Michael F. Arrigo Curriculum Vitae
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Offices in Boston, Pittsburgh, New York, Washington DC, Nashville, Atlanta, Miami,
Seattle, Salt Lake City, Denver, St. Louis, Chicago, Dallas, San Francisco, Orange County, San Diego, Honolulu

Education

Harvard Medical School, Cambridge, MA — **Clinical Bioethics** and Risk Management, **2018**. Focus on ethical, legal, technological, social issues in medicine including genetics, privacy, opioids for pain management. Topics: healthcare rationing[1] and distributive justice,[2] human rights in health and science,[3] public reporting of outcomes,[4] organizational ethics in changing hospital policy environment, appropriate actions of a hospital.[5] Conference - Precision Medicine **2019**: Can AI Accelerate Precision Medicine? Policy & the patient, value in prediction, hyper individualized[6] treatments.

Stanford Medical School, Palo Alto, CA —Biomedical Informatics [7] - 1. Paid tuition and audited graduate course 'Biomed Informatics 210' with permission from faculty while a student at Stanford. Course focus: **modeling biomedical systems**, **data, knowledge processing in biomedicine**,[8] controlled terminologies,[9] knowledge representation, rule-based systems, description logic, problem solving methods (as of 2019 considered to be components of 'Artificial Intelligence or 'AI' in medicine),[10] building systems with ontologies and problem solving methods,[11] - **2015; Curating digital health care information non-technical data sources**,[12] evidence based practice cycles for clinical decisions, PICO framework, [13] Certificate, **- 2019**

University of Southern California, Los Angeles, CA — Bachelor of Science, Business Administration, **1981**; studied in the Entrepreneur Program focused on management decision-making, leadership, marketing, financing of startups.

University of California, Irvine — Studies in Economics, Inferential Statistics,[14] and Computer Science (BASIC, Pascal, FORTRAN, LISP, COBOL, SQL, impact of computers on society), **1978** (transferred to U.S.C. to complete undergraduate work).

Training, certifications **HIPAA** Privacy and Security Rules, California Confidentiality of Medical Information Act (**CMIA**), Patient Access to Health Records Act (**PAHRA**), Insurance Information and Privacy Protection Act (**IIPPA**), Collection of Medical Information for Direct Marketing, Shine the light Certification, **National Patient Safety Goals**, **Certified Ambulance Documentation Specialist** - see Additional Course Work and Experience, addenda sections, **2017 – 2019;** includes detail on **Medical Coding**.

Rulings Regarding Motions to Exclude Expert, Stipulations

To date, a Chief U.S. District Judge, two U.S. District Judges, State Judges, and Arbitrators denied motions to exclude Arrigo or consented to a stipulation of Arrigo's expert qualifications.

1. DENIED [15, 16] - *UNITED STATES of AMERICA and STATE OF CALIFORNIA ex rel. Julie A. Macias v. PACIFIC HEALTH CORPORATION* CV 12–00960–RSWL–AJWx. **See Westlaw 2018 WL 1026361**. Senior U.S. District Judge Ronald S.W. Lew of the U.S. District Court, Central District of California: "…Mr. Arrigo is a damages expert…," "…Mr. Arrigo clearly has the relevant qualifications necessary …" and noted Arrigo's expertise in medical coding, billing, electronic health records, and Medicare fraud damages. "…Accordingly, the Court finds that Mr. Arrigo has sufficient specialized knowledge to provide an opinion…" Feb. 2018

2. DENIED - *UNITED STATES of AMERICA v. Clifford Shoemake* et al. CRIMINAL CASE NO. 16-00002. Order from the bench. Chief District Judge Frances Marie Tydingco-Gatewood of the U.S. District Court of Guam April 2018. Denied motion to exclude regarding expert opinions assessing prosecutions applications of methods, statistically invalid sample sizes, improper extrapolation, consistency in applying regulatory guidance, clinical documentation, medical diagnosis codes, procedure codes, (i.e., Local Coverage Determinations (LCDs)) and identification of duplicated or missing data in alleged $30 million Medicare fraud case. When Defendant's opposition prevailed, the Prosecution withdrew a Daubert challenge.

3. STIPULATED and admitted - *San Francisco Spine Surgeons v. Claim Works, LLC*. JAMS No. 1110018697 9/17/2017, Transcript Volume III. Arbitrator / Judge Ambler stated that parties stipulate that Arrigo is an expert in medical coding, medical billing and damages calculations. Case entailed, in part, orthopedic billing, pain management injections, assessment of data quality by plaintiff to support assertions in their complaint, industry standard roles and responsibilities of providers, coders, and billing entities when not specifically provided for by contractual agreement.

4. DENIED - *Lobin v. J.B. Hunt Transport* AAA 01-16-0000-0480 Order No. 4, Arbitrator / Judge William E. Hartsfield, 7/18/17 Dallas, TX. Denied motion to exclude. Opinions included Usual Customary and Reasonable (UCR) charges for care before considering insurance (collateral source), and, alternatively, assuming a Plaintiff's duty to mitigate medical costs, what an insureds' benefits under state Medicaid and Affordable Care Act 'metal' plans provide, Federal Poverty Level (FPL) guidelines on insurance eligibility and out of pocket maximum (OOPM) costs to an insured.

