CV ATTACHMENT 1 - Healthcare Transactions and Processes
to Support Claims, Care Coordination, and Financial Value of Care

Health Care Processes – Health Plans

- **Value-Based Care Reporting** for **Medicare Part C** and **Medicare Shared Savings Plan Accountable Care Organizations,** including: HEDIS, MSSP 33 measures, HCC coding, risk adjustment, risk corridors, RADV and RAC audits, and compliance platforms.
- **EOB (Explanation of Benefits)** — Advised health plans on the revisions in EOBs that must be made to comply with new laws and regulations, such as ICD-10.
- **Actuarial & Underwriting** — Mr. Arrigo and his team advised health plans on shifts in coverage determinations and medical policy based on the Affordable Care Act, ICD-10, CORE Operating rules, and other regulations.
- **Coverage determination** planning and policy, and IT systems supporting new regulations (including CMS Local Coverage Determinations and National Coverage Determinations). Advised health plans and providers.
- **Claims processing metrics** — Pass-through rates, manual vs. electronic claims adjudication, and **Utilization Management (UM) rates**.
- **Payor — provider contracting** — Mr. Arrigo leads a team that has over **30 years of health care provider and health insurance contract negotiation experience for hospitals, clinics, and diagnostic services providers.** Mr. Arrigo and his team advised 18 hospitals and clinics, four medical device and pharmaceutical firms, two healthcare IT firms, two insurance firms, and CMS in all 50 States on new regulatory impacts. Over time, he and his team have advised on over 2,000 contracts.

Health Care Processes and IT — Hospitals, Clinics, Physicians, and Other Providers

- Readmissions metrics
- Clinical documentation, coding, and claims reimbursement
- Admission and discharge processes and metrics
- Revenue cycle management and metrics (DNFB – discharged not final billed, etc.)

CV ATTACHMENT 2 - Private Payor, ACO, IDN, Medicare (Part A, B, C, D), Health IT Experience

Additional Experience with Providers by Place of Service

Evaluated medical billing and coding for the following types of providers:

Place of Service Code(s)	Place of Service Name
1	Pharmacy
2	Telehealth
3	School
11	Office
12	Home
13	Assisted Living Facility
14	Group Home *
15	Mobile Unit
17	Walk-in Retail Health Clinic
18	Place of Employment-
20	Urgent Care Facility
21	Inpatient Hospital
23	Emergency Room – Hospital
24	Ambulatory Surgical Center
26	Military Treatment Facility
31	Skilled Nursing Facility
32	Nursing Facility
33	Custodial Care Facility
34	Hospice
41	Ambulance - Land
42	Ambulance – Air or Water
50	Federally Qualified Health Center
51	Inpatient Psychiatric Facility
52	Psychiatric Facility-Partial Hospitalization
53	Community Mental Health Center
55	Residential Substance Abuse Treatment Facility
56	Psychiatric Residential Treatment Center
57	Non-residential Substance Abuse Treatment Facility
61	Comprehensive Inpatient Rehabilitation Facility
62	Comprehensive Outpatient Rehabilitation Facility
65	End-Stage Renal Disease Treatment Facility
72	Rural Health Clinic
81	Independent Laboratory

Over ten **Value-Based Care Organizations** (**Accountable Care Organizations or ACOs)** and **Medicare Advantage/Part C** Plans, including Essence Health Plan St. Louis, United Healthcare, and Preferred Care Partners.

CV ATTACHMENT 3 - Investor Transactions and Diligence

Investor	Target Company	Enterprise Value ($millions)
Confidential PE fund	Provided opinions re: coding for diagnostic medical devices and their FDA approval process relating to Independent Diagnostic Testing Facility (IDTF). Opinion re: Fair Market Value (FMV) of medical directors; risk assessment of professional component (PC), and technical component (TC) for EEG and EKGs.	Over $500 million
Confidential PE fund	Advised regarding Medicare Secondary Payor healthcare data, regs incl. Section 111 Medicare, Medicaid, SCHIP Extension Act of 2007 (MMSEA) re: liability insurer	$2.0 billion +
Confidential $4 billion PE fund, New York	Ability Networks (leading Medicare claims technology infrastructure).	$550
Confidential $4 billion PE fund, New York	Health Port, an electronic release of HIPAA information service provider.	$120
PE fund, confidential, West Coast	Confidential ePCR (electronic patient care record) EMS (emergency management system) platform.	Confidential
$300 million specialty PE fund, New York	Orange Health (now Citra Health) (Value-based care for ACOs, MA plans).	$25
$300 million specialty PE fund, New York	MZI, a healthcare claims processing software vendor.	$25
Kleiner Perkins Caufield & Byers, Menlo Park, CA	Lumeris, an Essence Global Holdings Co. (Value-based care for ACOs, MA plans).	$600
Large Private Equity firm, London	Covisint, a spin-off of Compuware (cloud user access management).	$450
U.S. Private Equity firm, San Francisco, CA	Evaluation of diabetic population insulin initiation and titration mobile technology for glycemic control compared with standard clinical practices.	TBD

U.S. Private Equity firm	Drug formulary business, impact of specialty reimbursement in endocrinology, hematology, dermatology, and new drug discoveries	Confidential
Public Debt Investor	Top 10 E.H.R. software co. debt offering.	Confidential
Confidential	Confidential healthcare analytics co.	$280
Confidential	Confidential hospital revenue cycle management (RCM) business.	$190
Confidential	Confidential Electronic Data Interchange claims co. health insurance.	$150
Confidential	Genetic Testing and Precision Medicine.	$300
Confidential	Health system with multi-site hospital, physician group, clinic diagnostic imaging.	$1,000
Confidential	Health IT solutions: Drug Dispensary automation for oral and Intravenous Anti-Emetic Drugs for Chemotherapy Chemotherapeutic Regimen.	Confidential
Confidential	Pharmacy Benefit Management (PBM) business.	$600
Intel/Symantec	Advised regarding intellectual property licensing for security software, electronic distribution, derivative works, patent licensing	Confidential
Oracle/CNN Interactive	Advised regarding new joint venture, content management solutions, and patents licensing.	Confidential
Leading Korean-based mobile technology and telephone electronics firm	Advised regarding intellectual property licensing for healthcare IT solutions in the mobile market, security solutions including block chain, patient engagement modules; evaluation of patent portfolio.	$300
Confidential	Independent Diagnostic Testing Facility (IDTF) that provides EEG and EKG services	$250
	Total Enterprise Value ($millions)	**$8.0 Billion +**

CV ATTACHMENT 4 - Affordable Care Act, Medicaid, Social Security, Insurance Exchange, Benefits Determination (1 of 2)

Experience with regulations, technology, and requirements for systems supporting 15 State HHS Medicaid insurance Exchange eligibility systems including these business requirements, which in turn provide State-by-State eligibility for Affordable Care Act insurance mandates:

Information Architecture:

The Medicaid Information Technology Architecture (MITA) initiative, sponsored by the Center for Medicare and Medicaid Services (CMS), is intended to foster integrated business and IT transformation across the Medicaid enterprise to improve the administration of the Medicaid program. Led engagements to extend and enhance Medicaid systems with enterprise software partners in several States prior to, during, and immediately after the MITA Architecture update to accommodate HIPAA 5010, ICD-10, the Affordable Care Act, HITECH Act, CHIPRA, and NCPDP standards.

