recognize undue influence, and will not enroll subjects who ignore the information required to provide legally effective informed consent.

Researchers can follow the same process for incentive payments, and it is not hard to detect subjects whose judgement is impaired by the promise of dollar signs. There is no doubt that many researchers would benefit from training and mentoring in this regard. However, changing the behavior of research teams is the only way to address undue influence caused by perceived or potential benefit, and has the side effect of addressing undue influence caused by incentive payments.

### **Identifying the One Percent**

This process directly addresses OHRP's aforementioned observation that "because influence is contextual, and undue influence is likely to depend on an individual situation, it is often difficult for IRBs to draw a bright line delimiting undue influence."<sup>9</sup> Most IRBs understand that capacity to consent depends on both the protocol and the individual.

A subject may have the capacity to consent to a study involving a single blood draw, but may lack the capacity to agree to take part in a complicated clinical trial. Ninety-nine percent of individuals may have the capacity to take part in a trial, while one percent do not. The same is true for undue influence—a subject may be unduly influenced by a \$2,000 incentive for one trial, but not another. Ninety-nine percent of individuals might not be

unduly influenced by a \$2,000 incentive for one trial while one percent are. The IRB can never draw a bright line, but the research team is in the ideal situation to detect and minimize undue influence.

## Conclusion

In summary, IRBs should understand that incentive payments can never be coercive. The issue with incentive payments is that they can be unduly influential. Undue influence is not unique to payments, but also occurs because of perceived or actual potential benefit.

Because undue influence depends on the subject, IRBs cannot define when a payment, a perceived potential benefit, or actual potential benefit will be unduly influential to a specific subject. Nonetheless, IRBs are required to determine that the consent process is conducted in such a way that incentive payments minimize the possibility of undue influence.

For undue influence related to perceived or actual potential benefits, the current process is for researchers to not enroll potential subjects who are being unduly influenced. Rather than restricting incentive payments to low levels, IRBs can use the same process to address undue influence caused by incentive payments as a unified and reasonable approach to minimize all forms of undue influence.

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## CLINICAL RESEARCHER—MARCH 2019 (Volume 33, Issue 3)

### HOME STUDY

#### *FINDING YOUR FINANCIAL FOOTING*

#### The Training Challenges in Billing and Research Compliance

##### LEARNING OBJECTIVE

After reading this article, the participant should be able to determine when training is necessary and when it is lacking in terms of maintaining a compliant research billing process.

##### DISCLOSURE

Kelly M. Willenberg, DBA, RN, CCRP, CHRC, CHC: *Consultant through Kelly Willenberg, LLC*

**1. According to the article, a coverage analysis is important to developing which of the following for a study?**

1. The informed consent
2. The published results
3. The budget
4. The contract

- a. 1, 2, and 3 only
- b. 1, 2, and 4 only
- c. 1, 3, and 4 only
- d. 2, 3, and 4 only

**2. Whose clinical knowledge of study calendars and protocols is cited as being valuable to conducting a coverage analysis?**

- a. Patient advocates
- b. Institutional review board members
- c. Data managers
- d. Study coordinators

**3. The designation of “deemed and qualifying” associated with clinical trials comes from which source?**

- a. The International Council for Harmonization
- b. The Centers for Medicare and Medicaid Services
- c. The Centers for Disease Control and Prevention
- d. The Office for Human Research Protections

**4. Which statement is true of Medicaid plans?**

- a. They are identical across the nation.
- b. They vary from state to state.
- c. They vary from county to county within each state.
- d. They are determined by popular vote every four years.

**5. What is the first part of the billing compliance process?**

- a. Coverage analysis
- b. Protocol amendment
- c. Statistical analysis
- d. Clinical Trial Agreement

**6. Which of the following is true about telling a patient what services their insurance or payer is going to be covering for a clinical trial?**

- a. Is not necessary unless mandated by hospital policies.
- b. It should be part of the informed consent process.
- c. Is not a best practice for most smaller study sites.
- d. It should only be done at the direct request of the patient.

**7. Which of the following is cited in the article as marring the consent process?**

- a. Principal investigators who refuse to abide by their state's Medicare decisions.
- b. Poor translation of coverage-related terminology into other languages for non-English speakers.
- c. Disagreement between financial documents and the coverage analysis.
- d. Sponsors retroactively deciding not to cover certain costs as promised to patients.

