Tools and Resources for New Healthcare Attorneys

American Health Lawyers Association
2010 Fundamentals of Health Law Luncheon
Co-sponsored by the Hospitals and Health Systems; Physician Organizations; and Regulation, Accreditation, and Payment Practice Groups
Monday, October 25, 2010
Hyatt Regency Chicago - Chicago, Illinois
Presenters

- **Barry D. Alexander**
  - Partner, Nelson Mullins Riley & Scarborough LLP
  - Raleigh, NC

- **Dinetia M. Newman**
  - Partner, Balch & Bingham LLP
  - Jackson, MS
Agenda

- Networking
- Mentoring
- Regulatory Research
  - Research Plans
  - Key Sources
- Researching Tips
- Real-Life Examples
Networking

It's not what you know, it's who you know.
Networking

- Learn about and use existing resources
  - AHLA Resources
    - In-person programs
    - Practice Groups
    - Membership Directory
    - Discussion lists
  - Bar Association Resources
    - ABA and State Health Law Sections
Networking

- Volunteer
  - Call for Authors
  - Call for Speakers
  - Serve on Committees/Task Forces
  - Practice Group Leadership
  - Affinity Groups
  - Mentor/Mentee
Networking

- Take advantage of social networking
  - Facebook
    - Become a fan of American Health Lawyers Association
  - LinkedIn
    - Link to American Health Lawyers Association
  - Twitter
    - Follow “healthlawyers”
Networking

- Communicate with other attorneys
  - AHLA Practice Group members
  - Young Lawyers Division
    - ABA/State Bar Associations
    - AHLA Diversity Programs
      - Diversity Receptions
  - AHLA Mentoring Program

- Market yourself every day
Mentoring

Mentoring is a brain to pick, an ear to listen, and a push in the right direction.
Mentoring

- Helps new attorneys learn the basics of “lawyering” from more experienced attorneys
- Bridges gap between law school and practice
- Brings together lawyers for the mutual exchange of information
  - Mentees gain support and guidance
  - Mentors have an opportunity to give back, support, and shape future attorneys
Mentoring

- American Health Lawyers Association
  - Two Pilot Mentoring Programs Initiated in 2008
    - PPMC Practice Group
      - 19 mentors served 20 mentees during pilot
    - Advisory Council on Diversity Mentoring Pilot Program
      - 43 mentors applied for matching with 44 mentees during pilot
AHLA Mentoring Program

- **Purpose**: to build on AHLA’s commitment to create a collegial community and meet members’ needs for networking and relationship building by bringing together stakeholders to provide guidance, oversight, and support for the association-wide mentoring program.

- **Goal**: to match mentors with mentees based upon mentee needs: practice area, geographic area, diversity, other needs
AHLA Mentoring Program

- Mentoring Committee: 11 Members
- Formal and informal mentoring opportunities
- Interactive website application
- Timeline:
  - November 2010 – Beta test website
  - December 2010 – Mentor & Mentee applications go live
  - January 2011 – Roll out program
Mentoring

- Bar Associations
  - ABA, State, and Local Bar Association

- Workplace Mentoring Programs

- Through Life Experiences
Regulatory Research

- Developing a Research Plan
- Memorializing the Research Plan
- Selecting Resources
Regulatory Research

- Developing a Research Plan
  - In what context does regulatory issue arise?
    - Compliance
    - Transaction
    - Reimbursement planning
    - Federal or state government investigation
    - Healthcare litigation
Developing a Research Plan

- What type of question is involved?
  - Stark/Anti-Kickback
  - Coverage
  - Enrollment/Participation
  - Survey and Certification
  - Reimbursement/Payment
  - Repayment
  - Patient Eligibility
Regulatory Research

- Memorialize the Research Plan
  - See research plan attached to outline
  - Draw a diagram of the relationships involved

- Select Resources
  - Background information and source materials, including firm research memoranda
  - Primary source information
  - Understand health law language
Regulatory Research

- **Background Information and Source Materials**
  - AHLA Materials: AHLA Archive, Practice Group substantive content
  - Ingenix Publications: *Medicare Part B Desk Reference for Physicians, CPT Expert*
  - Office of Inspector General (OIG) and General Accounting Office (GAO) reports
  - American Hospital Association Materials
  - Trade Press (e.g. *Modern Healthcare*)
  - MedPAC (Medicare Payment Advisory Commission) reports
Regulatory Research

- Medicare Program Primary Source Information
  - Statutes
    - Title 42 of the United States Code
    - Sections 1301—1320d-8, 1395—1395hhh
  - Legislative History
    - Congressional Record
    - Committee Reports
    - Conference Reports
  - CMS Resources
Regulatory Research

- Medicare Program Primary Source Information
  - OIG Issuances
    - Regulations, Fraud Alerts, Compliance Guidance, Advisory Opinions, Audit Reports, Settlement and CIA Agreements, OIG Work Plan
  - HHS Administrative Decisions
  - Local Carrier, Intermediary/MAC Issuances
  - Accreditation Organization Manuals
  - Coding Guidelines
  - Case Law
Regulatory Research

- Medicaid Program Primary Source Information
  - Statutes
    - Title 42 of the United States Code
    - Sections 13096a–1396v, 1301–1320(d)(8)
    - State Statutes
  - Legislative History
  - Federal and State Regulations
  - State Plans
Regulatory Research

- Medicaid Program Primary Source Information
  - Manuals—Federal/State
  - Informal issuances
  - Forms and Instructions
  - Case Law
  - Carrier Issuances
Researching Tips

- Use CCH Intelliconnect (Wolters Kluwer)
  - 3 research routes: browse into documents, use key word search, through libraries
  - Tools to narrow search: save as searchable PDF document or Word, email
  - Organize and save in Research Folders
    - Up to 1000 folders, 500 documents in each
    - Statutes/regulations saved in folders automatically updated to reflect amendments
  - Historical manuals more easily pulled and tracked
Researching Tips

- Use Google
  - Quick legal research tool—sometimes you will find an answer with one simple search
  - Practical place to start your research and get general footing on the issue and regulations
  - Caveat: Buyer beware - use primary sources and check dates
Researching Tips

- Understand the issue
  - Ask Questions and then MORE questions
    - Issues often more complex than they first appear
    - Understanding scope of issue before starting research lessens need to do more research later
    - After thinking about policy reasons, try to come up with possible answers before starting research
Researching Tips

- **Background Research is Important**
  - Provides a frame of reference
  - Don’t study roots without looking at the tree
  - Is necessary in understanding the scope of the question
  - After researching an area several times, makes background research less extensive and mainly involves checking on recent developments
Researching Tips

- Know what sources need to be reviewed
  - Understand CMS Manuals
  - Review index tables
    - Reviewing the entire manual or regulatory chapter can often prevent erroneous research results or can clarify a relevant section.
  - Use search tools
    - Get to know the limitations of the different sources
    - Always search on more than one source
Researching Tips

- Searching for the missing piece
  - Stick to your plan
    - Most difficult project is finding a rule that doesn’t exist
    - Go through research plan and check each type of information identified on the plan
  - Know when to stop
    - After reviewing materials, any additional materials?
    - After reviewing any additional materials and index tables, stop researching
    - Sometimes there is no needle in the haystack!
Researching Tips

- Interpreting the research
  - Deal with conflicting information
    - Research results can be conflicting
    - Be aware from a legal standpoint what implications are of conflicts between regulations and manuals
  - Talk and think it through
    - Review your research with someone else
    - Write out the conflict so it is understood
    - Which reading is more consistent with statutory scheme, policy, common sense?
    - Contact a regulator to discuss the conflict
Researching Tips

- Confirming research with Regulators
  - Know which agency to contact
    - Past experience and recommendations, CMS and other agency contact lists
  - Find the right person to answer the question
    - Official agency contact in Federal Register
  - Obtain confirmation of the answer
  - Know when to rely on regulator-provided information
  - Don’t call without partner/client approval!
  - Make blind calls where possible!
Real-Life Examples

Your client, Wheelchair Plus, Inc. (WP), has just received an overpayment determination from CMS. CMS alleges that WP has filed improper claims with Medicare and must now repay the program $2.5 million for supplying power wheelchairs to Medicare beneficiaries that did not qualify for the wheelchairs.

WP needs your assistance in appealing this overpayment determination.
Real-Life Examples

- Development of a Research Plan
  - In what context does the question arise?
    - Federal governmental investigation
  - What type of question is involved?
    - Reimbursement/payment, potential repayment
Real-Life Examples

Specific Issues Presented

- What requirements must be met before a Medicare beneficiary qualifies for a power wheelchair?
- What are penalties for providing unnecessary wheelchairs to Medicare Beneficiaries?
- What is the process for appealing the overpayment determination?
CCH Intelliconnect Search for Medicare Coverage Requirements

- Search terms: “wheelchair” & “coverage” - 1261 hits
  - By Document Type
    - Laws and Legislative Documents
  - By Library
    - Health Care Compliance and Reimbursement
    - CMS Program Manuals
    - Internet Only Manuals
    - Medicare National Coverage Determinations Manual
      - Chapter 1 - Coverage Determinations
      - § 280 - Medical and Surgical Supplies
- Search terms: “durable medical equipment & wheelchair & penalty”
  - By Library
    - Health Care Compliance and Reimbursement
    - Medicare and Medicaid Guide Explanations and Annotations
      - § 13,921.44 Kickbacks, bribes and rebates
Real-Life Examples
Real-Life Examples
Real-Life Examples

Urine autoclavable
Covered if patient is bed-confined (hospital type).

Vaporizers
Covered if patient has a respiratory illness.

Ventilators
Covered for treatment of neuromuscular disease, thoracic restrictive diseases, and chronic respiratory failure consequent to chronic obstructive pulmonary disease. Includes both positive/negative pressure types. (See §260.9 of this manual.)

Walkers
Covered if patient meets Mobility Assistive Equipment clinical criteria (see §260.9 of this manual).

Water and Pressure Pads and Mattresses
(See Alternating Pressure Pads, Mattresses, and Lambs Wool Pads.)