Types of Exchanges and Enrollee Characteristics:

- Federal (HHS) Exchanges "Federally-Facilitated Marketplace" ("FFM") which are being used in States, such as: (FL, GA, NC, SC, VA, AL, MS, MO, AR, LA, OH, PA, IL, OK, MT, UT, ND, SD, NE) and provider contracting.
- State-Based Exchange ("SBEs") and State-by-State variances (CA, WA, ID, CO, KY, MN, NY, VT, RI, CT, MA, DE, MD, DC).
- State MMIS – Medicaid Management Information Systems, which provide some of the eligibility technology platform for the Exchanges.

Eligibility Process, Technology for State Health and Public Welfare

- Request for insurance, pre-existing conditions under Affordable Care Act
- Section 1619(b) of the Social Security Act re: Social Security beneficiaries, Medicaid eligibility.
- 42 CFR § 435.603 - Application of modified adjusted gross income (U.S. Citizenship, criminal and State Residency, household size and FPL % [see FPL])
- FPL percentage – percent of Federal Poverty Level as determinant of Medicaid eligibility, Out of Pocket Maximums (OOPM)
- TANF – Temporary Assistance to Needy Families (formerly AFDC)/The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (Public Law 104-193) and **TEFRA**
- SNAP – Supplemental Nutrition Assistance Program (formerly food stamps)
- Medicaid – free and low-cost healthcare to low-income families
- CHIP – Children's Health Insurance Program (Medicaid for kids)
- Women, Infants & Children (WIC) – nutritional supplement for pregnant women, infants, and children (until school age)

CV ATTACHMENT 4 - Affordable Care Act, Medicaid, Social Security, Insurance Exchange, Benefits Determination (2 of 2)

Jurisdiction	State Systems and Processes
Alaska	Eligibility Information System (EI)
Arizona	Arizona Technical Eligibility Computer System (AZTECS)
Georgia	SHINES, COMPASS, Vitale Events, Medicaid Data Broker
Hawaii	Hawaii Automated Welfare Information System (HAWI)
Kansas	Kansas Automated Eligibility & Child Support Enforcement System (KAECSES)
Louisiana	Medicaid Eligibility Data System (LA MEDS)
Massachusetts	Mass 21st Century Disability Policy (MA-21)
Minnesota	MAXIS – State, county eligibility for public assistance, healthcare; exchanges data with Medicaid Management Information System (MMIS), MN Employment and Economic Development, MN Dept. of Finance, and U.S. Social Security Administration
Mississippi	Mississippi Applications Verification Eligibility Reporting Information and Control System (MAVERICS)
Pennsylvania	COMPASS – healthcare, cash, long-term, home, supplemental nutrition (SNAP) eligibility
Rhode Island	INRhodes and UHIP data and functions for the Family Independence Program, Food Stamps, Child Support Enforcement, Medicaid Eligibility, Child Care, Public Assistance
South Carolina	Family Independence Financial System (FIFS)
Tennessee	TennCare and **SSI** (Supplemental Security Income Under Social Security Administration)
Vermont	ACCESS
Washington DC	Automated Client Eligibility Determination System (ACEDS)
Wyoming	EPICS (Eligibility Payment Information Computer System)

CV ATTACHMENT 5 - Meaningful Use of Electronic Health Records, Workflows, Physician Experience Optimization (1 of 3)

Leader of a team that has advised 50 electronic medical records vendors and healthcare providers regarding achieving software certification for Meaningful Use (MU) under the HITECH Act as well as MU implementations, attestations, and audit defense v. CMS, OIG, and CMS Auditors.
Six of the Top 10 Electronic Health Record Companies — Allscripts, Athenahealth, Cerner, Epic, McKesson, NextGen; assessed five mid-tier E.H.R. companies with respect to Meaningful Use, HIPAA, and Information Safeguards compliance.

Meaningful Use (**MU**) is composed of a complex list of objectives, including HIPAA privacy, Personal Health Information Safeguards, Clinical Quality Measures (**CQMs**), clinical decision support (**CDS**), transitions of care, data portability, auditable events, patient engagement, and other measures. Mr. Arrigo has opined as an Expert regarding MU and provided opinions and guidance on all of the following factors:

- Authorized Testing and Certifications Bodies (ATCBs) and processes.
- Eligible Hospital (EP) and Eligible Provider (EP) attestations and audit defense under Medicare and Medicaid in civil and criminal defense cases.
- Data quality check on numerators and denominators in live data vs. attestation reporting.
- Stimulus funds, OIG, and CMS auditors.
- HHS OCR, HIPAA breaches, State CMIA breaches, and stimulus eligibility.
- Modular and Complete E.H.R. certifications.
- Discrete data structures.
- HIPAA Privacy and Security Assessments as a Component of MU and the Administrative, Physical, and Technical Safeguards of HITECH Act as well as Operational Policies, Procedures and Documentation, and HIPAA overlapping requirements.
- Clinical workflow for both acute care and ambulatory E.H.R.s.
- Rollout Phases I, II of E.H.R. implementation in Emergency and Radiology departments.
- Medication dispensing modules.
- Standardized the implementation process and used as quality control while contracted to U.S. HHS/ONC to educate Regional Extension Centers providing national education and quality standards that were adopted by ONC.
- Standardized at the highest benchmarking level so that every implementation met the same criteria.

