Auditing Clinical Trial Billing: A Real-World Approach
HCCA Compliance Institute
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Cynthie Lawson, Kelly Willenberg and Associates, LLC
Wendy Portier, Kelly Willenberg and Associates, LLC

Disclaimer

- No legal advice is provided.
- Please seek legal representation to have your questions clarified or discussed.
Objectives

- Conduct hands on review of clinical trials related claims and relate the review to the clinical trial billing rules
- Understand how to apply the coverage analysis in a clinical trial billing audit
- Review claims submitted on clinical trials that were denied and understand why

Identifying essentials of research billing compliance assurance
Clinical Trial Billing Compliance - Synchronous Work Flow is Key

- Vetting & Feasibility Analysis
- Coverage Analysis & Billing Plan
- Budgeting, Pricing & Contracting
- IRB Approval
- Enrollment & Informed Consent
- Identification, Registration, Scheduling & Tracking
- Authorization & Documentation for Medical Necessity
- Charge Capture
- Charge Segregation
- Claims Submission

Compliant Billing

Clinical trial revenue continuum

Start

Coverage Analysis

Budget

Contract

Consent

Study Account Setup

Study Account Close Out

End

Coding, Billing and Invoicing

Financial Management

Account Monitoring

Charge Capture and Bill Hold

Drugs/Biologics vs. Devices vs. CED

Coverage Documents

Site Initiation

Front End Process

Back End Process
What Does It Take to Get Clinical Trial Billing Compliance Right?

- A broad understanding of many fragmented, disconnected processes and systems
- An appreciate of many events that take place before and after billing
- Correctly debiting a study account and billing a third party (insurance, patient, etc.)
- Four main reasons for incorrect billing:
  1. Technological error
  2. Human error
  3. Training
  4. Awareness

The most basic basics!
Clinical trial billing compliance:
Primary rules*, 1

“Clinical Trials Policy”: National Coverage Determination 310.1
- Defines qualifying clinical trials and types of routine services

Investigational Device Guidelines
- Defines device and routine service billing requirements

*Other laws, regulations, rules also are relevant but are largely captured by 310.1 and claims requirements

Clinical trial billing compliance:
Primary rules*, 2

Medicare claims processing rules
- Research-specific and non-research-specific: all relevant rules to be met
- Federal payers follow Medicare; Medicaid may have specific alterations

False Claims Act protects federal taxpayers from overpayment for services provided:
- Overpayments result from false claims made by federal service providers
- In health care billing, an overpayment occurs when a federal insurer pays for a clinical service that was not allowable
- Rules stipulate requirements for reporting and correcting overpayments

*Other laws, regulations, rules also are relevant but are largely captured by 310.1 and claims requirements
NCD 310.1: What is a Qualifying Clinical Trial?

<table>
<thead>
<tr>
<th>Requirement</th>
<th>Yes</th>
<th>No</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Does the investigational item or service fall into a Medicare benefit category?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Note: The subject or purpose of the trial must be the evaluation of an item or service that falls within a benefit category and is not statutorily excluded from coverage (e.g., cosmetic surgery, hearing aids).</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the study have therapeutic intent stated in the study objective(s) or aim(s) and is consistent with institutional policy?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Does the study enroll patients with diagnosed diseases?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the study a deemed trial?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Study funded by NIH, CDC, AHRQ, CMS, DOD, or the VA or supported by cooperative groups funded by NIH, CDC, AHRQ, CMS, DOD, or the VA or Provided under BLA / IRB IND / IND # or IND Exempt as verified by the FDA or IRB)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Is the study a qualifying clinical trial?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(All questions must be answered &quot;Yes&quot; to qualify)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

NCD 310.1: What are Routine Costs?

- “Items or services that are typically provided absent a clinical trial (e.g., conventional care);”
- “Items or services required solely for the provision of the investigational item or service (e.g., administration of a non-covered chemotherapeutic agent), the clinically appropriate monitoring of the effects of the item or service, or the prevention of complications; and”
- “Items or services needed for reasonable and necessary care arising from the provision of an investigational item or service--in particular, for the diagnosis or treatment of complications.”
Research billing compliance assurance

Although there are many nuances, in a nutshell:

- **Do not bill patient/insurance** for services that are:
  - Not medically necessary
  - Otherwise not allowable / non-covered services
  - Promised by the sponsor (contract) / budget
  - Promised by the consent form
- Apply the Medicare-specified **research modifications** as applicable
- Follow all other (many) Medicare rules, for example:
  - **Medicare Advantage patients** in qualifying non-IDE studies routine charges revert to Traditional Medicare
  - National Coverage Determinations (**NCDs**)
  - Medicare Administrative Contractor Local Coverage Determinations (**LCDs**)
  - Non-covered benefits