Wheelchairs
- (manual) Covered if patient meets Mobility Assistive Equipment clinical criteria (see §260.9 of this manual).
- (power-operated) Covered if patient meets Mobility Assistive Equipment clinical criteria (see §260.9 of this manual).
- (scooter/POV) Covered if patient meets Mobility Assistive Equipment clinical criteria (see §260.9 of this manual).
- (specially-sized) Covered if patient meets Mobility Assistive Equipment clinical criteria (see §260.9 of this manual).
Real-Life Examples

Medicare and Medicaid Guide Explanations and Annotations, 13,921.44 Kickbacks, bribes, and rebates

There was sufficient evidence to sustain the conviction of the owner of a durable medical equipment (DME) supply company and a physician for conspiracy to violate, and violation of the Medicare anti-kickback statute at 42 U.S.C. § 1320a-7b(b), and health care fraud under 18 U.S.C. § 1347. The evidence shows the DME supplier and the physician conspired to have the physician evaluate Medicare patients and fill out prescriptions for wheelchairs for a fee of $250 per prescription written. The physician would then deliver certificates of medical necessity (CMNs) to the DME owner so that power wheelchairs could be ordered and billed to Medicare. The evidence showed the physician was aware that the Medicare patients he was evaluating did not need power wheelchairs because they were all walking and driving their own cars. The DME supplier took the CMNs and billed Medicare for the cost of expensive power wheelchairs but then only provided beneficiaries with low-cost power scooters. The DME supplied the physician split the difference in cost, $3,500, and pocketed the money. The evidence also showed that as the sole proprietor of the DME company, the owner was the sole person responsible for his company’s dealings, and the original CMNs submitted to Medicare showed he billed for power wheelchairs. The record is not complete enough to consider the DME supplier’s argument that he had ineffective assistance of counsel and that his counsel labored under an actual conflict at trial. When the DME owner was informed about his attorney’s potential conflict of interest, the DME owner was asked if he understood the situation and he waived the issue. There is a difference between a complete denial of counsel versus simply shaky representation. Finally, there is no error when the court determined there was only one conspiracy in the indictment. Accordingly, the defendants’ convictions for violations of the anti-kickback statute and health care fraud were affirmed.

United States of America v. Joe, 6th Cir., No. 09-5006, June 16, 2010. [This decision was reported at 589 U.S. 421]
Real-Life Examples

- CMS Website Search for Medicare Coverage Requirements
  - Search terms: “wheelchair” – 65 hits
    - Sort by date: Overview of Coverage of Medicare Power Mobility Devices (PMDs)
    - Sort by relevance: Medicare National Coverage Determinations Manual
  - Search terms: “wheelchair” & “regulations” – 52 hits
    - CMS Press Release on Updated Regulations with link to Interim Final Rule
      - Use to link to Interim Final Rule, identify statutory basis, regulations
Real-Life Examples
Real-Life Examples

In 2005, the Centers for Medicare & Medicaid Services (CMS) revised the Medicare conditions of coverage for power wheelchairs and Power Operated Vehicles (POVs) to conform to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA). Under the Medicare program, power wheelchairs and Power Operated Vehicles (POVs) are collectively classified as Power Mobility Devices (PMDs). PMDs are covered under the Medicare Part B benefits.

The Clinical Medical Equipment Administration Contractors (DME MACs) process Medicare claims for PMDs furnished by suppliers. To qualify for Medicare reimbursement, the physician or treating practitioner must do the following:

- Conduct a face-to-face examination of the beneficiary.
- Write a prescription for the PMD within 45 days after the examination.
- Furnish pertinent beneficiary medical information to the supplier to support medical necessity.

Effective May 5, 2005, CMS revised national coverage policy to create a new class of DME identified as Mobility Assistance Equipment (MAE), which includes a continuum of technology from power wheelchairs to POVs. CMS determined that MAE is reasonable and necessary for beneficiaries who have a personal mobility deficit sufficient to limit the participation in the community or Mobility-Restricted Activities of Daily Living (M-RADLs) such as toileting, feeding, dressing, grooming, and bathing in customary locations in the home. This Clinical Criteria for MAE Coverage must be used to determine the appropriateness of MAE for each individual, replacing the previously used "foot-chain-covered" criterion.

Medicare Coverage Provisions

A PMD is a covered item of DME in a class of wheelchairs that includes a power wheelchair or a POV that a beneficiary is medical necessary according to Medicare Coverage Policy. Medicare Coverage Policy, which is located at http://www.cms.gov/Medicare/Provider-Participa
tion/Enrollment-and-Certification/Clinical-Eligibility-Codes/index.html and updated annually, identifies which items and services are covered by Medicare Part B. Medicaid and Medicare Services replace the current clinical eligibility policy under the FMAP for the Social Security Administration (SSA) and the Medicare Administrative Contractor (MAC) policy. This policy is referenced in the Medicare Provider Determination Policy Manual, which is located at http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Polic
y/docs/Medicare_Beneficiary_Determination_Policy_Manual.pdf. The policy is updated annually to ensure the most current CMS information is determined in terms of its cost and benefits and the most recent Medicare provider determinations are available in the CMS website.
Real-Life Examples
Medicare National Coverage Determinations Manual
Chapter 1, Part 4 (Sections 200 – 310.1)
Coverage Determinations

Table of Contents
(Rev. 124, 09-24-10)

Transmittals for Chapter 1, Part 4

200 - Pharmacology
   200.1 - Nesiritide for Treatment of Heart Failure Patients (Effective March 2, 2006)
   200.2 - Nebulized Beta Adrenergic Agonist Therapy for Lung Diseases -
           (Effective September 10, 2007)
210 - Prevention
   210.1 - Prostate Cancer Screening Tests
   210.2 - Screening Pap Smears and Pelvic Examinations for Early Detection of
Real-Life Examples

- Google – Search for Consequences/Penalties of Overpayment/Lack of Coverage
  - Search terms: cms.hhs.gov/Manuals & overpayment determination
  - Search terms: penalties & wheelchair & medicare
    - Link to DOJ Press Release – Indictments in Wheelchair Scheme
Real-Life Examples
**Real-Life Examples**

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FOR IMMEDIATE RELEASE

News releases are available at www.usdoj.gov/usao/ks/press.html

Contact: Jim Cross
PHONE: 316-269-6481
FAX: 316-269-6420

Oct. 16, 2008

**INDICTMENT: POWER WHEELCHAIR SCHEME COST MEDICARE MORE THAN $1 MILLION**

Other indictments: bank robbery, arson, drug trafficking

WICHITA, KAN. – Rose E. Benson, 55, Mesquite, Texas; Emmanuel E. Benson, 56, Mesquite, Texas; Linda N. Marshall, 60, Wichita, Kan.; Baglence E. Ekpo, 50, Garland, Texas; and Venda A. Brown, 35, Wichita, Kan., are charged with conspiracy to commit health care fraud and violations of anti-kickback statutes. The crimes are alleged to have occurred from April 2003 through July 2005.

According to the indictment, Rose Benson and Emmanuel Benson, owners of Vertex Medical Supplies, Inc., in Garland, Texas, paid the other defendants to provide them with names of Medicare patients and Medicare beneficiary numbers. The Bensons used the information to make false and fraudulent claims to Medicare for power wheelchairs. Linda Marshall, Baglence Ekpo and Venda Brown obtained information from Medicare beneficiaries and physicians’ offices by promising to provide patients with wheelchairs at no cost to them, even though the Medicare reimbursement rate for a power wheelchair was approximately $4,200. Marshall, Ekpo and Brown received fees of $400 to $500 from Rose Benson and Emmanuel Benson for each referral.

The fraudulent claims misrepresented authorization by examining physicians and the equipment that was delivered. As a result of the scheme, Medicare received more than $2.1 million in fraudulent claims and made payments of more than $1 million.

In addition to the health care fraud conspiracy count against all five defendants, Rose and Emmanuel Benson are charged with 10 counts of health care fraud, and Rose Benson is charged with two counts of paying kickbacks.
Real-Life Examples

- Google – Search for Specifics of Medicare Appeals Process
  - Search terms: Medicare appeals process
  - Initial result: Link to MedLearn Brochure
  - Preferred result:
    - Link to Office of Medicare Hearings and Appeals
    - Link to 42 C.F.R. Part 405, Subpart I – Determinations, Redeterminations, Reconsiderations, and Appeals Under Original Medicare (Parts A and B)
Real-Life Examples

Web

Medicare Power Wheelchair
theScooterstore.com/PowerWheelchair We've Helped Thousands of Disabled & Elderly Americans Regain Mobility

Elrod Mobility
electromobility.net Home Stairlifts, Elevators, Wheelchairs Scooters power, auto lifts

Medicare Appeals Guide
www.DecisionHealth.com File Quick Claim Appeals & Decode Medicare Denial Codes In Seconds!

Medicare Appeals Information - Medicare.gov
Jun 2, 2008 — This section of Medicare.gov provides links to pages containing information regarding the appeals process, downloadable appeals forms, ...
www.medicare.gov/basics/appeals/overview.asp - Cached - Similar

Medicare.gov - Appeals Forms
This is called a redetermination and is the first level of the appeals ...
www.medicare.gov/basics/forms/default.asp - Cached - Similar

Medicare.gov - Medicare Appeals and Grievances
This section of Medicare.gov provides information about Medicare Appeals and ...
www.medicare.gov/basics/appeals.asp - Cached - Similar

How to File a Medicare Part A or Part B Appeal in Original Medicare
File Format: PDF/Adobe Acrobat - Quick View
The Appeals Process: There are five levels in the Part A and Part B appeals ...

Medicare Appeals Process
File Format: PDF/Adobe Acrobat - Quick View
Medicare offers five levels in the Part A and Part B appeals process. For more information about the Medicare appeals process, please visit the ...
Real-Life Examples

THE MEDICARE APPEALS PROCESS

Five Levels to Protect Providers, Physicians and Other Suppliers

This brochure provides an overview of the five levels of the Medicare Part A and Part B administrative appeals process.
Real-Life Examples
Real-Life Examples

An ambulance company (AC) you represent provides ambulance services to nursing home residents. These services are either billed to the nursing home as part of the Part A Medicare per diem rate or billed directly to Medicare as Part B reimbursable services.

AC desires to contract at a discounted rate with Sunshine Nursing Home for all Part A ambulance trips. Your client believes that doing this will result in a significant increase in Sunshine’s referral of Part B ambulance trips to AC. Should AC do this?
Real-Life Examples

- Developing a Research Plan
  - What type of question is involved?
    - Stark/Anti-Kickback, Reimbursement/Payment
  - In what context does regulatory issue arise?
    - Compliance, Reimbursement Planning
Real-Life Examples

- Google
  - Key words: ambulance, discount, rates, and Medicare
Real-Life Examples
FEDERAL RESTRICTIONS ON PRICING AMBULANCE SERVICES

AAA Policy Paper

This document is designed to provide an overview of what is required under the Federal Anti-Kickback Statute and the Substantially-in-Excess Rule.