**8. Which of the following is cited in the article as a cause of charges being directed to the wrong payer?**

- a. Sponsors and study sites not using the same edition of the relevant diagnosis codes.
- b. Patients pretending to have more serious medical conditions than is actually the case.
- c. Incorrect understanding of the coverage analysis by study coordinators.
- d. Disagreement between institutional review boards and principal investigators regarding use of placebos.

**9. Which of the following is a true statement?**

- a. Coverage analysis applies to only a very limited range of drug studies.
- b. Coverage analysis applies to all types of drug studies but only one kind of device study.
- c. Coverage analysis applies to all studies at a site until a preordained dollar limit is reached.
- d. Coverage analysis affects the more familiar types of drug studies and IDE device studies.

**10. The "three C's" of billing compliance can be described as:**

- a. Meeting the challenges, fostering collaboration, and accepting a spirit of compromise.
- b. Meeting the challenges, canceling credits, and confronting clinical trials participants.
- c. Managing confrontation, mitigating challenges, and minimizing confrontation.
- d. Manipulating compliance, meeting challenges, and confronting clinical trials participants.

*[Questions 11 through 20, based on this issue's second peer-reviewed article, begin on the following page.]*

## Paying Subjects to Take Part in Research: A New Perspective on Coercion and Undue Influence

### LEARNING OBJECTIVE

After reading this article, the participant should be able to differentiate between “coercion,” “undue influence,” and “compliance” in clinical trials; describe factors in determining the impact of incentive payments for trial participants; and explain the importance of legally effective consent.

### DISCLOSURES

David Borasky, MPH, CIP; Jeffrey A. Cooper, MD, MMM; Kelly FitzGerald, PhD: *Nothing to disclose*

- 11. The terms “coercion” and “undue influence” are defined in which of the following?**
  - a. The Helsinki Accord
  - b. The Belmont Report
  - c. The Good Clinical Practices
  - d. The Common Rule
  
- 12. The Office for Human Research Protections and the FDA are parts of which government entity?**
  - a. IRS
  - b. HHS
  - c. FAA
  - d. FCC
  
- 13. Which of the terms below is described in this article as “an overt threat of harm that is intentionally presented by one person to another to obtain compliance”?**
  - a. Undue influence
  - b. Coercion
  - c. Bias
  - d. Compliance
  
- 14. Which of the terms below is described in this article as “agreeing to take part in research or to continue participation in research”?**
  - a. Undue influence
  - b. Coercion
  - c. Bias
  - d. Compliance
  
- 15. Which of the terms below is described in this article as “a means to impact, determine, guide, shape alter, change, or transform”?**
  - a. Incentive
  - b. Benefit
  - c. Influence
  - d. Reimburse

- 16. According to this article, which of the following statements is true about incentive payments?**
- a. Offering an incentive payment for participation can never be coercive.
  - b. Incentive payments cannot be unduly influential.
  - c. IRBs should always define what would be considered unduly influential for a specific subject.
  - d. Offering an incentive payment for participation can easily be coercive.
- 17. Which of the following is true about the theoretical likelihood of undue influence?**
- a. It goes up with a decreasing incentive.
  - b. It goes down with a decreasing incentive.
  - c. It is unchanged with a decreasing incentive.
  - d. It is unassociated with the value of the incentive.
- 18. What is the standard IRB approach to reducing the likelihood that payments will unduly influence subjects?**
- a. Increase the difficulties to participants of qualifying for and receiving payments.
  - b. Enact standard operating procedures prohibiting sites from offering payments.
  - c. Appeal to sponsors to make identical payments available for patients in all trials.
  - d. Reduce the size of payments offered to the potential study participants.
- 19. Which statement is NOT included in the article's description of the term "legally effective consent"?**
- a. The individual has been provided enough information about the research.
  - b. The individual understands the information that has been provided.
  - c. The individual can understand the implications of a decision to take part.
  - d. The individual has the financial resources to take part in the study.
- 20. According to the article, which of the following are individuals who are unable to provide legally effective consent?**
- a. Those who have cognitive impairment and lack the capacity to give consent.
  - b. Those who are already enrolled in another clinical trial for some other product.
  - c. Those who have a therapeutic misconception about the purpose of the study.
  - d. Those who don't have the financial resources to participate in the study.