CV ATTACHMENT 5 - Meaningful Use of Electronic Health Records, Workflows, Physician Experience Optimization (2 of 3)

Leadership of Team with the Following Qualifications

- Served as co-chair of Critical Access Hospital boot camp for U.S. HHS for hospital E.H.R. implementations across the country
- Experience training the implementation process for Regional Extension Centers; co-chaired the committee that built the curriculum
- Served as E.H.R. advisors for the American Society of Oncologists, and American Gastro Institute standardized institute
- E.H.R. contract negotiation process Value Added Reseller (VAR) selection
- Hospital, Critical Access Hospital, Federally Qualified Health Centers, and Community Hospital (Medicare and Medicaid stimulus). Managed E.H.R. implementations teams and audits as follows:

LOCATION	MONTH/YEAR	ASSIGNMENT
Johnstown PA	2013 – 2014	ICD-10 Transition review of Allscripts, Epic systems for Duke LifePoint, / Conemaugh Health system and processes
Lane Regional Medical Center, Zachary, LA	Apr 13 –Sep 14	CPOE, RXM, E-Prescribe implementation for Magic 5.66 site. Built all PHA and RXM dictionaries including all Order Strings. Primary resource for system preparation and workflow recommendations.
Centura Englewood, CO	Oct 12 – Mar 13	CPOE building & support. NPR for OE, RXM, BAR PHA, dictionary scripting, CPOE workflow optimization through PHA and POM Rules programming, advanced query attributes, Order set maintenance, user support, rotating on call & task completion.
The Galway Clinic Galway, Ireland	Jul 12 –Aug 12	MEDITECH Magic Optimization. Pharmacy Assessment and recommendations. Remediation. NPR for MM, PHAMM, PHA)
St. Luke's Cornwall Newburg, NY	Apr 12 – Jun 12	Magic 5.66 RXM and CPOE assessment, recommendations, and remediation. Build support. Workflow assessment and recommendations. Med Reconciliation NPR (ADM, NUR, PHA)
USMD Healthcare Arlington, TX	Jan 10 - Mar 10	Pharmacy module training for new pharmacy director, Included MEDITECH, Pyxis, module integration, billing process reformat.
USMD Healthcare Arlington, TX	Jul 09 - Sep 09	Remote module support. Problem analysis / remediation. Dictionary work, NPR report writing for PHA, ADM, BAR, SCH, Rules
Community Memorial Hospital Ventura, CA	Jun 08 – Jan 09	Magic to Client Server Migration: (Magic version 5.5 to Client Server 5.64) Responsible for all aspects of pharmacy portion of the project. Extended to bring pharmacy to a higher level of MEDITECH utilization

Memorial Hospital Fredericksburg, TX	Nov 06 – Dec 06	Clinical Workflow Assessment - Workflow review and recommendations. Dictionary rebuild, MEDITECH Task completion, NPR Label reformat. EMAR/BMV project lead.
Holy Cross Hospital Taos, New Mexico	Oct 06 – Nov 06	PHA Workflow & Billing Assessment – Performed on-site dictionary and workflow review for PHA, BAR, AP, GL. Provided written assessment and recommendations for multidisciplinary problems; Remediation.
Sid Peterson Hospital Kerrville, Texas	May 06 –Sep 06	EMAR/BMV Installation - Project Manager
Freeman Hosp. Joliet, MO	Jan 06 – May 06	EMAR/BMV Installation - Created a "closed loop" pharmacy where every step0 11iv n the medication cycle is scanned. Project Manager with Nursing Analyst
Gilbert Regional Hospital Gilbert, Arizona	Nov 05 – Dec 05	Pharmacy Expansion: Assess and support pharmacy for the opening of an additional hospital for a corporation.
Chandler Regional Hospital Chandler, Arizona	Jun 05 – Nov 05	EMAR/BMV Install Pharmacy Analyst for multidisciplinary team. Build, testing, medication stock preparation. QA/Metric validation.
SIH Healthcare Carbondale, Illinois	Mar 05 – Jun 05	New MEDITECH Installation – Clinical module dictionary build, testing, training. go live support.
Mt. Diablo Hospital Walnut Creek, CA	May 04 – Oct 04	EMAR/BMV Installation - Assessment, preparation of Clinical dictionaries, bar coding pharmacy stock, project management. User go-live support. Forms and label
Methodist Hospital Dallas, Texas	Jan 05 – Feb 05	Pharmacy/Nursing Assessment: Clinical Workflow and Dictionaries. Recommendations and remediation.

- Advised U.S. Department of Justice regarding E.H.R., §495.6 Meaningful Use objectives and measures for EPs (physicians), eligible hospitals, and Critical Access Hospitals.
- Attestation processes, including compliance with:
    a. Computerized provider order entry (CPOE) for medication orders
    b. Drug-drug and drug-allergy interaction checks, adverse drug reactions (ADR), and: "The EP, EH, or CAH has enabled and implemented the functionality for drug-drug and drug-allergy interaction checks for the entire EHR reporting period."
    c. Maintain an up-to-date problem list of current and active diagnoses
    d. Generate and transmit permissible prescriptions electronically (eRx) and access to external formularies
    e. Medication information as structured data
    f. Maintain Active Medication allergy list

g. Patient demographics, vital signs, smoking status, quality measures, patient education, clinical decision support, syndromic surveillance, immunization records, and transitions of care

h. Patient access to records via web or mobile port

Past evaluations of electronic health record software for **Depart of Justice** and **private and public Electronic Health Record companies** have included complete workflow, physician experience, and efficiency evaluations, including:

1. Standard terminology,
2. History of Present Illness (HPI),
3. Constitution,
4. Relevance of Clinical Documentation (Meaningful Use requirements, support for evaluation and management or E&M coding, risk assessments, and HCC coding),
5. Usability Factors including usability study, a quantitative time study, and qualitative analysis of information-seeking behaviors. While being recorded with Morae Recorder software and "think-aloud" interview methods, 10 primary care physicians first searched their EHR for 10 diabetes data elements using a conventional approach for a simulated patient, and then using a new diabetes dashboard for another.
6. Change in total throughput for tasks v. prior method, number of mouse clicks to access, mean time to find data, Gaps, Priorities, and Workflow Scope design;
7. Best practices for:
    a. user dashboards,
    b. clinical desktops,
    c. face sheets,
    d. patient charts,
    e. checkout workflow;
    f. orders,
    g. progress notes,
    h. CMS guidelines,
    i. review of systems (types),
    j. business intelligence,
    k. clinical decision support workflows;
8. Team rehearsals for audits.
9. Team rehearsals for E.H.R. proctor evaluations for certification

Meaningful Use Stage 1:

Eligible professionals (physicians):

- 13 required core objectives
- 5 menu objectives from a list of 9
- Total of 18 objectives

Eligible hospitals and CAHs:

- 11 required core objectives
- 5 menu objectives from a list of 10
- Total of 16 objectives

Meaningful Use Stage 2:

Eligible professionals:

- 17 core objectives
- 3 menu objectives that they select from a total list of 6
- Total of 20 objectives

Eligible hospitals and CAHs:

- 16 core objectives
- 3 menu objectives that they select from a total list of 6
- Total of 19 objectives

CV ATTACHMENT 6 - Healthcare Business Transactions, Supporting HIPAA X12

45 CFR Part 162 Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA); Final Rules

Consulted to some of the largest self-insured employers in the U.S. with ERISA – Taft-Hartley Trust plans regarding the transition from HIPAA 4010 to HIPAA 5010, enabling new coding standards to be used in healthcare. These included revisions to these EDI transactions:

1. Health Care Eligibility Benefit Inquiry and Response – EDI 270/271
2. Health Care Claim Status Request/Response – EDI 276/277
3. Health Care Services Request for Review/Response (Prior Auth.) – EDI 278
4. Payroll deductions for premiums – EDI 820
5. Benefit enrollment and maintenance – EDI 834
6. Health Care Claim: Payment/Advice – EDI 835,
7. Health Care Claim: institutional, professional/dental –
    a. EDI 837, Pharmacy Claim (NCPDP),
    b. Coordination of Benefits (COB) and third-party liability,
    c. Fraud waste and abuse analytics and Special Investigative Unit (SIU).