Introduction

One of the questions that is often raised by ambulance service providers involves legal restrictions on discounting. Healthcare facility principals constantly ask ambulance service providers to discount prices for facility responsible transports. Ambulance service providers may believe that they have some pricing flexibility but are concerned that any action they take may subject them and their customers to liability under the Federal Anti-Kickback Statute and the Substantially-in-Excess Rule.
Real-Life Examples

- Medicare Primary Source Information
  - OIG Issuances
    - OIG website http://oig.hhs.gov/
    - Fraud Alerts
      - Fraud Prevention & Detection → Alerts Bulletins, & Other Guidance → Other Guidance
  - Advisory Opinions
    - Fraud Prevention & Detection → Advisory Opinions
      → Go to Advisory Opinion List
Real-Life Examples
Text of Remarks by Daniel R. Levinson, Inspector General of the Department Of Health & Human Services
Prepared for the Workshop Regarding Accountable Care Organizations and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws
October 5, 2010
Baltimore, Maryland

Good morning. It is a pleasure to be here today at this important event with my colleague from the Department, CMS Administrator Dr. Donald Berwick, and FTC Chairman Jon Leibowitz. Partners from the Department of Justice and the Internal Revenue Service are also here today.
Real-Life Examples

U.S. Department of Health & Human Services
Office of Inspector General

Advisory Opinions

In accordance with section 1120(b) (5) (A) of the Social Security Act and 42 CFR 1.08a-47 of our regulations, advisory opinions issued by the Office of Inspector General (OIG) are being made available to the general public through this OIG website. One purpose of the advisory opinion process is to provide meaningful advice on the application of the anti-kickback statute and other OIG sanction statutes in specific factual situations. Please note, however, that advisory opinions are binding and may be relied upon only by the requestor. Since each opinion will apply legal standards to a set of facts involving certain known persons or specific factual issues, third parties are bound only if they legally rely on those advisory opinions.

We have redacted specific information regarding the requestor and certain privileged, confidential or financial information associated with the individual or entity, unless otherwise specified by the requestor.

Current Regulations

Adobe Acrobat Reader required to view PDF files.

2000

- The OIG Final Rule (73 FR 40582) ever revising the procedural aspects for submitting payments for advisory opinion costs.
- The OIG Interim Final Rule (73 FR 14907) ever revising the procedural aspects for submitting payments for advisory opinion costs.
REGULATION, ACCREDITATION AND PAYMENT
PRACTICE GROUP

MEDICARE RESEARCH TOOLKIT

Edited by: Dinetia M. Newman, Esq., Richard Sanders, Esq. and Lawrence W. Vernaglia, Esq.¹

I. BACKGROUND INFORMATION AND SOURCE MATERIALS

A. The Medicare Program.

1. Medicare Primary Source Material.

   a. Statutes –
     Title 42 of the United States Code, §§ 1301-1320d-8,²
     1395-1395hhh (see http://frwebgate.access.gpo.gov/cgi-bin/usc.cgi?ACTION=BROWSE&TITLE=42USCC7)

        (1) Sec. 1395ii. Application of certain provisions of subchapter II
        (2) Sec. 1395jj. Designation of organization or publication by name
        (3) Sec. 1395kk. Administration of insurance programs
        (4) Sec. 1395kk-1. Contracts with medicare administrative contractors
        (5) Sec. 1395ll. Studies and recommendations
        (6) Sec. 1395mm. Payments to health maintenance organizations and competitive medical plans
        (7) Sec. 1395nn. Limitation on certain physician referrals
        (8) Sec. 1395oo. Provider Reimbursement Review Board

¹ The Editors wish to thank a team of dedicated volunteers who assisted in the proofreading of this Toolkit, including: Kate Dennis, Balch & Bingham; Jason Caron, Epstein, Becker & Green, P.C.; Tizgel High and Kirk Dobbins, King & Spalding; Maria Gonzalez Knavel, Foley & Lardner, LLP; Carol Bowen, Moore & Van Allen; and Amanda Wallis, Phelps Dunbar LLP. The web links were check and updated on October 12, 2010.
² State statutes regarding individual and facility licensure, certificate of need, insurance, managed care and drug control also affect an analysis of Medicare issues.
(9) Sec. 1395pp. Limitation on liability where claims are disallowed

(10) Sec. 1395qq. Indian health service facilities

(11) Sec. 1395rr. End stage renal disease program

(12) Sec. 1395ss. Certification of medicare supplemental health insurance policies

(13) Sec. 1395tt. Hospital providers of extended care services

(14) Sec. 1395uu. Payments to promote closing or conversion of underutilized hospital facilities

(15) Sec. 1395vv. Withholding payments from certain medicaid providers

(16) Sec. 1395ww. Payments to hospitals for inpatient hospital services

(17) Sec. 1395xx. Payment of provider-based physicians and payment under certain percentage arrangements

(18) Sec. 1395yy. Payment to skilled nursing facilities for routine service costs

(19) Sec. 1395zz. Provider education and technical assistance

(20) Sec. 1395aaa. Transferred

(21) Sec. 1395bbb. Conditions of participation for home health agencies; home health quality

(22) Sec. 1395ccc. Offset of payments to individuals to collect past- due obligations arising from breach of scholarship and loan contract

(23) Sec. 1395ddd. Medicare Integrity Program

(24) Sec. 1395eee. Payments to, and coverage of benefits under, programs of all-inclusive care for elderly (PACE)

(25) Sec. 1395fff. Prospective payment for home health services

(26) Sec. 1395ggg. Medicare subvention demonstration project for military retirees
b. Legislative History, including Congressional Record, Committee Reports and Conference Reports. See http://thomas.loc.gov/ for legislative history.

c. CMS Resources

(1) CMS Regulations –

(a) 42 C.F.R. Part 400 – Introduction; Definitions

(b) 42 C.F.R. Part 401 – General Administrative Requirements

(c) 42 C.F.R. Part 402 – Civil Money Penalties, Assessments, and Exclusions

(d) 42 C.F.R. Part 403 – Special Programs and Projects

(e) 42 C.F.R. Part 405 – Federal Health Insurance for the Aged and Disabled

(f) 42 C.F.R. Part 406 – Hospital Insurance Eligibility and Entitlement – Part A

(g) 42 C.F.R. Part 407 – Supplementary Medical Insurance (SMI) Enrollment and Entitlement – Part B

(h) 42 C.F.R. Part 408 – Premiums for Supplementary Medical Insurance – Part B

(i) 42 C.F.R. Part 409 – Hospital Insurance Benefits – Part A Benefits

(j) 42 C.F.R. Part 410 – Supplementary Insurance Benefits (SMI) – Part B Benefits

(k) 42 C.F.R. Part 411 – Exclusions from Medicare and Limitations on Medicare Payment
(l) 42 C.F.R. Part 412 – Prospective Payment Systems for Inpatient Hospital Services

(m) 42 C.F.R. Part 413 – Principles of Reasonable Cost Reimbursement; Payment for End-Stage Renal Disease Services; Optional Prospectively Determined Payment Rates for Skilled Nursing Facilities

(n) 42 C.F.R. Part 414 – Payment for Part B Medical and Other Health Services (Physician Services, Non-Physician Practitioner, Ambulance Services, Manufacturer’s Average Sales Price Data)

(o) 42 C.F.R. Part 415 – Services furnished by Physicians in Providers, Supervising Physicians in Teaching Settings and Residents in Certain Settings

(p) 42 C.F.R. Part 416 – Ambulatory Surgery Services

(q) 42 C.F.R. Part 417 – Health Maintenance Organizations, Competitive Medical Plans and Health Care Prepayment Plans

(r) 42 C.F.R. Part 418 – Hospice Care

(s) 42 C.F.R. Part 419 – Prospective Payment System for Hospital Outpatient Department Services

(t) 42 C.F.R. Part 420 – Program Integrity: Medicare

(u) 42 C.F.R. Part 421 – Medicare Contracting

(v) 42 C.F.R. Part 422 – Medicare Advantage Program

(w) 42 C.F.R. Part 423 – Voluntary Medicare Prescription Drug Benefit

(x) 42 C.F.R. Part 424 – Conditions for Medicare Payment

(y) 42 C.F.R. Part 426 – Reviews of National Coverage Determinations and Local Coverage Determinations

(z) 42 C.F.R. Part 475 – Quarterly Improvement Organizations
(aa) 42 C.F.R. Part 476 – Utilization and Quality Control Review

(bb) 42 C.F.R. Part 478 – Reconsiderations and Appeals

(cc) 42 C.F.R. Part 480 – Acquisition, Protection and Disclosure of Quality Improvement Organization Information

(dd) 42 C.F.R. Part 482 – Conditions of Participation for Hospitals

(ee) 42 C.F.R. Part 483 – Requirements for States and Long Term Care Facilities

(ff) 42 C.F.R. Part 484 – Home Health Services

(gg) 42 C.F.R. Part 485 – Conditions of Participation: Specialized Providers

(hh) 42 C.F.R. Part 486 – Conditions for Coverage of Specialized Services Furnished by Suppliers

(ii) 42 C.F.R. Part 489 – Provider Agreements and Supplier Approval

(jj) 42 C.F.R. Part 491 – Certification of Certain Health Facilities (Rural Health Clinics and Federally Qualified Health Clinics)

(kk) 42 C.F.R. Part 493 – Laboratory Requirements

(ll) 42 C.F.R. Part 498 – Appeals Procedures for Determinations that Affect Participation in the Medicare Program and for Determinations that Affect Participation of ICFs/MR and Certain NFs in the Medicaid Program

(mm) 42 C.F.R. Part 505 – Establishment of the Health Care Infrastructure Improvement Program

(2) CMS Manuals (http://www.cms.hhs.gov/manuals)

(a) Paper Based Manuals (Manuals in bold have been incorporated into internet-only manuals).