Areas to watch in research billing and finance

- Inadequate financial accounting
- **Research subjects not identified**
- **Document non-concordance**: Protocol, Coverage Analysis, Budget, Contract, ICF
- **Charge capture/billing** for research related services and routine costs, study drugs and devices
- No monitoring of billing inquiries
- Poor budget process, lack of proper accounting and invoicing to Sponsors
- Claims lack proper **research coding**: dx, modifiers, CCs, and NCT # on claim
- **Charge segregation** occurring between research and payer or Medicare and Medicare Advantage
- Communication on **denials management** not thorough or lack of attention to detail
Research billing audit goals

Although there are many nuances, and scope depends upon specific institutional goals, in a nutshell:

- Identify system or human error in research billing
- Make repayments if overpayments are found, following required timelines
- Identify underpayments and invoice as possible
- Correct process errors or gaps
- Educate users as applicable
- Conduct follow-up review to assure sufficient remediation
- Document quality assurance diligence

Charge segregation exercise
Common audit findings

Auditing clinical trial billing and finance:
common findings, 1
- Non-employed physician group not notified of clinical trial / subject
- Under budgeting
- Lack of fund accounting
- Excessive residual balances and no residual funds policy
- Claims submission errors
  - Misdirection of charges – double billing
  - Denials
    - For example: pre-authorization, investigational article
  - Coding errors and mismatches
    - IDE, NCT numbers on claim no CC or Q-modifiers
    - IV administration with no study drug on claim
  - No follow-up on denials: write-offs
Auditing clinical trial billing and finance: common findings, 2

- **Charges not posted** in billing systems; “Off the books” research activities
- Billing of professional (pro) and technical (tech) **charges not coordinated**. For example, pro charge is billed:
  - to insurance and tech charge is billed to sponsor/research
  - to Medicare and tech charge is billing to Medicare Advantage
  - with clinical trial coding but the tech charge lacks coding
- **Patient reimbursements** held or not paid

Audit scope and planning
Areas to understand prior to audit testing

- Operations
  - Charge segregation
  - Registration
  - Charge Capture
  - Billing
- Financial Management
  - Budgeting, Pricing, Contracting
  - Accounts Receivable
  - Professional Fees
- Compliance Management
  - Investigations & Monitoring
  - Training
- Personnel
  - Roles & Responsibilities
  - Communication

What areas at your organizations do you understand fully?

Before audit can be planned, identify standards

1. Audits are designed to track and evaluate existing processes and their results

2. In order to identify audit scope, need to have evaluated the potential failure of existing process(es) to provide intended results: risk assessment of entire process

3. In order to evaluate existing processes, need to compare to minimum necessary to achieve compliance assurance: regulations, other external requirements, and organizational policies

What does clinical research billing compliance assurance require?
Three types of clinical trial billing audits

1. Process / Internal Control
2. Study Level (Document Concordance & Coverage Analysis Validation)
3. Patient Level (Claims)

Audit scope: preliminaries

Stakeholders and auditors, internal and external

- Depends upon the content scope
- Skill set to be parallel to content: e.g., denials review requires person with denials experience
- Do internal audit or compliance departments have authority?
- Is Office of General Counsel to be consulted?
- Decision to go external may be related to risk assessment results
Audit scope: preliminaries

Time span
- Are you auditing a process improvement?
- Do you want to see before and after or just after?
- Are you performing it for cause and need a specific time point?

Sample size
- Determining significant sample
- Unless reviewing a process only, number of studies?
- If conducting billing review, number of patients, number of claims?

Interviewees and assistants
- Depends upon the content scope
- Will involve those according to assigned operational tasks
- Leadership channels to be considered

Audit scope: one or all of the following, 1

Coverage analysis
- Is the coverage analysis concordant with study documents? (protocol, ICF, budget, contract, coverage analysis)
- Does the study qualify for billing?
- Do the justifications support billing the subject’s insurance?
- Were all costs included?

Document concordance
- Are all study documents concordant? (protocol, ICF, budget, contract, coverage analysis)
- Do study documents contain clear language?
Audit scope: one or all of the following, 2

Subject identification
- Are the subjects identified “flagged” in the systems?
- Was the “flag” applied timely?

Claims review
- Did the claim go to the appropriate payer? (Medicare, Medicare Advantage, Sponsor, Commercial Insurance, etc.)
- Does the claim contain correct coding? (Z00.6, Q1, Q0, CC30, IDE#, Rev Code 256/624, NCT#, etc.)
- Does the medical record documentation support medical necessity?