Modifications to § 162.1102, § 162.1202, § 162.1302, § 162.1402, § 162.1502, § 162.1602, § 162.1702, and § 162.1802 to adopt the ASC X12 Technical Reports Type 3 (TR3), Version 005010 (Version 5010) reporting of clinical data, enabling the reporting of ICD–10–CM diagnosis codes and ICD–10–PCS procedure codes.

CV ATTACHMENT 7 - Revenue Cycle Management, Clinical Documentation and Coding Processes

Lead team that implements hospital system assessments for ICD-10 and CPT coding compliance and quality, including:

CDI (Clinical Documentation Improvement) strategy and alignment between HIM department, coders, nursing, and physicians. Benefits of coder-physician collaboration and securing results in improved coding. Engage case managers to focus on CDI trends, work with physicians that are the largest admitters. Understanding of key processes, including:

Patient intake
Patient assessment
Documentation of care
Insurance coverage determination
Discharge activities
Provider communications
Referrals
Prior authorizations
Coding
Charge capture, super bills
Billing
Revenue collection
Vendor impacts
EHR and other system readiness to support clinical documentation improvement
IT plans
Impact on concurrent initiatives
Reporting
Quality improvement efforts
Payor readiness and processes; medical policy assumptions for contracting
Institutional Review Board (IRB) impact review for ICD-10
Data warehouse and business intelligence "retooling" of analytics required
National Correct Coding Initiative (NCCI), Modifiers, Bundling and Unbundling Criteria According to Centers for Medicare and Medicaid

CV ATTACHMENT 8 – Drug Pricing Practices Using Analytics to identify - UCR (Fair Market Value) in Pharmaceutical Pricing

- Re-Defining AWP
- % Factor
- NDC price reporting
- Mark-Ups & Price Spreads
- Backroom Processor Schemes
- Rebate Schemes
- Flat, Access, Market Share
- Rebates
- "Brand" and "Generic"
- Formulary Steering
- Pre-Authorization Schemes
- Clinical Rules & Protocols
- Mail-Order
- Leveraging Captive Facility
- Multiple MAC Lists
- Drug Switching
- Drug Repackaging
- Fraudulent Plan Design
- Zero Cost Scripts
- Higher Than Logic
- Pocketing Refunds, Reversals, and Returns
- Payor Account Crediting
- Specialty Drug Issue

. Published author on drug classifications such as RxNorm, National Drug Codes (NDC), and Generic Drug Identifiers (GDI).

Lead team that assesses and advises regarding industry best practices and implementation of HIPAA Privacy and Security as well as HITECH Act, including:

Security best practices for HIPAA Covered Entities

HHS Security Standards:

1. **Administrative** Safeguards
2. **Physical** Safeguards
3. **Technical** Safeguards
4. **Organizational Policies and Procedures** and Documentation Requirements

Opinions, regarding but not limited to:

- "Breach" under the Privacy Rule, including but not limited to 45 C.F.R. § 164.402.
- "Business Associate" under the Privacy Rule, including but not limited to 45 C.F.R. § 160.103.
- "Covered Entity" under the Privacy Rule, including but not limited to 45 C.F.R. § 160.103.
- "Designated Record Set" under the Privacy Rule, including but not limited to 45 C.F.R. § 164.501.
- "Disclosure" under the Privacy Rule, including but not limited to 45 C.F.R. § 160.103.
- "Electronic Protected Health Information" or "ePHI" under the Privacy Rule, including but not limited to 45 C.F.R. § 160.103.
- "Individual" under the Privacy Rule, including but not limited to 45 C.F.R. § 160.103.
- "Minimum Necessary" under the Privacy Rule, including but not limited to 45 C.F.R. §§ 164.502(b) and 164.514(d).
- "Privacy Rule" Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Part 160 and Part 164, Subparts A and E.
- "Protected Health Information" or "PHI" in 45 C.F.R. §§ 160.103 and 164.501, and is the information created or received by BA.
- "Required by Law" in 45 C.F.R. § 164.103.
- "Security Incident" shall have the meaning given to such term under the Security Rule, including but not limited to 45 C.F.R. § 164.304.
- "Security Rule" 45 C.F.R. Part 160 and Part 164, Subparts A and C.
- "Subcontractor" under the Privacy Rule, including but not limited to 45 C.F.R. § 160.103.
- "Unsecured Protected Health Information or PHI" under the Privacy Rule, including but not limited to 45 C.F.R. § 164.402.
- "Use" under the Privacy Rule, including but not limited to 45 C.F.R. § 160.103.

Section 10501(i)(3)(B) of the Affordable Care Act

Rural Health Clinics Act (P.L. 95-210)

- Use of grants under TRICARE program under chapter 55 of title 10, United States Code for administrative programs.
- All-Inclusive Rate Reimbursement (**AIRR**), FQHC cost reports (CMS-222-92 and FQHC14 **Cost Report** Data, Prospective Payment System (**PPS**).
- CMS 222 financial reports for RHCs and FQHCs and basis for reports supported by clinical documentation and medical coding.
- Baseline Practitioner Productivity Standards.
- Historical perspective regarding Benefits Improvement and Protection Act of 2000 (BIPA) and State Medicaid program reimbursement RHCs. (In lieu of cost-based reimbursement, Medicaid shifted RHCs to a PPS methodology.)
- Industry best practices and guidelines and compliance to U.S. HHS/Health Resources and Services (HRSA) standards, including:

		STATUTE
1.	Needs Assessment	(Section 330(k)(2) of the PHS Act) (Section 330(k)(3)(J) of the PHS Act)
2.	Required and Additional Services	(Section 330(a) of the PHS Act) (Section 330(h)(2) of the PHS Act)
3.	Staffing Requirement	(Section 330(a)(1), (b)(1)-(2), (k)(3)(C), and (k)(3)(I) of the PHS Act)
4.	Accessible Hours of Operation/Locations	(Section 330(k)(3)(A) of the PHS Act)
5.	After Hours Coverage	(Section 330(k)(3)(A) of the PHS Act and 42 CFR Part 51c.102(h)(4))
6.	Hospital Admitting Privileges and Continuum of Care	(Section 330(k)(3)(L) of the PHS Act)
7.	Sliding Fee Discounts	(Section 330(k)(3)(G) of the PHS Act, 42 CFR Part 51c.303(f)), and 42 CFR Part 51c.303(u))
8.	Quality Improvement/Assurance Plan	(Section 330(k)(3)(C) of the PHS Act, 45 CFR Part 74.25 (c)(2), (3) and 42 CFR Part 51c.303(c)(1-2))