(i) Coverage Issues Manual – CMS Pub. 6

(ii) State Operations Manual – CMS Pub. 7
(iv) Hospital Manual – CMS Pub. 10
(v) Home Health Agency Manual – CMS Pub. 11
(vi) Skilled Nursing Facility Manual – CMS Pub. 12
(vii) Intermediary Manual – CMS Pub. 13 (Claims Process – Part 3 only)
(ix) Provider Reimbursement Manual Parts I and II – CMS Pub. 15
(x) Peer Review Organization Manual – CMS Pub. 19
(xi) Hospice Manual – CMS Pub. 21
(xii) Regional Office Manual – CMS Pub. 23 (available to CMS staff)
(xiii) Medicare Rural Health Clinic and Federally Qualified Health Center Manual – CMS Pub. 27
(xiv) Medicare Renal Dialysis Facility Manual – CMS Pub. 29
(xv) State Medicaid Manual – CMS Pub. 45
(xvi) ESRD Network Organization Manual – CMS Pub. 81

(b) Internet Only Manuals

(i) Introduction – CMS Pub. 100
(ii) Medicare General Information, Eligibility and Entitlement – CMS Pub. 100-1
(iii) Medicare Benefit Policy – CMS Pub. 100-2
(iv) Medicare National Coverage Determinations – CMS Pub. 100-3
(v) Medicare Claims Processing – CMS Pub. 100-4
(vi) Medicare Secondary Payer – CMS Pub. 100-5
(vii) Medicare Financial Management – CMS Pub. 100-6
(viii) State Operations – CMS Pub. 100-7
(ix) Medicare Program Integrity – CMS Pub. 100-8
(x) Medicare Contractor Beneficiary and Provider Communications – CMS Pub. 100-9
(xi) Quality Improvement Organization – CMS Pub. 100-10
(xii) State Medicaid Manual (under development) – CMS Pub. 100-12
(xiii) Medicaid State Children’s Health Insurance Program (under development) – CMS Pub. 100-13
(xiv) Medicare ESRD Network Organizations – CMS Pub. 100-14
(xv) State Buy-In – CMS Pub. 100-15
(xvi) Medicare Managed Care – CMS Pub. 100-16
(xvii) CMS/Business Partners Systems Security – CMS Pub. 100-17
(xviii) Demonstrations – CMS Pub. 100-19
(xix) One-Time Notification – CMS Pub. 100-20
(3) Federal Register Preamble or Commentary –
That part of Notice of Final Rule that discusses policy
decisions and reasons.

(4) CMS Communication Vehicles

- Program Memoranda & One-Time Notifications –
Prior to October 1, 2003, CMS augmented its
manuals with additional explanations in Program
Memoranda to Intermediaries and Carriers.
Program Memoranda included reminders and one-
time requests for action.

CMS now publishes One-Time Notifications (CMS
Pub. 100-20) to provide instructions to its
intermediaries, carriers and Medicare administrative
contractors that may include some or all of the
following features: a transmittal page, general
information, a business requirements table, provider
education information, CMS contact information,
funding information and various attachments. CMS
has been incorporating some memoranda into the
internet based manuals. Program Memoranda for
2000-2003 are on the CMS website at
http://www.cms.hhs.gov/Transmittals/CMSPM/List
.asp and the CCH Medicare and Medicaid Guide
archives Program Memoranda and Information
Memoranda back to 1971.

- Program Transmittals, Manual Instructions –
Program transmittals communicate manual
instructions on new or revised policies and
procedures that update manuals.

- Recurring Update Notification (CMS Pub. 100-21)
– CMS previously issued “Recurring Update
Notifications” that contained instructions to
Medicare contractors. A Recurring Update
Notification contains a transmittal sheet
communicating background information, the policy
and perhaps provider education that will follow and

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3 See http://www.cms.hhs.gov/Manuals/IOM/list.asp (includes all recurring change requests issued between January
5 and August 5, 2005).
a business requirements template. CMS Pub. 100-21 currently contains all recurring change requests issued between January 1, 2005 and October 3, 2005.

(5) CMS Forms and Instructions –
CMS has billing and participation forms with explanatory information (e.g., Minimum Data Set Manuals and Forms, OASIS and Provider Enrollment forms; Research and Grant Applications). See at http://www.cms.hhs.gov/CMSForms/CMSForms/list.asp#TopOfPage.

(6) CMS Quarterly Provider Update –
CMS publishes the QPU on the first business day of the quarter to identify regulations and policies under development, completed or cancelled and to alert the public to new and revised manual instructions. Instructions are generally implemented 90 days after they are included in the QPU. See at http://www.cms.hhs.gov/QuarterlyProviderUpdates/.

(7) Medicare Coverage Database (MCD) –
The CMS webpage (http://www.cms.hhs.gov/mcd/overview.asp?from2=overview.asp&) offers access to the MCD, including all National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), local policy articles, proposed NCD decisions, national coverage analyses (NCAs), coding analyses for labs (CALs), Medicare Evidence Development & Coverage Advisory Committee (MedCAC) proceedings, Medicare coverage guidance documents and a comment tool allowing the public to submit comments on National coverage documents. Updates to the MCD are in “real time,” except that the NCDs and LCDs are updated weekly. LCDs retired for more than 2 years are found in the MCD archives.

National Coverage Determination (NCD) Process –
CMS has established a process for issuance of NCDs. The CMS website includes links regarding critical process components such as the Medicare Coverage Advisory Committee review and Technology Assessment at http://www.cms.hhs.gov/center/coverage.asp (Medicare Coverage Center) and description of the process at http://www.cms.hhs.gov/DeterminationProcess.
(8) CMS Issuances

(a) FAQs: The CMS website contains explanations of rules often in the form of questions and answers and sometimes the results of open door forums and town meetings. Searching capability is available by terms or phrases. While the FAQ answers do not always contain citations to relevant regulations or manual sections, they do often point to additional evidence frequently in Med Learn Matters that generally reference a Federal Register cite or rule and a CMS transmittal and revised manual section. The FAQs also survey researchers as to whether answers are “very helpful,” “somewhat helpful” or “not helpful,” direct researchers to “related answers” and ask researchers if they want to be notified if the answer is updated. See CMS website/Site Tools and Resources at www.cms.hhs.gov/mlngeninfo.

(b) Coding Guidance: The CMS website contains coding guidance on:

- HCPCS – General Information
- HCPCS Release & Code Sets
- ICD-9-CM
- ICD-10
- National Correct Coding Initiative Edits
- Outpatient Code Editor (OCE) at http://www.cms.hhs.gov/home/medicare.asp


(10) Beneficiary Notices Initiative – CMS communicates beneficiaries’ rights and protection regarding their financial liability and appeal rights through providers’ notices, such
as FFS General Use and Laboratory Advance Beneficiary Notices. These various notices are found at www.cms.hhs.gov/BNI/.

(11) CMS Open Door Forums (Outreach & Education)

(12) Federal Physician Self Referral Law (commonly referred to as the “Stark Law”) – The CMS website contains a number of Stark Law resources, including a summary of the Stark Law, a copy of the Stark Law, relevant Federal Register issuances, Frequently Asked Questions, the Stark Law Advisory Opinions and the list of codes for certain Stark Law designated health services. These materials and others can be found at: http://www.cms.hhs.gov/PhysicianSelfReferral.

d. Officer of Inspector General (OIG) Resources – Risk areas for government review regarding Medicare and Medicaid payment to various providers, suppliers and other entities can be identified in these materials. Fraud and abuse issues may be present when there is a Medicare or Medicaid payment issue.

(1) Regulations –

(2) OIG Issuances


(b) Compliance Guidance – The OIG has issued compliance guidance for different providers, suppliers and other entities. Compliance guidance may include payment-related issues (i.e., certain payment-related issues may be identified as compliance “risk areas”). The compliance guidance documents are available at: http://www.oig.hhs.gov/fraud/complianceguidance.asp.

(c) Corporate Integrity Agreements (CIAs) – The OIG negotiates certain compliance obligations with health care providers and other entities as part of the settlement of Federal health care program investigations arising under a variety of civil false
claims statutes. A number of CIAs contain payment-related claims and systems reviews and the current CIAs are available at: http://www.oig.hhs.gov/fraud/cias.asp.


(e) Open Letters – The OIG has issued a number of Open Letters to the health care industry which are available at: http://www.oig.hhs.gov/fraud/openletters.asp.


(g) Office of Audit Services and Office of Evaluation and Inspection reports include payment-related reports and other similar reports and are available at: http://www.oig.hhs.gov/reports.asp.

(h) Advisory opinions – Advisory opinions issued by the OIG are available at: http://www.oig.hhs.gov/fraud/advisoryopinions/2011/.


(k) The Orange Book and Red Books Archives – These archives contain non-monetary recommendations


(m) Exclusion Program – The OIG maintains a list of all currently excluded parties called the List of Excluded individuals/entities which is available at: http://www.oig.hhs.gov/fraud/exclusions.asp.

(n) The OIG has a number of other resources available on its website at: http://www.oig.hhs.gov/.

e. Administrative Decisions

(1) The levels of the Medicare appeals process are available at: http://www.hhs.gov/omha/levels/index.html.

(2) Provider Reimbursement Review Board (PRRB) and Administrator appeal instructions and decisions covering cost reporting issues, CMS rulings (precedential administrator decisions clarifying and interpreting Medicare, Medicaid and private health insurance law or regulations) and various hearing procedures for appealing denials of ESRD exceptions and children’s hospital graduate medical education. See http://www.cms.hhs.gov/PRRBReview/; see also http://www.cms.hhs.gov/PRRBReview/PRRBD/list.asp#TopOfPage.


(4) HHS Department Appeals Board (DAB) – Decisions regarding Medicare participation, as well as coverage and payment determinations for Medicare Parts A and B. See http://www.hhs.gov/dab/; see also, http://www.hhs.gov/dab/decisions/browsecr.html.
Medicare Appeals Council Decisions (MAC) – Within DAB’s Medicare operations division, the MAC performs final administrative review (on a de novo basis) for beneficiaries, suppliers and providers that appeal ALJ decisions regarding payment denied for claims on Medicare items and services. MAC decisions are the final decisions of the Secretary of DHHS and are appealable to a federal court. See http://www.hhs.gov/dab/macdecision.

Civil Remedies ALJ Decisions – CRD ALJ hearings involve “provider/supplier enforcement and certification determinations by CMS,” OIG and CMS fraud and abuse determinations, Program Fraud Civil Remedies Act determinations, Equal Access to Justice Act determinations and terminations of grants to or continuation of federal funding because of civil rights violations. See http://www.hhs.gov/dab/civil/.

Case Law –

Federal cases at district, circuit and Supreme Court levels.

Local Carrier/Intermediary Issuances

(1) Local Medical Review Policies
(2) Provider Bulletins
(3) Provider Manuals
(4) Fee Schedules

Accreditation Organization Manuals (i.e., JCAHO, NCQA, URAC, AAPHC) – May be relevant in answering participation related questions, identifying quality and performance standards and educational programs.