Audit scope: one or all of the following, 3

Payer selection
- Audit Medicare/Medicaid only or include commercial payers?
- If commercials payers to be included, do you want
  - A different sample size?
  - A subset of them?

Invoicing
- Did invoicing occur?
- Was invoicing timely?
- Was the proper amount billed?
- Was overhead included?
Audit scope: one or all of the following, 4

Denials
- Are research related denials identified?
- What causes research related denials?
- Who manages research denials?

Summary: how to audit a clinical trial, 1
- Take the standard steps:
  - Risk assessment
  - Objectives: what are we trying to achieve?
  - Scope: what and who are to be included in the audit?
  - Approval(s) required: Identify necessary authorities, advisors, stakeholders
- Create an audit plan
  - What is the objective of each step?
  - Does the step tie to the overall audit objective?
Summary: how to audit a clinical trial, 2

- Conduct sample selection
- Request and review documents
  - Study Level – protocol / study documents, ICF, CTA, budget, CA, IND/IDE
  - Patient Level – UBs/1500s, EOBs, study accounts, subject calendars, EMR
- Perform interviews and testing
  - Documentation
  - Work papers
  - Data collection
- Write a report

Document Concordance Auditing
Term alert: document concordance

We use “document concordance” to refer to a key and complex practical requirement in research billing: the consistency and accuracy of all study-initiation and continuation documents relevant to billing for protocol-specified clinical services

Without concordance, accurate billing is impossible
(— or accidental)

Example: document concordance and content review

Compare key documents

- Contract
- Budgets (Internal and External)
- Informed Consent Form (ICF)
- Coverage Analysis
- Protocol

Are there any discrepancies between the documents?
Were there any discrepancies on the Coverage Analysis?
Did the budget contain invoiceable items?

Were there any additional regulatory issues identified?

- Did the contract or ICF contain language the violate the Medicare Secondary Payer Rule?
- Did the ICF contract Medicare Advantage language for drug trials?
### Sample checklist

**IRB #: 12-00000 PI Name: MD**  
**Study Name: XYZ Study Consistency Checklist Date:**

<table>
<thead>
<tr>
<th>Issue</th>
<th>Agreement / Budget Date</th>
<th>ICF Version Date</th>
<th>Protocol</th>
<th>Reviewer</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A. Confidentiality</strong> Describe how data or information will be shared between INSTITUTION, or sites and the research sponsor.</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
</tr>
<tr>
<td><strong>B. Benefits of Taking Part in the Study</strong> Describe the benefits of participating for the subject and/or others in the context of therapeutic intent.</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
</tr>
<tr>
<td><strong>C. Research vs. Conventional Care</strong> The procedures that will be performed during the course of the trial that are considered to be part of the subjects' conventional care and that would be performed anyway notwithstanding the research study are differentiated from the procedures that will be performed during the course of the study that are for research purposes only.</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
</tr>
<tr>
<td><strong>D. Additional Costs</strong> Subjects will be required to bear additional costs beyond those associated with their conventional care as a result of participating in the study.</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
</tr>
<tr>
<td><strong>E. Subject Compensation</strong> Subjects will be compensated for agreeing to participate in the study.</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
</tr>
<tr>
<td><strong>F. Research Related Injury</strong> Identify the individual or entity responsible for the costs of any research-related injuries to subjects.</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
</tr>
<tr>
<td><strong>G. Future Use Of Data</strong> Are subjects asked or expected to donate data, materials, samples etc. to databases or tissue repositories and if the sponsor receive any future rights to the data or materials collected in the course of the study?</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
</tr>
<tr>
<td><strong>H. Study is registered at clinicaltrials.gov and statement is in the ICF</strong></td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
</tr>
<tr>
<td><strong>I. Medicare Advantage statement included in the ICF</strong></td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
<td>XXX</td>
</tr>
</tbody>
</table>