9.	Key Management Staff	(Section 330(k)(3)(I) of the PHS Act, 42 CFR Part 51c.303(p), and 45 CFR Part 74.25(c)(2),(3))
10.	Contractual/Affiliation Agreements	(Section 330(k)(3)(I)(ii), 42 CFR Part 51c.303(n), (t), Section 1861(aa)(4) and Section 1905(l)(2)(B) of the Social Security Act, and 45 CFR Part 74.1(a) (2))
11.	Collaborative Relationships	(Section 330(k)(3)(B) of the PHS Act and 42 CFR Part 51c.303(n))
12.	Financial Management and Control Policies	(Section 330(k)(3)(D), Section 330(q) of the PHS Act and 45 CFR Parts 74.14, 74.21, and 74.26)
13.	Billing and Collections	(Section 330(k)(3)(F) and (G) of the PHS Act)
14.	Budget	(Section 330(k)(3)(D), Section 330(k)(3)(I)(i), and 45 CFR Part 74.25)
15.	Program Data Reporting Systems	(Section 330(k)(3)(I)(ii) of the PHS Act)
16.	Scope of Project	(45 CFR Part 74.25)
17.	Board Authority	(Section 330(k)(3)(H) of the PHS Act and 42 CFR Part 51c.304)
18.	Board Composition	Subsection (g), (h), (i), or (p). (Section 330(k)(3)(H) of the PHS Act and 42 CFR Part 51c.304)
19.	Conflict of Interest Policy	(45 CFR Part 74.42 and 42 CFR Part 51c.304(b)).

1. National Correct Coding (NCCI) claims edits, September 2012.
2. Ambulance billing and trauma activation; State, Federal CDC trauma criteria, September 2012. NAAC **Certified Ambulance Documentation Specialist (CADS)** May 2018.
3. Home health agencies HHRGs, OASIS episodes of care, November 2012.
4. Behavioral health, November 2013.[2]
5. Cardiology, November 2013.
6. Family practice and internal medicine, November 2013.
7. Obstetrics, November 2013.
8. Oncology, November 2013.
9. Urology, November 2013.
10. Orthopedics, November 2013.
11. General Surgery, and Dental, November 2013.
12. Plastic Surgery, November 2013.
13. HCC, risk adjustment, November 2013.[3]
14. DRG calculations, ICD-10, IPPS, OPPS payment systems, November 2013.[4]
15. Diagnostic Imaging & Nuclear Medicine (PET-Scans), September 2014.[5]
16. Medical Auditing, including focus on anesthesiology, pathology, evaluation management, radiology, chemotherapy, psychotherapy, physical therapy, modifiers, and medical necessity. November 2015.[6]
17. Dermatopathology diagnosis relevant to medical specialty, 2016.
18. Dietetics and Nephrology, insulin DME billing for diabetes, December 2015, AHIMA.
19. Liens, balance billing, subrogation seminar, 2014.
20. Affordable Care Act "metal" plans, Medicaid expansion, Federal Poverty Level guidelines on cost of care, 2014.
21. Coding and reimbursement for Pain Management, December 2015; outpatient physical, occupational, and speech therapy, ambulance and non-emergency transportation, January 2016.[7]

22. Valuing episodes of Care: a) episodic, b) bundled payments, c) value-based payment/risk adjustments, d) episode groupers, methodologies, e) PBM/pharmacy charges, f) costs associated with complications, g) prospective, retrospective, and predictive modeling; h) claims adjudication in episodic processes, ACOs, MAOs, fiscal intermediaries, PROMETHIUS analytics payment model for risk adjustment, comorbid factors and cohorts, and data required to produce episodic care analysis; June 2016.[8]

23. HIPAA Privacy and Security test certification, HIPAATraining.com; June 2017.

24. Pain and the Reward Pathway: Preclinical Studies on the Impact of Pain on Opioid-Seeking Behavior, American Academy for Pain Medicine (AAPM) presented by Catherine Cahill PhD, Jose Moron-Concepcion PhD, Truan Trang PhD.

25. Urology and toxicology screening guidelines training, In-Office Urine Drug Testing: Avoid Investigations and Audits, January 23, 2018.[9]

26. Certified Professional Coder curriculum, 10,000 Series Integumentary[10] System, February 25, 2018.[11]

27. Non-covered services and Advance Beneficiary Notices, GA, GZ, GX, GY modifier (not reasonable and necessary where ABN is issued or statutorily excluded), February 28, 2018.[12]

28. Certified Professional Coder curriculum, Endocrine System and Nervous System, June 2018

CV ATTACHMENT 12 - Medical/Laboratory Test Fees

Economic value and medical necessity (based on the diagnosis of a licensed medical professional or retained medical expert provided to me as a precursor to rendering my opinion) as determined in payor medical policies and coverage determinations for medical laboratory tests that can be used to detect, diagnose, or monitor diseases, disease processes, and susceptibility to disease or predisposition based on genetics. Areas of expertise include:

1. Diagnosis (associated diagnosis codes are an important indicator of medical necessity as determined in payor medical policies and coverage determinations) and billing codes including:
    a. ICD-10-CM which is U.S. standard from October 1, 2015 forward
    b. ICD-9-CM – for dates of service prior to October 1, 2015
    c. CPT – for outpatient procedures (for example, 8500 - Blood count; blood smear, microscopic examination with manual differential WBC count)
    d. NCCI – National Correct Coding Initiative to verify whether bundled procedures and other factors are acceptable
2. Overview of the test
3. Utility - when/why/how the test is used
4. Diseases that the test is often used to detect or monitor, as this pertains to coding and billing and economic value of the test in a specific geographic market or based on national standards, as well as:
    a. Specimen collection methods/procedures (for example, whole blood collection)
    b. Testing methodology (for example, hematology)
    c. Usual turnaround time (for example, days elapsed time)
    d. Reference ranges for test results (normal, abnormal, male/female values, etc.)
    e. Additional or related tests

NOTE: Interpretation of tests is performed by a licensed medical professional, and if that interpretation is provided to me in patient medical record(s), it may be useful in opinions regarding payor determinations or economic value. I do not give medical opinions.

CV ATTACHMENT 13 - Ambulance, Trauma Activation Fees, Anesthesiology

Industry best practices and guidelines for determining economic value and medical necessity (which may be based on the diagnosis of a licensed medical professional or retained medical expert provided to me as a precursor to rendering my opinion) as determined in payor medical policies and coverage determinations.