(1) American Medical Association (AMA) CPT Professional Edition
(2) 2008 HCPCS Level II by AMA
(3) ICD-9-CM Books for Physicians and for Hospitals by Ingenix

a. Manual Organization –
The web-based manual system for all users is now organized into functional areas of program integrity, eligibility, entitlement and claims processing. Where previously the paper manuals were organized based upon provider type (i.e., Hospital Manual, SNF Manual) or contractor type (i.e., Carriers Manual, Intermediary Manual), the current manuals (based upon function) are not differentiated by provider type or contractor type. Consequently, the new organization may make it difficult to determine what sections apply to different types of providers and suppliers.

The CMS website contains the entire paper manual and, in the Internet-Only Manuals, those paper manual sections that have been transferred and updated. Although CMS earlier stated that by April 1, 2006, all paper manual sections should be transferred to the Internet-Only Manual with the exception of Provider Reimbursement Manual, Pub. Nos. 15.1 and 15.2, all manual transfers have not occurred. See infra pgs. 4 and 5. CMS has stated that if paper manual sections are currently effective, they will be moved, but if they are no longer effective, they will be left in paper format for reference only purposes.4 Currently, the Provider Reimbursement Manual and the State Medicaid Manual, Pub. No. 45 are the only active paper-based manuals.5

b. Revision to Manuals –
CMS updates its manuals through six (6) policy vehicles: (1) Program transmittals (communication vehicle), (2) Manual Instructions, (3) Business Requirements, (4) One-time Notifications, (5) Recurring Update Notifications and (6) Confidential Requirements. A transmittal sheet accompanies each

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4 The paper manuals have not been updated since October 2003.
5 All CMS manuals may be viewed on the CMS website at http://www.cms.hhs.gov/Manuals/.
manual update, indicating the CMS publication to be updated and includes a business requirements template and the manual provision being revised. While previously manual provisions contained only a revision number and date, currently, manual sections being revised include a revision number, an issuance date, an effective date and an implementation date.

A One-Time Notification instructs a Medicare contractor regarding tasks that will not be part of a manual. CMS uses Recurring Update Notifications to communicate recurring updates to a manual such as rate increases.

Because this process could be confusing, researchers should review the Internet-Only Manual, paper manuals, the Recurring Update Notification Manual and the Future Updates to Internet-Only Manuals when researching any issue. The Updates to Internet-Only Manuals chart includes a table of contents that contains the file and identifies the communication date, the publication being revised, the subject matter, the implementation date and the change request number.

CMS manuals are not updated until the implementation date. If, for example, a manual section revision is effective March 1, 2008, CMS has five business days to publish this revised section on its website.

CMS also includes on its website the CMS Quarterly Provider Update, published the beginning of each quarter, that includes regulations and major policies under development, regulations and major policies completed or cancelled and new or revised manual instructions.

c. **CMS Crosswalks** –
CMS has published crosswalks between the old and new manuals, some at the beginning of the manual and some between manual chapters. In CMS’ transmittals publishing the crosswalks, CMS states that it has deleted certain old manual chapters, while indicating through the crosswalk where older manual chapters are related to new manual chapters. According to CMS, if a manual section is in both paper manuals and the Internet-Only Manuals, the correct source is the Internet-Only Manual section.

d. **New Materials** –
CMS incorporates program memoranda into the Internet-Only Manuals. When researching Medicare issues, be aware of the prior program memoranda. Also check old manuals to identify new material in the internet only manual.
In some manuals, transmittals containing manual revisions are identified just prior to the chapter index.

In the Medicare “Regulations and Guidance” section is a drop down link to “Quarterly Provider Updates” and a quarterly “What’s New Page” listing regulations released and publications and instructions released during a particular quarter. See http://www.cms.hhs.gov/QuarterlyProviderUpdates/03 WhatsNew.asp.

e. **Search Engines in CMS Manuals** –
Currently, when one uses the search engine in either the Internet-Only or paper-based manual sections, the search is for the entire CMS website. According to CMS, eventually, there will be a search engine, first for only the CMS manuals and eventually by specific manual.

Also, inexplicably, with various manual chapters, one can click on and retrieve certain sections, while in another chapter within the same manual, this is not possible. For example, in the Medicare General Information, Eligibility and Entitlement Manual, one may access sections in Chapter 6 by clicking on the index number, but cannot do so in Chapter 7.

f. **Significance of Manuals’ Informal Authority** –
At least one federal appeals court, the Eleventh Circuit in *United States ex rel Walker v. R&F Properties of Lake County, Inc.*, 433 F. 3d 1349 (11th Cir. 2005) has relied on CMS manual provisions to interpret a regulation (in that case, the incident to regulations) which at the time was silent regarding a payment principle.

3. **Obtaining Primary Source Information.**

a. **Hardcopy Materials**

(1) U.S. Code and U.S. Code of Federal Regulations

(2) Federal Register and Legislative History

(3) CMS Manuals –
Older non-internet hardcopy manuals may be obtained from CMS.

(4) CCH –
CCH publishes the CCH Medicare and Medicaid Guide including excerpts from CMS manuals, transmittals and program memoranda, administrative and court decisions.
CCH’s regular updates and materials are extensively cross-referenced.

(5) Coding Guides –
Code reference books are updated yearly, while the CPT Assistant is a monthly publication and AHA Coding Clinic for ICD-9-CM is a quarterly publication. AMA Press and Ingenix sell the reference books.

b. Electronic Materials

(1) Legislative and Administrative Materials


(2) CMS Website –
www.cms.hhs.gov – CMS maintains manuals, transmittals, memos, Federal Register issuances, forms and instructions, informal information, the Med Learning Network, and the Medicare Coverage Database. The CMS reorganized its website late in 2005 and periodically revises links to materials. Search capability is available, may be sorted by relevance or date, but may also yield thousands of hits because search capability extends to the entire website. PDF documents on the site are separately searchable.

(3) OIG Website –
http://oig.hhs.gov – The OIG maintains its materials on this website available by category and through the search engine. Actual corporate integrity agreements and, more recently, certification of compliance agreements may be viewed on the OIG website. The website also includes press releases containing terms of various settlement agreements between the OIG and providers or suppliers. See also the Department of Justice website at www.usdoj.gov.

(4) Local Intermediary/Carrier Websites –
These websites contain bulletins, manuals and fee
schedules. The directory of current carriers and intermediaries\(^6\) is available at http://www.cms.hhs.gov/apps/contacts/. Note that sometimes carrier/intermediary information can be difficult to locate when there have been contractor changes.

(5) CCH (http://health.cch.com) or MediRegs (www.mediregs.com) online or on CD-ROM – These health care research tools contain the following information:

(a) Statutes, legislative history, regulations and federal register

(b) CMS paper and internet-only manuals

(c) CMS program memoranda and other transmittals

(d) CMS forms and instructions

(e) CMS administrative decisions

(f) Federal and state cases (archived cases back to 1969)

(g) Healthcare compliance materials

(h) Selected state healthcare laws and regulations

(i) Selected coding manuals

CCH offers Archived Documents in the date range between 1968 and 1996, including U.S. Supreme Court, U.S. Appeals Court, U.S. District Court, U.S. Court of Claims, U.S. Claims Court, U.S. Bankruptcy Court and miscellaneous state court cases; HCFA Rulings, HCFA Administrator Decisions, PRRB Decisions, SSA Rulings, DAB Decisions, GAO Reports, Intermediary Letters and miscellaneous documents. The CCH database also includes OIG Reports in the date range between 1980 and 1996.

(6) Lexis/Westlaw Databases – Search these databases for health care related statutes,

\(^6\) Medicare fiscal intermediaries and carriers will be phased out and replaced by Medicare Administrative Contractors (“MACs”). The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 implemented Medicare Contracting Reform that requires this transition to occur. More information about the Medicare Contracting Reform may be found on the CMS website at http://www.cms.hhs.gov/MedicareContractingReform/.
regulations and cases. Recently, Westlaw began offering AHLA seminar materials as a database in its “Health Law” tab. The database is titled “AHLA-PAPERS.” In addition, both Westlaw and Lexis offer:

(a) Federal and state cases  
(b) State and federal statutes and legislative materials  
(c) Administrative Materials and Regulations (i.e., CMS Program Manuals, Code of Federal Regulations and the Federal Register)  
(d) Health care accreditation materials  
(e) Health Policy Tracking Service – Medicaid  
(f) Treatises and Legal Periodicals


(8) Civil Remedy Division (CRD) – CRD ALJs issue decisions regarding provider/supplier enforcement, CMS certification decisions and SSA civil money penalty determinations among others. See http://www.hhs.gov/dab/civil/.

(9) Coding Guides – Most coding information is also available in searchable CD-ROMs and sometimes on-line. See www.cdc.gov/nchs/data/icd9/icdguide10.pdf for the Official ICD-9-CM Coding Guidelines from the Public Health Service and CMS.

   a. AHLA Materials  
      (1) AHLA’s Health Law Archive (sign in to access) at http://archive.healthlawyers.org/archive_home.cfm?initiate =  
          • All Program Papers, 1993-2007 (many with audio!)
- Example: Institute of Medicare and Medicaid Payment Issues, Fundamentals of Health Law and the Annual Meeting

- All *Journal of Health Law* issues, 1984-2007

- All Health Lawyers Non-Dues publications, 2000-2007
  - Example: Excerpts from *Diagnostic Imaging Centers, 2nd Edition*, 2006 regarding provider-based issues

- All *Health Lawyers Weekly* articles, 2001-present
  - Example: January 2007 – Articles & Analyses – *Congress Approves Medicare, Medicaid Changes*

- All *Health Law Digest* articles, 1995-present
  - Example: *U.S. Court In Missouri Issues Enjoins Enforcement Of Law Regulating Abortion Facilities* – October 2007

- All *Life Sciences and Health Law Daily* briefings, 2007-present
  - Example: *Georgia rule would change CON requirements for physician-owned ambulatory surgery centers* – January 28, 2008

- All Practice Group Newsletters, Member Briefings, Toolkits, and Teleconference Recordings (Documents are between 9 and 12 months old)
States
R. Brent Rawlings, JD, MHA, FACHE

- Editor’s Notes
  Kenneth Marcus, Esq.

- Whether Days of Medical Assistance Provided By A State Plan Approved Under Title XIX Should Be Included Among “Eligible Days” In the Medicare DSH Computation: The Case of Adena Regional Medical Center, et al. v. Leavitt Steven Roosa, Esq.

- The Final Medicare Inpatient Prospective Payment System Rule for Federal Fiscal Year 2008: Payment and Compliance Challenges
  Lance Loria, CPA, FACHE, FAAMA

- Chair’s Corner
  Andrew Ruskin, Esq.