5. DENIED [17] – *United States v. Ganesh and Belcher* Case No. 16-CR-00211-LHK (retained by Defendant Belcher) U.S. District Judge Lucy Koh, October 20, 2017. "…Court denies request to preclude insofar as it would preclude Arrigo from testifying about patterns of Defendant Belcher's billing (including CPT codes), what modifiers are, how they impacted Belcher's billing and reimbursement, and modifier's position in the industry."

6. DENIED [18] – *Allure Nichols v. Eskaton, Inc., et al*., CASE NO.: CVPO-2017-916 California Superior Court. Judge Peter M. Williams. March 28, 2019. Retained by Plaintiff, personal injury case. Defendants argued that the Plaintiff's medical care was paid by a capitated Medicare Part C plan, and regardless of the services provided, there was, in effect no payment

made for Plaintiff's hospital care. The Court ruled that the reasonable value of the medical services is at issue – not the amount incurred—must be used instead. According to Judge Williams, "This value is generally determined by expert testimony."

7. DENIED [19] - Thomas McGuigan v. Source One, et al, Docket MER-L-2096-16 Superior Court of New Jersey, County of Mercer. "Plaintiff's request to bar defendant's expert report of December 21, 2018, is Denied" "Arrigo's December 21, 2018 report is NOT barred as a net opinion and Arrigo is able to testify as an expert witness at trial. This is subject to a proper foundation and proper presentation in the judgment of the trial judge." Opinions pertaining to damages, rebuttal to Plaintiff's expert opinions and methodological deficiencies including error rates, sample sizes, improper extrapolation.

8. DENIED [20] – *Marina Ascarate v. College Hospital Costa Mesa*; JAMS Ref. No. 1220059632, Hon. Rex Heeseman (Ret.) motion to preclude testimony denied, October 10, 2019; Arrigo opinions regarding HIPAA admissible : 1. privacy and security policies and procedures did not meet industry standards, 2. sanction policies for its employees who commit a breach did not meet industry standards, 3. required four-factor risk assessment required by the HIPAA Omnibus Rule of 2013 to determine whether an alleged breach of HIPAA was in fact a breach, 4. assessment of what harm was caused to the alleged impacted patient, 5. policies regarding patients with an infectious disease did not meet public health authority standards.

U.S. Court of Appeals Ruling Where Expert's Opinions Were Adduced

UNITED STATES OF AMERICA, Plaintiff-Appellee, v. MICHAEL MIRANDO, Defendant-Appellant. See:

a. Appellant's Opening Brief, Attorneys for Defendant-Appellant James W. Spertus (CA SBN 159825), filed April 4, 2018
b. Opinion of the honorable Circuit Judges Gould, Nguyen and Marbley, filed April 9, 2019 No. 17-50386, D.C. No. 2:16-cr-00215-PA-1 "…VACATED AND REMANDED…")

Excerpts of the U.S. Court of Appeals Opinion

- "As part of its calculation of [Defendant-Appellant] Mirando's sentence in accordance with the Sentencing Guidelines, the district court made a finding of the 'intended loss' amount from the fraud. Mirando argues that this was calculated incorrectly. We agree."

- "In cases of health care fraud, courts must determine the loss amount, which is a 'a specific offense characteristic that increases the defendant's offense level pursuant to the Guidelines." Popov, 742. F3d at 914. To calculate the loss amount, *Popov* established that the 'amount billed to the insurer" is "prima facie evidence of an intended loss for sentencing purposes," but this is a rebuttable presumption…."

- The Court of Appeals observed that in the original trial, the lower court concluded that "…the intended loss enhancements increase Guidelines offense level from six to thirty."

- "The district court abused its discretion when it concluded that the Government's evidence met this 'clear and convincing' standard. The Government offered prima facie evidence, but at sentencing Mirando, per *Popov*, tried to rebut the presumption. He testified that he knew he would never receive a full reimbursement of the amount billed."

Summary of Expert Arrigo's Scope and Outcome of Appeal

1. Reviewed Presentence Investigation Report as provided for by the U.S. Sentencing Guidelines 26 (USSG) §2B1.1 standard, and evaluated it using U.S. Sentencing Commission (USSC) methods and my specialized knowledge, training, education and experience.

2. Performed rebuttal of methods: sample size, lack of comprehensive clinical documentation review, 'intended loss' vs. 'actual loss.' The Government's intended loss standard resulted in an increase in the level for sentencing guidelines from six to thirty. As a result, the lower court initially imposed a 97-month sentence, which was appealed.

3. Expert Arrigo's work was related to sentencing and damages calculations, not the underlying fraud trial. Counsel for the Defendant said that Arrigo's work rebutting the Government's methodology helped lay the foundation for his opposition. Result: **successful appeal** of the lower court's sentencing decision.