Ambulance Fees

1. NAAC Certified Ambulance Documentation Specialist (CADS) May 2018
2. Documentation of patient's condition in Physician Certification Statement (PCS), Patient Care Report (PCR). Familiar with various documentation standards including SOAP, DRAATT medically indicated/contraindicated based on coverage determinations, and Medical Necessity as determined by CMS
3. Emergency, basic life support, scheduled transportation for End Stage Renal Disease (ESRD) patients, criteria and Local Coverage Determination (LCD) guidance regarding ambulatory status and clinical diagnosis criteria for covered and non-covered ambulance services
4. Transportation to or from one hospital or medical facility to another hospital or medical facility, skilled nursing facility, or free-standing dialysis center in order to obtain medically necessary diagnostic or therapeutic services

Trauma Activation Fees

- CDC Guidelines for Field Triage of Injured Patients: Recommendations of the National Expert Panel on Field Triage
- County and Provider standards for Triage and documentation for Trauma Activation

Anesthesiology Fees

1. **Time unit** intervals, or fraction thereof, starting from the time the physician begins to prepare the patient for induction and ending when the patient may safely be placed under post-operative supervision and the physician is no longer in personal attendance. Actual time units will be paid and are not to be rounded.
2. **Base Units** and their values are described by industry regulatory and standards bodies.
3. **Anesthesia Conversion Factors** for geographic adjustments.
4. CMS Supervision Rules for Nurse Anesthetists ((1) A qualified anesthesiologist; or (2) A physician qualified to administer anesthesia, a certified registered nurse anesthetist (CRNA) or an anesthesiologist's assistant as defined in § 410.69(b))

CV ATTACHMENT 14 –Safety Policies for Healthcare Providers - Certification Review Processes Guidelines and Joint Commission Best Practices:

Health Care Medication Management, Drug Interaction Best Practices Materials and Staffing Services Certification, Personnel File Review, Risk Management Joint Commission Standards [2] which are designed in part to avoid Sentinel Events[3]:

1. Development and approval of criteria for selecting medications, which, at a minimum, include the following: Indications for use, effectiveness, drug interactions, potential for errors and abuse, adverse drug events, and sentinel event advisories
2. Supply chain of critical supplies and medical technology; supplier integrity
3. Current licensure, certification, or registration required by the State, the firm, or customer from primary sources
4. Education and training associated with residency or advanced practice, experience, and competency appropriate for assigned responsibilities
5. Clinical work history/references
6. Initial and ongoing evaluation of competency
7. Information on criminal background per law, regulation, and customer requirements
8. Compliance with applicable health screening and immunization requirements established by the firm or customer
9. Information on sanctions or limitations against an individual's license is reviewed upon hire, and upon reactivation or expiration.
10. For individuals who are practicing as Licensed Independent Practitioners, in addition to the aforementioned requirements, the firm performs the following according to law, regulation, and firm policy: Voluntary and involuntary relinquishment of any license or registration is verified and documented
11. Voluntary and involuntary termination of *hospital* medical staff membership is verified and documented
12. Any evidence of an unusual pattern or an excessive number of professional liability actions resulting in a final judgment against the applicant is investigated and documented
13. Documentation that the staff person has received orientation from the organization

[2] For a health care organization to participate in and receive payment from the Medicare or Medicaid programs, it must meet the eligibility requirements for program participation—including a certification of compliance with the Conditions of Participation (CoPs) or Conditions for Coverage (CfCs), which are set forth in federal regulations. The certification is based on a survey conducted by a State agency on behalf of the Federal Government, the Centers for Medicare & Medicaid Services (CMS), or a national accrediting organization, such as The Joint Commission, that has been approved by CMS as having standards and a survey process that meets or exceeds Medicare's requirements. Health care organizations that achieve accreditation through a Joint Commission-deemed status survey are determined to meet or exceed Medicare and Medicaid requirements.

[3] A sentinel event is an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase "or the risk thereof" includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.

CV ATTACHMENT 15 - Medical Devices, Pharmaceutical 510(k) premarket submissions, Adverse Events

Medical Device Approvals for Specific Purpose, Embedded Systems Development and Testing for Market, Pharmacovigilance for FDA Adverse Event Reporting

I. 510(k) premarket submissions to FDA to demonstrate that device is to be marketed as safe and effective—that is, substantially equivalent to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to Premarket Approval (PMA):

II. Device predicates as it pertains to FDA approval for a specific purpose:

- intended use;
- technological characteristics vs. predicate;
- technological characteristics and the information submitted to FDA;
    - does not raise new questions of safety and effectiveness;
    - demonstrates that device is at least as safe, effective as predicate.

III. Audits of healthcare providers and claims with respect to approved devices matched to medically necessary procedures:

a. Frequencies and bandwidths applicable to cardiac and brain diagnostic monitoring (ECG, EKG, EEG) and applicable medical procedure codes
b. Independent Diagnostic Testing Facility form CMS-855B (device inventories)
c. CPT codes matched to devices, procedure billing timelines

IV. Performance Qualification (PQ), IQ (Installation Quality), Operational Qualification (OQ)

a. Led embedded systems software team
b. Coordinated regulatory affairs work, liaison regarding IQ/OQ/PQ validation process as provided for in 21 CFR part 11

V. Triage process for FDA Event Reporting System (FAERS) compliant complaint handing

a. Pharmaceuticals
b. Led implementation of a global pharmacovigilance complaint handing system

CV ATTACHMENT 16 – Pain Management Practices and Opioid Prescribing under Federal Controlled Substances Act and State Laws

Execution of provider, prescribing data, and payor audits for Controlled Substances Act compliance and pain management. Prior experience in both coding and billing disputes and DEA Diversion Control investigations of controlled substances providers.

1. Audit Protocol Development Methodology
2. Goals in Reviewing a Pain Management Practice
3. Physician Prescribing Analytics
4. Examine Prescribing Volume and Days of Supply per Patient
5. Diagnoses of population and medical necessity of opioids
6. Initial Patient Intake and Examination
7. Formulation of Treatment Plan
8. Pain Management Agreement
9. Re-Assessment
10. Objective Measures and Corrective Action
11. State PDMP Database Checks
12. Toxicology / Drug Screening
13. Titration / Weaning
14. Termination
15. PEG Screening Tool
16. Objective tools to describe pain levels in patients based on CDC and other standards
17. DOJ Diversion Control Division CSA Guidelines
18. Medical Necessity and the CSA
19. The Practitioners Manual, Section IV – Record Keeping
20. The Practitioners Manual, Section V – Valid Prescription Requirements
21. The Practitioners Manual, Section VI – Opioid Addiction Treatment Programs
22. State Treatment with Opioid Patient Agreement

CV Attachment 17 - Durable Medical Equipment, Prosthetics, Orthotics, Supplies (DMEPOS)