- MedPAC’s New Area Wage Adjustment—What Could It Mean for Providers?
  Theodore Giovanis, FHFMA, MBA

- New Developments With Long Term Care Hospitals
  Stephen Sullivan, JD, MPH, and Mollye Monceaux, JD, MHA

- Example: RAP Member Briefings:
  Ambulatory Surgery Center Payment Changes Finalized (January 2008)

- Example: RAP toolkits:
  - CMS Hospital Surveys: The Legal Perspective
  - GME & Non-Provider Training
  - EMTALA Toolkit
• Provider-Based Status Toolkit

  • Example: RAP recent teleconference:
    February 19, 2008 – *Telemedicine Legal Update: Fraud and Abuse, Credentialing, and Medicare Issues for Telehealth Ventures*
    Co-sponsored by the Fraud and Abuse, Self-Referrals, and False Claims; Health Information and Technology; Medical Staff, Credentialing, and Peer Review; and Regulation, Accreditation, and Payment Practice Groups

  • All issues of *Health Lawyers News*, 1997-present


  • AHLA Listserve conversations of the past 24 months

  • Example: *Block Lease Issue – Purchased Diagnostic Test Rule* – December 14, 2006

  • Note: As of the printing of this Toolkit, Listserve discussions are not on the AHLA Archives.

  (2) AHLA publications on payment issues including *Federal Healthcare Laws & Regulations* (3 volumes) and *Medicare Law* (2d edition)

  (3) AHLA “News” – Click on “News Center” on tool bar
    [http://www.healthlawyers.org/News/Pages/default.aspx](http://www.healthlawyers.org/News/Pages/default.aspx)

    • *Health Lawyers News* – monthly magazine (PGs include lead substantive article)

    • *Health Lawyers Weekly* – Top weekly news, articles and analyses; Health Law Digest for week plus
archive; Listserve Roundup; Regulatory Comments Calendar with links to Federal Registers; Accreditation Comments Calendar; and Health Law Documents
http://www.healthlawyers.org/News/Health%20Lawyers%20Weekly/Pages/default.aspx

• **Health Law Digest** – Case summaries and regulatory developments (included in Health Lawyers Weekly)
http://www.healthlawyers.org/News/Health%20Law%20Digest/Pages/default.aspx

• **Health and Life Sciences Daily** – The Daily is a digest of the most important health and legal news culled from thousands of sources and delivered, as a benefit, to members’ email inboxes

• **Journal of Health & Life Sciences Law** – Articles on developing topics peer reviewed by veteran editorial board

(4) AHLA Web Links
(http://www.healthlawyers.org/Resources/Websites/Pages/default.aspx)

(5) AHLA Web Links
(http://www.healthlawyers.org/Resources/Websites/Pages/default.aspx) or to go website, click on “Health Law Resources” on tool bar and then on “Health Law Web Sites.”


c. Medicare Part B Desk Reference for Physicians (Ingenix).

d. **CPT Expert** (Ingenix).


g. Trade Press (e.g., *BNA Daily Report, BNA Medicare Report, Medicare Drug Watch*).

h. State Hospital Association publications.

i. MedPAC (Medicare Payment Advisory Commission) reports.

B. **The Medicaid Program.**

1. **Medicaid Primary Source Materials.**

   a. Statutes – Federal – Title 42, United States Code, §§ 1396a to 1396v; §§ 1301-1320b-21 [note: (d)(8) includes Peer Review and Administrative Simplification provisions].

      (1) Sec. 1396. Appropriations

      (2) Sec. 1396a. State plans for medical assistance

      (3) Sec. 1396b. Payment to States

      (4) Sec. 1396c. Operation of State plans

      (5) Sec. 1396d. Definitions

      (6) Sec. 1396e. Enrollment of individuals under group health plans

      (7) Sec. 1396f. Observance of religious beliefs

      (8) Sec. 1396g. State programs for licensing of administrators of nursing homes

      (9) Sec. 1396g-1. Required laws relating to medical child support

      (10) Sec. 1396h. Transferred

      (11) Sec. 1396i. Certification and approval of rural health clinics and intermediate care facilities for mentally retarded

      (12) Sec. 1396j. Indian health service facilities

      (13) Sec. 1396k. Assignment, enforcement, and collection of rights of payments for medical care; establishment of procedures pursuant to State plan; amounts retained by State
(14) Sec. 1396l. Hospital providers of nursing facility services
(15) Sec. 1396m. Withholding of Federal share of payments for certain Medicare providers
(16) Sec. 1396n. Compliance with State plan and payment provisions
(17) Sec. 1396o. Use of enrollment fees, premiums, deductions, cost sharing, and similar charges
(18) Sec. 1396p. Liens, adjustments and recoveries, and transfers of assets
(19) Sec. 1396q. Application of provisions of subchapter II relating to subpoenas
(20) Sec. 1396r. Requirements for nursing facilities
(21) Sec. 1396r-1. Presumptive eligibility for pregnant women
(22) Sec. 1396r-1a. Presumptive eligibility for children
(23) Sec. 1396r-1b. Presumptive eligibility for certain breast or cervical cancer patients
(24) Sec. 1396r-2. Information concerning sanctions taken by State licensing authorities against health care practitioners and providers
(25) Sec. 1396r-3. Correction and reduction plans for intermediate care facilities for mentally retarded
(26) Sec. 1396r-4. Adjustment in payment for inpatient hospital services furnished by disproportionate share hospitals
(27) Sec. 1396r-5. Treatment of income and resources for certain institutionalized spouses
(28) Sec. 1396r-6. Extension of eligibility for medical assistance
(30) Sec. 1396r-8. Payment for covered outpatient drugs
(31) Sec. 1396s. Program for distribution of pediatric vaccines
(32) Sec. 1396t. Home and community care for functionally disabled elderly individuals

(33) Sec. 1396u. Community supported living arrangements services

(34) Sec. 1396u-1. Assuring coverage for certain low-income families

(35) Sec. 1396u-2. Provisions relating to managed care

(36) Sec. 1396u-3. State coverage of medicare cost-sharing for additional low-income medicare beneficiaries

(37) Sec. 1396u-4. Program of all-inclusive care for elderly (PACE)

(38) Sec. 1396u-5. Special provisions relating to medicare prescription drug benefit

(39) Sec. 1396v. References to laws directly affecting medicaid program

b. State Medicaid Acts and Fraud Statutes.

c. Legislative Histories including Congressional Records, Committee Reports and Conference Reports.

(1) Regulations –
   42 C.F.R. Part 430 – Grants to States for Medical Assistance Programs

(2) 42 C.F.R. Part 431 – State Organization and General Administration

(3) 42 C.F.R. Part 432 – State Personnel Administration

(4) 42 C.F.R. Part 433 – State Fiscal Administration

(5) 42 C.F.R. Part 434 – Contracts

(6) 42 C.F.R. Part 435 – Eligibility in the States, District of Columbia, the Northern Mariana Islands, and American Samoa

(7) 42 C.F.R. Part 436 – Eligibility in Guam, Puerto Rico, and the Virgin Islands

(8) 42 C.F.R. Part 438 – Managed Care
d. State Plans –
Description of Medicaid program for each state available on state program website (i.e., Mississippi State Plan at http://www.medicaid.ms.gov/MississippiStatePlan.aspx.

e. Manuals

(1) Federal Manuals

(a) CMS Medicaid Manual – CMS Pub. 45 (paper-based).

(b) CMS State Medicaid Manual CMS Pub. 100-12 (internet-only) is under development.

(c) CMS Medicaid Children’s Health Insurance Program, CMS Pub. 100-13, is also under development.

(2) State Manuals and Formal Information: Provider Manuals, ESC Manuals, Fee Schedules, FAQs.

f. Informal issuances –
Sometimes states publish newsletters for providers/suppliers or issue guidance through memos or letters.

g. Forms and instructions –
Published by CMS and by State Medicaid programs. Forms often
contain instructions that are useful in answering enrollment and billing questions.

h. Case law –
   Federal and state

i. Carrier issuances –
   State Medicaid programs often contract with fiscal intermediaries or fiscal agents to administer the payment aspects of the program. Sometimes states also allow counties to administer portions of programs such as mental health. These entities also may issue materials that contain program requirements.


      (1) Federal Code
      (2) State Code and Agency Regulations
      (3) State Agency Manuals
      (4) Carrier Bulletins and Manuals
      (5) CCH and Other Commercial Guides
      (6) Coding Guides

      (1) State legislature and administrative websites.
      (2) CMS and State Agency Websites – CMS’ website contains useful information and the State Medical Plans and Plan Amendments pages contain a helpful index.
      (3) Fiscal intermediary, carrier and Medicare Administrative Contractor websites
      (4) CCH or MediRegs – Databases include selected state statutes, regulations and manuals and charts.
      (5) Lexis/Westlaw databases
      (6) OIG and AG Issuances
(7) Medicare Appeals Council Decisions
(8) Civil Remedy Division Decisions
(9) Coding Guides

   a. AHLA Program Materials, Teleconference Materials, Newsletter Articles
   b. BNA Publications
   c. CCH
   d. Westlaw/Lexis Databases
   e. AHLA Public Interest – Medicaid Basics: A Question and Answer Guide about Eligibility Coverage and Benefits – http://www.healthlawyers.org. Click on “Public Interest,” then “Public Information Series,” Then view Medicaid Basics on right under “Related Resources.”

II. TECHNIQUES FOR RESEARCHING SPECIFIC MEDICARE RELATED ISSUES

A. How Medicare Issues Arise.

1. Compliance Questions
2. Corporate Transactions
3. Reimbursement Planning
4. Government Investigations
5. Day-to-Day Advising on Operations Involving Reimbursement
6. Litigation Support
B. Types of Issues.

Medicare issues fall into several categories. For example, there are coverage issues, patient eligibility issues, enrollment/participation issues, survey and certification issues, reimbursement/payment issues and repayment issues. It is helpful to identify the type of issue before starting the research. Below are brief outlines of sample research plans on various issues.

C. The Coverage Issue.

The Question: Does Medicare Part B cover drugs provided to an oncologist’s patient if the oncologist purchases the drugs from a Canadian supplier?