### Billing grid/sponsor budget review

**Exercise**

**What’s missing/incorrect?**

**Green = billing grid; Blue = sponsor budget**

<table>
<thead>
<tr>
<th>Procedure/Event</th>
<th>CPT/HCPCS Codes</th>
<th>Billing Designation</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI BRAIN STEM W/O &amp; W/DYE</td>
<td>70553</td>
<td>S</td>
</tr>
<tr>
<td>CBC</td>
<td>85025, 85027</td>
<td>S</td>
</tr>
<tr>
<td>Chemo Admin</td>
<td>96413</td>
<td>S</td>
</tr>
<tr>
<td>Chemo Study Drug</td>
<td>J9999</td>
<td>S</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Procedure/Event</th>
<th>CPT/HCPCS Codes</th>
<th>Amount Paid</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI BRAIN STEM W/O &amp; W/DYE</td>
<td>70553</td>
<td>1131</td>
</tr>
<tr>
<td>CBC</td>
<td>85025, 85027</td>
<td>27</td>
</tr>
<tr>
<td>Venipuncture</td>
<td>36415</td>
<td>9</td>
</tr>
<tr>
<td>Chemo Admin</td>
<td>96413</td>
<td>429</td>
</tr>
<tr>
<td>Chemo Study Drug</td>
<td>J9999</td>
<td>0</td>
</tr>
</tbody>
</table>
Insurance claims review & exercises

Summary: Medicare requirements – drug trials

<table>
<thead>
<tr>
<th>Claim Type</th>
<th>Coding Requirements</th>
<th>Location on Claim</th>
</tr>
</thead>
</table>
| Technical UB-04 (CMS1450) | - 200.6 - Secondary Diagnosis  
- Modifier Q0 & Q1 as needed (Outpatient Only)  
  - Q0 - Investigational Clinical Service (Drug)  
  - Q1 - Routine Costs  
- Condition Code 30 "Qualifying Clinical Trial"  
- Rev Code 256 - Drug Trial  
- NCT# (www.clinicaltrials.gov) | - Field 66  
- Field 44  
- Field 18 - 28  
- Field 42  
- Field 39; D4 & Value Code = 8 digit NCT# |
| Professional CMS1500 | - 200.6 - Secondary Diagnosis  
- Modifier Q0 & Q1 as needed  
  - Q0 - Investigational Clinical Service  
  - Q1 - Routine Costs  
- NCT# (www.clinicaltrials.gov) | - Field 21  
- Field 24.D - Modifier  
- Field 19 (Use CTpre-fix on paper claim only) |
### Summary: Medicare requirements – device trials

<table>
<thead>
<tr>
<th>Claim Type</th>
<th>Coding Requirements</th>
<th>Location on Claim</th>
</tr>
</thead>
</table>
| **Technical UB-04 (CMS1450)** | - Z06.6 – Secondary Diagnosis  
- Modifier Q0 & Q1 (Outpatient Only)  
- Q0 – Investigational Clinical Service (Procedure)  
- Q1 – Routine Costs  
- Condition Code 30 "Qualifying Clinical Trial"  
- Condition Code 33 - Free Devices (Outpatient only)  
- NCT # (www.clinicaltrials.gov)  
- Value Code FD (Free Device as part of a trial, Outpatient Only)  
- Rev Code 0624 - Device Trial  
- Device charge – list as non-covered (token) charge if device is provided at no cost  
- Rev Code 278 – Medical/Surgical Supplies: Other Implants  
- Category B IDE device HCPCS code, as applicable  
- Generally, Category A not reported on institutional claim. Follow Medicare’s specific instructions for the trial  
- Field 66  
- Field 44  
- Field 18 - 28  
- Field 39; D4 & Value Code = 8 digit NCT#  
- Field 39; Credit amount for device  
- Field 42  
- Field 47 & 48  
- Field 21  
- Field 44  
- Field 24.D – Modifier  
- Field 23 | |
| **Professional CMS1500** | - Z06.6 – Secondary Diagnosis  
- Modifier Q0 & Q1 as needed  
- Q0 – Investigational Clinical Service (Procedure)  
- Q1 – Routine Costs  
- NCT # (www.clinicaltrials.gov)  
- IDE Number  
- Category B IDE device HCPCS code, as applicable  
- Generally, Category A not reported on institutional claim. Follow Medicare’s specific instructions for the trial  
- Field 21  
- Field 24.D – Modifier  
- Field 19; Use CType-fix on paper claim only  
- Field 23 | |

---

### Medicare Q&A 2014

**Mandatory Reporting of NCT# Identifier on Medicare Claims**

<table>
<thead>
<tr>
<th>Medicare coverage of clinical trials, prospective studies, and registries</th>
<th>CTP</th>
<th>IDE</th>
<th>CED</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>CMS approval required</strong></td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>- must qualify under NCD 310.1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Public notification</strong></td>
<td>No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- provider determines qualification</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Routine services (Q1)</strong></td>
<td>Covered if otherwise coverable by Medicare in qualified study</td>
<td>Covered if study is approved by CMS and otherwise coverable by Medicare</td>
<td>Covered if study is approved by CMS and otherwise coverable by Medicare</td>
</tr>
<tr>
<td><strong>Investigational item/service (Q6)</strong></td>
<td>Covered if otherwise coverable by Medicare in qualified study</td>
<td>Covered if study is Category B, and approved by CMS</td>
<td>Covered if study is approved by CMS</td>
</tr>
</tbody>
</table>

*https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Downloads/Mandatory-Clinical-Trial-Identifier-Number-QnAs.pdf*
# Billing grid/claim Exercise

What’s missing/incorrect?