Generally familiar with 280 classifications of HCPS usual customary and reasonable charges, specifically:

1. Alarm Device
2. Ambulatory Traction Device
3. CPAP Device
4. Dynamic Flexion Devices
5. EMG Device
6. Foot Off Loading Device
7. Monitoring Feature/Device
8. Ocular Prosthetics
9. Oral Device to Reduce Airway Collapsibility
10. Orthopedic Devices
11. Pain Management
12. Passive Motion Exercise Device
13. Power Mobility Devices
14. Reaching/Grabbing Device
15. Repair of Prosthetic Device
16. Repair/Modification of Augmentative Communicative System or Device
17. Skin Piercing Device
18. Speech Generating Device
19. Standing Devices/Lifts
20. Stimulation Devices
21. TMJ Device and Supplies
22. Ventricular Assist Devices

CV Attachment 18- Patent Statutes, Sub Parts, Rules, Case Law, Scope of Work as Technical and Damages Expert (1 of 4)

Familiarity with patent statutes, rules, requirements, case law

A. Statutory: Patent code 35 U.S.C - Overview

a. Part II - PATENTABILITY OF INVENTIONS AND GRANT OF PATENTS (§§ 100 to 212

b. Part III - PATENTS AND PROTECTION OF PATENT RIGHTS (§§ 251 to 329)

B. Familiarity with Specific Sub Parts of Patent Code

1. Utility (*see* 35 U.S.C. § 101 which covers Utility, Statutory Subject Matter) especially in the three areas of:
    i. Process
    ii. Composition of matter
    iii. New and useful improvement
2. Novelty (*see* U.S.C. §102)
    a. Prior art §102(a) - Prior art including information available for consideration when determining whether an invention is patentable, public information including patents, publications, article, product, information on the internet, etc. and printed publications both U.S. or foreign.
    b. Exceptions §102(b), disclosures
    c. Common ownership under joint research agreements §102(c)
    d. Patents and published applications as effective prior art §102(d)
3. Non-obviousness (*see* U.S.C. §112)
    a. General §112(a) including the written description, manner and process of making and using, terminology, skill level, and the best mode contemplated by the inventor or joint inventor…
    b. Conclusion §112(b) – conclusion distinctly claiming subject matter…
    c. Form §112(c) written in independent or multiple dependent form…
    d. Reference in dependent forms §112(d) a dependent form reference to the limitation of subject matter…
    e. Reference in multiple dependent forms §112(e) concerning multiple dependent forms, a reference to more than one claim previously set forth…

CV Attachment 18 - Patent Statutes, Sub Parts, Rules, Case Law, Scope of Work as Technical and Damages Expert (2 of 4)

f. An element in a claim for combination §112(f) expressed as a means or step for performing a specified function without the recital of structure, material or acts…

C. Rules: Patent Regulations in 37 C.F.R.

a. Chapter I - USPTO

b. Chapter IV - National Institute of Standards and Technology 'N.I.S.T.' or 'NIST'

D. Case law

1. Markman

Markman v. Westview Instruments, Inc. 517 U.S. 370, 372 (1996)) regarding the doctrine of equivalents, public notice of function of patent claims in equivalents cases and liable infringing parties [13] [14]

2. Georgia-Pacific

Georgia-Pacific Corporation v. U.S. Plywood Corporation regarding damages

E. America Invents Act (AIA)

Overview: relevant for filings on or after March 16, 2013. Before AIA, priority was given to first to invent. After enactment of AIA, priority is given to first to file

1. Filing reforms
2. Examination reforms
3. Third party reforms
4. USPTO Fee setting
5. Priority Examination fee
6. Surcharges and supplemental examination
7. Patents on tax strategies
8. Virtual marketing and false marketing limits
9. Establishment of satellite offices
10. Creation of ombudsman
11. Pro bono and studies programs

CV Attachment 18 - Patent Statutes, Sub Parts, Rules, Case Law, Scope of Work as Technical and Damages Expert (3 of 4)

Scope of Expert Work
I have performed work on Utility patents in software, healthcare information technology, and genetics such as (cDNA). Developed several IPR petitions as well as infringement and invalidity reports and testimony as provided for in **§42.65 Expert testimony; tests and data.**

> (a) Expert testimony that does not disclose the underlying facts or data on which the opinion is based is entitled to little or no weight. Testimony on United States patent law or patent examination practice will not be admitted.
>
> (b) If a party relies on a technical test or data from such a test, the party must provide an affidavit explaining:
>
> (1) Why the test or data is being used;
>
> (2) How the test was performed, and the data was generated;
>
> (3) How the data is used to determine a value;
>
> (4) How the test is regarded in the relevant art; and

A. Technical Expert

Perform analysis and opinions on infringement or validity. My scope has included assistance to counsel in:

1. claims, counterclaims, and discovery as well as affirmative defense (patent invalidity, non-infringement, equitable defenses),
2. claim construction / Markman hearing and deposition preparation
    a. Scope of claims
    b. Prior art
    c. Educating retaining counsel about the subject matter and claim terms
    d. Technology tutorials
    e. Person of ordinary skill (POSA) testimony preparation
        i. Explain what a patent reference means, what a person of ordinary skill would understand (level of skill required in the art)
        ii. Differentiating between POSA and 'person of extraordinary skill' in the art in testimony preparation
        iii. Preparing with counsel to determine direct / cross-examination focused on easy to understand terminology

B. Damages Expert

Assistance to counsel as an expert consultant in Damages under 35 U.S.C. §284 with general knowledge of important case law (Georgia-Pacific Corporation v. U.S. Plywood Corporation) regarding damages. (As noted in CV, recently declared qualified to testify on damages in the 9th Circuit, Federal case by HONORABLE RONALD S.W. LEW Senior U.S. District Judge).

In patent litigation, served as expert consultant regarding:

1. '…adequate compensation for the infringement…'
2. '…reasonable royalty…'
3. '…lost profits…'

C. Case history – please contact expert for details on prior case retentions

Retained as an expert consultant:

1. Expert consultant for plaintiff regarding infringement
2. Expert consultant for the defendant to counter infringement case and support invalidity
3. Damages/loss calculations expert consultant for plaintiff and defendant in rebuttal to plaintiff

D. Scope of subject matter

Horizontal technology and medical / healthcare specific patents and intellectual property

1. database software including indexing algorithms,
2. software distribution and encryption algorithms,
3. complementary DNA (cDNA)
    a. use of cDNA correlated with patient diagnosis, diagnosis codes
    b. use of cDNA correlated with medical procedures and procedure codes
4. healthcare software including but not limited to
    a. physician productivity metrics,
    b. electronic health records (EHRs),
        i. electronic prescribing
        ii. encryption hashtags
        iii. audits
        iv. clinical decision support
        v. voice to text for progress notes
        vi. authentication and patient portals
        vii. medication management and medication formularies

c. medical coding encoders, which analyze physician progress notes or terminology and recommend likely medical diagnosis or procedure codes
d. computer-assisted coding a.k.a. 'C.A.C.'),
e. and general medical diagnosis and procedure coding as it is used for medical necessity determination and health insurance claims adjudication