1. The Research Plan Should Include:
   a. Medicare statutes and regulations governing coverage of drugs (remember the issue concerns Part B v. Part D coverage).
   b. Recent Federal Register issuances concerning coverage of the item or service at issue. Reimbursement updates typically include coverage information (e.g., physician fee schedule rule).
   c. Medicare Manuals:
      (1) Internet Only Manuals:
         • Medicare Benefit Policy (CMS Pub. 100-2) (replaces Medicare general coverage instructions that are not National Coverage Determinations and that formerly were in the Carriers Manual, (Chapter II), the Intermediary Manual, various provider manuals and in Program memoranda);
      (2) Paper-Based Manuals:
         • Coverage Issues Manual;
         • Carrier or Intermediary Manual;
         • Provider/supplier specific manual (i.e., Hospital, Medicare Rural Health Clinic and Federally Qualified Health Center).
      (3) Future Updates to Internet-Only Manuals.
d. Medicare Coverage Database

One of the “Top Ten Links” on the CMS homepage is the “Medicare Coverage Database.” This database includes, among other links, a link inside CMS to the “Medicare Coverage Center” and to the “Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations” as well as a link outside CMS to the “Medicare Coverage Database – Archives” site. These sites contain a wealth of information about the coverage process, facilities/trials registries, coverage guidance documents and information exchanges, including public comments and related instructions.

e. AHLA Health Law Archives (search terms “import”, “drug”, “Part B”, “Canada”) (will reveal AHLA program materials, listserve discussions, Digest articles, Life Sciences and Health Law Daily briefings).

f. Medicare memoranda and notifications.

g. Carrier/Intermediary Issuances.

h. CMS/AMA Coding Guidance.

i. CCH Explanations & Annotations

2. Research Tips.

a. Check the Medicare Coverage Database – http://www.cms.hhs.gov/med/overview.asp – The database allows searching of:

   (1) National Coverage Determinations (formerly the Coverage Issues Manual);
   
   (2) National Coverage Analysis;
   
   (3) Laboratory National Coverage Determinations; and
   
   (4) Local medical review policies and local coverage determinations (and retired LCDs/LMRPs).

b. Check to see if the item or service has been reviewed by the Medicare Coverage Advisory Committee.

c. Coverage policies can also contain reimbursement/payment limitations. For example, certain services may be covered, but are reimbursed by the Medicare program only when provided in a
certain setting (i.e., inpatient or home) and by a specific type of provider or supplier (i.e., hospital or durable medical equipment company).

D. **The Enrollment/Participation Issue.**

*The Question: Our client wants to form an independent diagnostic testing facility and qualify it to participate in the Medicare and Medicaid programs.*

1. **The Research Plan Should Include:**
   
a. **Medicare**

   (1) Medicare statutes and regulations governing participation.

   (2) Medicare Manuals:

   (a) State Operations Manual (CMS Pub. 100-07) that includes as Appendices the Interpretive Guidelines.

   (b) Program Integrity Manual (CMS Pub. 100-8), Chapter 10 – Provider/supplier enrollment.


   (4) Future Updates to Internet-Only Manuals.

   (5) CMS memoranda and notifications.

   (6) CMS survey and certification letters.

   (7) Medicare local carrier/intermediary and Medicare Administrative Contractor websites and personal contact with Medicare contractor.

b. **Medicaid**

   (1) State statutes and regulations.

   (2) Medicaid Provider/Supplier Policy Manuals.

   (3) Contacts with Medicaid enrollment for enrollment packet.

c. **Other**

   (1) The Joint Commission (formerly JCAHO) and other accreditation agency materials. See [www.jointcommission.org](http://www.jointcommission.org).
(2) State licensure statutes and regulations.

2. Research Tips.
   a. Change in ownership procedures may vary depending upon the state surveyor and the CMS Regional Office’s interpretation of requirements.
   b. State licensure practice limitations must be understood for non-physician practitioners and for employer/contractor relationships for billing purposes.
   c. Some states have certificate of need processes that could impact enrollment or participation.
   d. State law requirements and carrier discretion also could affect what services can be provided.
   e. Failures to meet certification requirements or providing services beyond the scope of state law could potentially taint Medicare and Medicaid claims.

E. The Reimbursement/Payment Issue.

The Question: A client radiology group desires to engage a “night hawk” group as independent contractors to interpret films during weekends and desires for the “night hawk” radiologists to reassign to client their rights to receive Medicare payment.

1. The Research Plan Should Include:
   a. Medicare statutes and regulations.
   b. Recent Federal Register issuances setting yearly updates of rate structures to identify changes in regulations affecting reassignment rules and billing for interpretations of diagnostic testing.
   c. Medicare Manuals:
      (1) Medicare Claims Processing Manual (CMS Pub. 100-4) contains information on billing requirements by providers/suppliers, including carrier jurisdictional rules.
      (2) In the older manuals, such as the Carriers Manual, Provider Reimbursement Manual and individual provider manuals (i.e., skilled nursing, home health, etc.), there are similar billing requirements, some of which make obsolete references. Check for consistency with new manuals.
d. Future Updates to Internet-Only Manuals.

e. Medicare memos and notifications.

f. Local carrier/intermediary manuals and issuances (i.e., Medicare contractor fact sheets).

g. Medicaid policy manuals.

h. AHLA Health Law Archive (AHLA materials from Medicare & Medicaid Institute, The RAP Sheet and teleconferences on new regulatory issuances (e.g., revisions to Stark rules regarding exceptions applicable to group practices).

i. Coding Guides.

2. Research Tips for Other Types of Payment Issues.

   a. If there is a code associated with the item or services, search coding materials as important information can be included in the code description.

   b. For some important issues, CMS has “preempted” the requirements and there is very little to be learned from carrier/intermediary instructions. In many cases there is limited statutory and regulatory guidance. For example, the ABN requirements are comprehensively addressed in the Claims Processing Manual.

F. The Repayment Issue.

   The Question: Our client has received a certified letter from Assistant U.S. Attorney stating that it has filed improper claims with Medicare and must repay the program $2.5 Million.

   1. The Research Plan Should Include:

      a. Identify the specific coverage, participation and billing issues to determine the scope of the research (i.e., inpatient hospital claims, claims for outpatient services or claims related to physician services).

      b. AHLA Health Law Archive and program materials regarding repayment and statistical sampling.

      c. Medicare statutes and regulations regarding the payment issue.
d. Medicare manuals regarding determining overpayments through samples and making repayments.
   (1) Program Integrity Manual (CMS Pub. 100-8).
   (2) Claims Processing Manual (CMS Pub. 100-4).
   (3) Carriers Manual (CMS Pub. 14) and Intermediary Manual (CMS Pub. 13) to check consistency with Program Integrity and Claims Processing Manuals.

e. Medicare regulations regarding provider/supplier appeals of contractor determinations.

f. Future Updates to Internet-Only Manuals.

g. CMS transmittals and issuances regarding repayments.

h. OIG related statutes, regulations and guidance on repayments, including OIG issuances on the specific overpayment issues. Often repayment issues may involve a fraud and abuse component to consider.

2. Research Tips.

a. Distinguish between CMS guidance given to providers/suppliers and instructions to intermediaries/carriers. As new CMS manuals are not specifically addressed to one group, there may be less of a distinction to be made in the future. However, changes in CMS policy that occur in the new manuals should be considered when there is a repayment issue.

b. If there is a fraud and abuse issue under OIG related statutes and regulations, repayment responsibility may extend to other federal health care programs.

c. Repayment questions may involve more judgment calls because CMS guidance does not always address the specific repayment issues.

d. Frequently, contacting the applicable carrier/intermediary will either confirm your research or identify carrier/intermediary repayment process preferences.

e. Whether a provider supplier has a Corporate Integrity Agreement or Certification of Compliance agreement in place can affect repayment decisions, particularly as regards the process and format.
f. A repayment obligation could also lead to reporting to the OIG.

III. MEDICARE AND MEDICAID RESEARCHING TIPS

A. **Understanding the Issue.**

1. Ask questions and then more questions. Issues are often more complex than they first appear.

2. Understanding the scope of the issue before starting the research lessens the need for further research later.

3. Think about the policy reasons and try to come up with possible answers before starting the research.

B. **Recognizing the Importance of Background Research.**

1. Background research provides a frame of reference to answer the question.

2. Understanding the regulatory framework is necessary to determine the scope of the question.

3. After researching an area several times, background research can be less extensive and mainly will involve checking on recent developments.

C. **Understanding How Items or Services are Billed to the Programs.**

1. There are different coverage and payment rules depending on the provider/supplier of services.

2. **Understanding how and where the items or services are furnished can eliminate unnecessary research.**

D. **Knowing What Sources Need to be Reviewed.**

1. **Understand CMS Manuals.**

   a. Reduce research time by understanding what is covered in CMS (or Medicaid) program manuals.

   b. Check on searches by going directly to the relevant manual provisions.

   **Key Practical Tip**: If you do not know the relevant manual section, one suggestion is to use a commercial search engine (i.e., CCH). Then, once you identify the manual, chapter and section, use the CMS site as it allows you to view the entire chapter in the manual, both on the index and scrolling from one section to another (as does CCH).
2. **Review index tables.**
   
   a. Reviewing index tables is an excellent way to gain familiarity with statutes, regulations and manuals. Also, transmittals identifying recent manual revisions may be included with indexes.
   
   b. Check other citations around relevant documents that you find to understand the genesis for the document and find other relevant provisions, such as definitional sections.

   **Key Practical Tip:** Reviewing the entire manual or regulatory chapter containing a relevant section can often prevent erroneous research results or can clarify a relevant section.

   **Key Practical Tip:** An alternative way to search the CMS website is to use “Google.com,” and its “Advanced Search” and type in “CMS.hhs.gov.” The advantage is that you may then search an individual Internet-Only Manual (not a capability using the CMS website only) and Google’s search box is larger.

   **Key Practical Tip:** Using the “Health Law” tab in Westlaw links you to numerous health law databases that may offer search ideas.

3. **Make a research plan.**
   
   a. Identify the question(s).
   
   b. Identify what information needs to be reviewed.
   
   c. Update the plan with additional information that is reviewed and follow-up questions.
   
   d. Using a research checklist is helpful in guiding your research and memorializing your efforts.

4. **Tip for Research in Medicare Regulation.**
   
   a. If you know the citation, go to National Archives and Record Administration site (http://www.access.gpo.gov/nara/cfr/cfr-table-search.html), scroll to chart at bottom of page, to Title 42 and review indices. This technique allows you to review all subjects
covered by a Part or Subpart and may reveal a related issue covered by a different regulations.

- The National Archives site allows for comparison of different versions of the regulation going back to October 1996.

b. In searching regulations, review the Federal Register citations at the end of the regulation and pull the relevant Federal Register to review preamble materials (http://www.gpoaccess.gov/fr/index.html). “Browse the Table of Contents” allows review of back issues to 1998.

c. If regulation citation is unknown, use CCH (or comparable commercial database) search engine that may be more user-friendly.