Green = billing grid; Blue = Facility Claim

\[ S = \text{Sponsor Paid} \quad M = \text{Medicare/ 3rd Party Payer} \]

<table>
<thead>
<tr>
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<td>Venipuncture</td>
<td>36415</td>
<td>S</td>
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<tr>
<td>CBC</td>
<td>85025, 85027</td>
<td>S</td>
</tr>
<tr>
<td>Chemo Admin</td>
<td>96413</td>
<td>S</td>
</tr>
<tr>
<td>Chemo Study Drug</td>
<td>J9999</td>
<td>S</td>
</tr>
</tbody>
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<table>
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<tr>
<th>Procedure/Event</th>
<th>CPT/HCPCS Codes</th>
<th>Amount Paid</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRI BRAIN STEM W/O &amp; W/DYE</td>
<td>70553</td>
<td>3500</td>
</tr>
<tr>
<td>CBC</td>
<td>85025, 85027</td>
<td>65</td>
</tr>
<tr>
<td>Port Draw</td>
<td>36591</td>
<td>190</td>
</tr>
<tr>
<td>Chemo Admin</td>
<td>96413</td>
<td>750</td>
</tr>
<tr>
<td>Chemo Study Drug</td>
<td>J9999</td>
<td>0</td>
</tr>
</tbody>
</table>

### Claims review exercise drug study
Denials review exercise

Invoicing review
Example: invoiceable items

Review contracts, budgets, coverage analysis for invoiceable items

Identify activities that are invoiceable
- Conduct a process audit
- Conduct internal control testing
- For example:
  - External vendor invoices – PEAR* groups
  - Items/services performed for specific cases
  - Was overhead included?

* Pathology, Emergency, Anesthesia, Radiology

Data collection & error rates
Data collection during a claims review audit

General
- Subject identifier
- Payer Type – Primary, Secondary and Tertiary
- Visit #, DOS

Claim Information
- Claim type
- Encounter Number
- Claim Number
- Item / Service Description
- CPT/HCPCS Codes
- Coding: NCT#, Modifiers, Dx code, IDE#, CC 30, CC53

Documentation requirements

Amount billed and amount paid

Overpayments / Underpayments
- Calculate overpayments
- Calculate underpayments
- Calculate error rates

CMS error rate data – A/B MACs

Improper Payment Rate Scores/Rankings:
- 1  0.0% - 3.9% (Oh Yeah!)
- 2  4.0% - 7.9% (Getting Better)
- 3  8.0% - 11.9% (Tighten Up)
- 4  12.0% - 15.9% (Processes?)
- 5  16.0% and above (Uh-OH!)

Source:
- https://www.cms.gov/Research-Statistics-Data-and-Systems/Monitoring-Programs/Medicare-FFS-Compliance-Programs/CERT/MedicareFFSJurisdictionErrorRateContributionData.html
Error rate calculations - examples

Payment Error Rate
- Total dollars paid in error / total dollars paid
- EX: $195,000 / $500,000 = 39% payment error rate

Claim Error Rate
- Total # of claims billed to the incorrect payer / Total # of claims reviewed
- EX: 90 / 500 = 18% claim error rate

Line Item Error Rate
- Total # of line items billed to incorrect payer / Total # of line items reviewed
- EX: 975 / 5000 = 20% line item error rate

Coding Error Rate
- Total # of claims billed to correct payer, incorrect coding / Total # of claims reviewed. Coding errors count as 1 error per claim.
- EX: 200 / 500 = 40% coding error rate

Wrapping up
Not to be a broken record, but...

- Audit **planning effort** cannot be underestimated!
- Scope and objectives follows responsible **risk assessment**
- Thorough knowledge of billing regulations and rules, as well as institutional policies, is crucial
- **Matching** audit to **auditors** and interviewees is key to planning
- Did we mention that audit planning is really important?

Contact us

Wendy Portier, MSN, RN, CHRC, CHC, CCM  
Consultant  
Kelly Willenberg and Associates, LLC  
wendy@kellywillenberg.com  
504-782-1328

Cynthie Lawson, BSM, CPC, CHRC  
Consultant  
Kelly Willenberg and Associates, LLC  
cynthie@kellywillenberg.com  
208-321-4638