- **U.S. Patent and Trademark Office** (*see* attachment 17, continued next page)
    1. Prior Art Access, Roundtable, Alexandria (December 2013)
    2. Glossaries, Roundtable, U.C. Berkeley (October 2013)
    3. Software Partnership Listening Session, Roundtable, Silicon Valley (February 2013)
    4. Crowdsourcing, Roundtable, Alexandria (April 2014)
    5. Software Partnership Meeting, Roundtable, Alexandria (July 2014)
    6. Examiner Guidance for Internet Searching and Use of Crowdsourcing to Locate Prior Art, New York (December 2014)
- **Patent Trial and Appeal Board (PTAB)**
    1. Non-appealable issues / Petitionable Matters in Ex parte Appeals (April 2018) PTAB Judges Adriene Lepiane Hanlon, Bruce Wieder, and Anthony Knight
    2. Motions to Exclude and Motions to Strike in AIA Trials (June 2017)
    3. Motions to Seal, Protective Orders, and Confidential Information in AIA Trials (October 2017)
    4. Hearsay and Authentication (December 2017)
    5. Supplemental Information vs. Supplemental Evidence (February 2018)

CV Attachment 19 – Medicare Medicaid SCHIP Extension Act of 2007 reporting under section 111

1. Non-Group Health Plan (NGHP) Responsible Reporting Entities (RREs) submitting Section 111 claim information via an electronic file submission or via Direct Data Entry (DDE).
2. Total Payment Obligation to Claimant (TPOC) dollar threshold reporting requirements established in Section 111 reporting
3. Ongoing Responsibility for Medicals (ORM)
4. TPOC dollar thresholds and liability insurance (including self-insurance) and workers' compensation (Plan Insurance Type 'L' or 'E') as specified in 42 U.S.C. 1395y(b)(8) (Section 111 MSP reporting requirements for liability insurance (including self-insurance), no-fault insurance, and workers' compensation)
5. Worker's Compensation Exclusion

CV Attachment 20 – EEG and Telemedicine for Primary Care and the Neurology Specialty

1. Place of service codes for remote monitoring of seizures using EEG with video
2. Technical component
3. Professional component
4. Primary care physician interpretations
5. Neurologist overreads as portion of technical component
6. Prevailing guidance on medical necessity and coverage determinations
    a. Local Coverage Determinations under Medicare
    b. Coverage Determinations of private payors
7. Use of National Correct Coding Initiative and claims scrubbers as basis for codes that may be used together or separately
8. Industry best practices and guidelines for medical coding of EEGs
9. Research regarding efficacy of digital spike analysis with EEGs
10. Documentation requirements for EEGs
11. Advisor to national independent diagnostic testing facility (IDTF)

CV Attachment 21 – Ambulatory Surgical Center Facility Fees, Exclusions

Regulatory and Structural Issues regarding ASCs:

- Whether ASCs traditionally subject to Stark Law regarding physician ownership and referral
- Whether ASC subject to federal Anti-Kickback Statute (AKS) as well as state laws
- Safe harbors regarding ASC structures found at 41 C.F.R. Section 1001.952(r)
- Physician hospital joint ventures
- Management Company ventures
- Group Practice Ownership structures

Billing guidance and economic issues regarding ASCs

- Split billing for physician and facility fees
- Professional fees, facility fees
- Status indicators, Medicare Administrative Contractor Payment Indicators (PIs)
- Ambulatory Procedure Codes (APCs)
- Outpatient Prospective Payment System (OPPS)
- Usual Customary and Reasonable Charges

ASC facility fees and exclusion criteria including:

- Nursing
- Technician and related services
- Diagnostic or therapeutic services or items directly related to the provision of a surgical procedure
- Administrative, recordkeeping and housekeeping items and services
- The operating surgeon's supervision of the services provided by an anesthetist

- Drugs
- Biological
- Surgical dressings
- Supplies
- Splints
- Casts
- Appliances and equipment that are directly related to the provision of surgical procedures
- Anesthesia materials and implants, including intraocular lenses (IOLs)

- Some anesthetic agents
- Biologics
- Radiologic services

[1] Although the name "health informatics" only came into use in about 1973 (Protti 1995), it is a study that is as old as healthcare itself. It was born the day that a clinician first wrote down some impressions about a patient's illness and used these to learn how to treat their next patient. The world is aging and there are increasing numbers of people with chronic disease; it is recognized that the only sustainable option is planning and delivery of healthcare through technological innovation.

Biomedical Informatics seeks to discern the difference between data, information, knowledge, and wisdom by increasing sharing and comprehension. Professor Enrico Coiera of the Macquarie University argues that health informatics is the logic of healthcare. Dr. Mark Musen, MD PhD (Professor, Medicine — Biomedical Informatics Research at Stanford), points out that digital information has made knowledge infinitely larger for clinicians, and they are now in a knowledge management crisis: getting the right information at the right time is the challenge.

[2] Training delivered by MD, board-certified orthopedic surgeon, and AHIMA-certified trainer who advised CMS in all 50 States; AHIMA-certified inpatient coder and chart auditor, AAPC-certified outpatient coder, and chart auditor.

[3] Used in Medicare Part C (Medicare Advantage "MAO"), Accountable Care (ACO) organizations.

[4] Training delivered by MD, board-certified orthopedic surgeon who advised CMS in all 50 States.

[5] Training delivered by Radiology Certified Coder (RCC), Certified Interventional Radiology Cardiovascular Coder (CIRCC), and Certified Professional Coder (CPC) credentialed instructor.

[6] American Academy of Professional Coders (AAPC).

[7] Training delivered by National Association of Rehabilitation Providers (NARP) trainer.

[8] Health Care Incentives Improvement Institute, HC3i.

[9] Health Care Incentives Improvement Institute, HC3i.

[10] Pertaining to, or composed of, an integument such as skin. Source: Dorland's Medical Dictionary.

[11] American Academy of Professional Coders (AAPC) Certified Professional Coder (CPC) curriculum.

[12] Non-Covered Services provider education — Noridian Healthcare Services, LLC.

[13] David L. Schwartz, Explaining the Demise of the Doctrine of Equivalents, 26 Berkeley Tech. L.J. 1157 (2011). Available at: h p://scholarship.law.berkeley.edu/btlj/vol26/iss2/6

[14] John R. Thomas, Claim Re-Construction: The Doctrine of Equivalents in the Post-Markman Era Georgetown University Law Center, jrt6@law.georgetown.edu