*Key Practical Tip:* If searching on National Archives site or in hardcover C.F.R., remember that the C.F.R. is revised on October 1 annually. To identify updated regulations issued in rules effective since October 1 in a federal fiscal year, check Federal Registers issued since the C.F.R. update or a commercial database to check for revised regulations.

5. **Tip for Payment Issue Research in Federal Register Preambles.**


*Key Practical Tip:* Once the payment rule is identified, click on the PDF file which will be in the Federal Register format. You may then perform a key word search using the “Find” mechanism to identify the preamble section. Depending upon the particular provider/supplier category, the preamble generally contains critical information including contacts at CMS Baltimore, background information including frequently entire statutory and regulatory history and, with regard to particularly large rules such as the inpatient prospective payment rule or outpatient prospective payment rule, a Table of Contents listing the section headings for the entire rule. The Table of Contents gives a good overview of the topics discussed and assists in locating the topics in your search. Also, for newer health lawyers, many of the final payment rules include a List of Acronyms, helpful in understanding the payment rule.

*Key Practical Tip:* If you know a regulation has issued recently, use CCH and click on “Federal Register Issuances” on the “Health Care Reimbursement” Main Menu page for a reverse chronological listing of issuances sorted by “Adopted,” “Proposed” and “Notices.”
Key Practical Tip: To make sure that you have not missed any Federal Registers or clarifications or correction notices, use the “What’s New” link under “Quarterly Provider Updates” link on the CMS Manuals page (http://www.cms.hhs.gov/QuarterlyProviderUpdates/03_WhatsNew.asp.) or, sign up for the CMS-QPU listserv on the “What’s New” page and always be abreast of new regulations and instructions that are released.

E. Using Source Materials.

1. Using different sources.
   a. Much of the primary source material is available in multiple locations in hardcover materials or online through CMS, CCH and Lexis/Westlaw.
   b. Search different sources to find your preferred source.
   c. Identify the relevant manual(s) for the applicable type of provider/supplier or research issue. Until you are very familiar with the CMS manuals, it is helpful to search one manual at a time. This is because it is often difficult when researching electronically to determine the source of found documents. Also, researching one manual at a time allows you to learn about the contents of different manuals.

2. Using search tools.
   a. Get to know the limitations of the different sources.
   b. Always search on more than one source when researching and then check index tables.

Key Practical Tip: If you are new to Medicare research, searching first on a commercial database e.g., CCH) is most helpful. Also, searching each specific category separately (i.e., statutes/regulations, manuals, cases, Federal Register, etc.), rather than searching a broad number of categories, is less confusing.

Key Practical Tip: Searching state regulations on CCH (and perhaps on other commercial databases) saves time because all the regulations are in one place.

Key Practical Tip: If you are searching for a particular piece of legislation, click on “Laws and Regulations,” then “Federal Legislation” for a reverse chronological listing, some of which include committee reports.
F. Searching for the Missing Piece.

1. Stick to your plan.
   a. The most difficult type of research is trying to locate a rule that does not exist.
   b. Go through the research plan and check each type of information identified on the plan.

2. Know when to stop.
   a. After you have completed reviewing the materials identified on the research plan, consider any additional materials and review those materials.
   b. After reviewing any additional materials and index tables, stop researching and talk to a colleague.

G. Getting the Quick Answer.

1. Which source to review.
   a. Background materials such as CMS and CCH explanations, CMS Frequently Asked Questions (https://questions.cms.hhs.gov/cgi-bin/cmshhs.cfg/php/enduser/std_alp.php?p_sid=JSPa59rj), and AHLA materials often contain answers to questions.
   b. Go to the statute, regulation and manual provisions first.
   c. Check for recent changes in the Federal Register and CMS transmittals.

2. Qualifying your answer.
   a. Note the specific issue you research and any issues that you did not address, as well as the materials you did review and those that you did not review.
   b. Try to complete your research.
   c. Updating research.
      (1) Check statutes or regulatory history for any noted changes.
      (2) Check Federal Register and CMS transmittals or Recurring Update Notifications.
(3) Check CMS “internet only” manuals and paper manuals that are still in effect.

(4) Check CMS One-Time Notifications or carrier/intermediary bulletins.

(5) Check OIG website and case law.

(6) Run searches with date restrictions.

**H. Interpreting the Research.**

1. **Dealing with conflicting information.**
   a. Research results can be conflicting. Try to determine the source of the conflict such as older provisions or a different audience.
   b. Be aware from a legal standpoint. Conflicts between regulations and manuals can implicate the Administrative Procedure Act (5 U.S.C. Subchapter II), while conflicts between state and federal law can implicate the Supremacy Clause of the U.S. Constitution.

2. **Talking and thinking it through.**
   a. Review your research with someone else.
   b. Write out the conflict so it is understood.
   c. Contact a regulator to discuss the conflict.

**I. Researching Historical Issues.**

1. **Finding the accurate sources for background and primary sources materials.**
   a. Internet materials often do not contain archives of historical data.
   b. CD-Rom material may be difficult to save and retrieve.
   c. Use statutory and regulatory histories, Federal Registers and CMS transmittals and Recurring Update Notices to understand historical issues.
   d. If possible, consider archiving paper-based materials electronically to your document retention system, or printing and saving important internet materials in subject files.
2. Freedom of Information Act (FOIA) requests.
   a. As internet materials become more popular, agencies and providers may change their practices regarding retaining hardcopy material.
   b. FOIA requests can be time consuming, but are often useful. See, http://www.hhs.gov/foia/ for instructions for making FOIA requests to the Department of Health and Human Services.

J. Confirming Research with Regulators.

1. Knowing which agency to contact.
   a. Use past experience and recommendations.
   b. Locate CMS and other agency contact lists. For example, the Department of Health and Human Services employee directory at http://directory.psc.gov/employee.htm and the CMS Regional Office directory at http://www.cms.hhs.gov/RegionalOffices. In addition, CMS Federal Register preambles typically list contact persons responsible for questions on particular aspects of the a regulation.
   c. Do not contact agency personnel without client or partner approval. Some issues should not be disclosed without the client having prior knowledge.

2. Finding a person to answer the question.
   a. If contacting CMS or contractor personnel, ask who knows the area or issue.
   b. If the person does not seem to know, then move on.
   c. Network with other payment attorneys at AHLA meetings. Use (but do not abuse) those contacts to discuss issues.

3. Obtaining confirmation of the answer.
   a. When using email to ask a question, instant confirmation can be obtained. The downside is that the question needs to be framed correctly at the beginning of inquiry.
   b. Although asking for a letter is a good practice, regulators are often reluctant to provide letters. An email response may be equally as good.
c. Write confirmatory letters with or without signature requests. Here, the issue can be framed correctly, but the downside is the regulator can disagree with the summary. Obtain a confirmatory signature from the regulator whenever possible.

4. Reliance on Regulator Provided Information.
   a. Oral discussions with regulators are useful, but do not provide protection from changes in interpretation. Having the advice in writing is always better. At a minimum, write a memo to the file or keep a log.
   b. Interpretations by regulators may change in the future. If the rules change, the provider/supplier will be deemed to know of the changes.

K. Keeping Knowledge Current.
      a. Current maintenance of knowledge helps focus on the right issue.
      b. The scope of a question and the possible answers become easier to find with greater background knowledge.
      c. Less background research is necessary.
      d. Red herring issues are eliminated quickly.
      e. Searches can be broader and materials can be reviewed more quickly leading to more effective searching.
      f. Current knowledge facilitates accomplishing research with less effort.
   2. Assistance in identifying risk areas.
      a. Areas where rules are changing can signal next important compliance issue.
      b. Where one provider/supplier has had a problem, others probably have the same or similar problems.
   3. Tools for “Keeping Knowledge Current”.
Law; “Of Note” and “Latest Health Law Documents” at http://www.healthlawyers.org, click on “News Center”.

b. CMS’ “Medlearn Matters” at www.cms.hhs.gov/medlearn/matters contains information for Medicare providers designed to help providers understand new or changed Medicare policy.

c. CCH Online Medicare and Medicaid Guide Daily Document Update or “What’s New.”

d. *BNA Health Law Daily and Medicare Report* (weekly and internet)

e. *Part B News* (www.partbnews.com/)

f. *Medicare Compliance Alert*  
(www.decisionhealth.com/Facilities/compliance.aspx)

g. Websites with expansive links:

(1) www.megalaw.com/top/health.php

(2) www.healthlawyers.org, click on “News Center” or “Health Law Resources” then “Health Law Web Sites”
Exhibit A - Form

PLAN FOR REGULATORY RESEARCH

Attorney: ___________________________ Date: _____________
Client No.: _________________________

1. **Preliminary Inquiry.**

   Health care insurance program: Medicare, Medicaid, TriCare, commercial insurance _________________________________

   Type of Research Project:
   - Coverage, patient eligibility, licensure/certification, enrollment/participation, reimbursement/payment or repayment issue: __________________
   - Medicare/Medicaid/Other: _________________________________

   Type of Provider/Supplier: _________________________________

   Payment Methodology: PPS/Fee-for-Service/Cost Based/Other: __________________

   Contacts To Be Used:
   - Local Carrier/Intermediary/MAC: __________________________
   - CMS Regional Office/Baltimore Contact: ____________________
   - State Agency(ies): _______________________________________

   Context of research project:
   - Compliance: ________________________________
   - Corporate transaction: ________________________________
   - Reimbursement planning: ________________________________
   - Government investigation: ________________________________
   - Health care litigation: _________________________________

2. **Background Materials (check if reviewed and identify resource).**

   ____ AHLA program materials: ______________________________

   ____ AHLA Health Law Weekly or Health Law Digest: ____________
3. Primary Source Information.

- Statutes:
- Legislative History:
- CMS Regulations:
- Medicaid Regulations/Manuals:
- OIG Regulations:
- Federal Register Issuances:
- CMS Materials:
  - Manuals:
  - Paper-based Manuals:
  - Internet-only Manuals:
  - CMS Program Memoranda/Transmittals/OTNs/RUNs:
- CMS Forms:
- Other CMS Issuances:
- PRRB/DAB Decisions/Other Administrative Decisions:
- Federal/State Cases:
- Local Carrier/Intermediary/MAC Issuances:
- OIG Issuances:
- The Joint Commission/Other Accreditation Organization Manuals:
New Websites Identified.

Website Name/URL ________________________________

Website Name/URL ________________________________

Website Name/URL ________________________________

4. Thoughts for Continued Monitoring.

________________________________________________________________________

________________________________________________________________________