Rulings, Orders Re: Arrigo Opinions in Class Certifications

To date, Arrigo provided testimony in support of Class Certification in four cases. One Federal Judge has certified a de novo subclass, noting Arrigo's opinions in his Ruling.

- CERTIFIED - *Jenee Hill v. United Healthcare Insurance Company* CASE NO.: SACV15-00526 DOC (RNBx). U.S. District Judge David O. Carter certified the de novo subclass and found that Defendant failed to explain why the exercise of producing industry standard data was burdensome and complicated and that it failed to properly cooperate with discovery (See the Order RE Renewed Motion for Class Certification [76] filed 3-21-17, **noting Arrigo opinions**). Arrigo's opinions focused in part on health plan Industry Standards, customary guidelines followed by health plans in the normal course of business processes, and information technology with respect to producing electronic claim data based on Standards, storage, retrieval and reporting.

Rulings, Stipulations Re Arrigo Opinions - Trade Secret, Patent Infringement

To date, Arrigo provided testimony in support of a motion to dismiss a case involving in part, alleged infringement of Trade Secrets.

- DISMISSED with PREJUDICE – *Consortia Health Clinical Continence Services, LLC v. Shardae Exposito Pena and Cathex Solutions, LLC.* CASE NO: 17-004471 CA 27. CIRCUIT COURT OF THE 11th JUDICIAL CIRCUIT, MIAMI-DADE, FLORIDA. 12/20/18. Retained by Defendant, assisted counsel in identifying weaknesses in Plaintiff's claims. Scope of work included prior art regarding protocols incorporating biofeedback, protocols for the diagnosis and treatment of medical conditions, **opinions regarding the novelty, usefulness, and non-obviousness** of groupings of diagnosis codes and medical procedure codes in superbills,[1] viability of breach of non-compete based in part on non-obviousness of customer concentration in the market, Federal and Florida State Standards (see Florida's version of the Uniform Trade Secrets Act - "FUTSA") regarding trade secrets and a subsequent decision to determine whether or not to convert the trade secret asset into a patent asset, and **Damages calculations**. Applied FUTSA and Federal standards to the case, specifically:

    - Under FUTSA, protected information can take many forms, and can, in fact, be contained in a "program," a "device," a "method," a "technique," or "process."[2] Florida Standard two part test for trade secrets: the information sought to be protected must gain economic value from not being known by the public; and, reasonable efforts must be made to maintain its secrecy. [3]
    - Whatever form the information takes however, the claimant must be prepared to specifically *identify* the information in question to the court (and opposing parties) to allow them the opportunity to evaluate the claim and engage in the dispute.[4]
    - The traditional approach is based on the NUN factors: (novelty, usefulness, non-obviousness).
    - If the trade secret asset meets the patentability requirements, then the decision tree often dictates that the owner seek patent protection because a patent will provide greater protection.

Additional Course Work and Experience

- **U.S. Patent and Trademark Office** roundtables focus on healthcare / medical: PTAB seminars re: Prior Art Access, Non-appealable issues / Petitionable Matters in Ex

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[1] Medical coding and billing related patent infringement litigation: *Prometheus v. Mayo*, where court denied Prometheus claim in favor of Mayo because it could not uphold claims to law of nature

[2] Section 688.002(4) initially defines a "trade secret" to be "information," and then specifically provides that the information can take the form of a "program, device, method, technique, or process...".

[3] *Id.*

[4] *See, e.g.,* Virginia Electronics and Lighting Corp. v. Koester, 714 So. 2d 1164, 1164 (Fla. 1st DCA 1998), finding a trial order deficient for failing to "specify" exactly what trade secrets were found to exist, and failing to set out express findings of fact supporting its conclusion that the disclosure of the "secret" was "reasonably necessary to resolve the issue in dispute.") *See also* Lovell Farms, Inc. v. Levy, 641 So. 2d 103, 105 (Fla. 3rd DCA 1994).

parte Appeals, Preparation of IPR petition, infringement and invalidity report as provided for in §42.65 Expert testimony; tests and data.

- **Massachusetts Institute of Technology,** Cambridge, MA -- cybersecurity for electronic healthcare using blockchain, 2018-2019 certificate program partially complete as of Nov '19
- **Clinical documentation, medical coding, billing reimbursement, HIPAA transactions, value based care, and risk adjustment** (*see* attachment 11 in this CV re: medical coding).
- **Villanova University** – Lean Six Sigma and Process Improvement (2007)
- **Wharton School, University of Pennsylvania –** Leadership Strategies (1982)
- **Ongoing management of team** of physicians, healthcare IT experts, regulatory and policy experts formerly with CMS, and AAPC, AHIMA certified coders in our engagements with insurance, hospital, physician and other payors, providers, and IT companies, and electronic health record, patient safety and document authenticity advisories based on HIPAA, HITECH Act, and Joint Commission standards. Regular speaker and attendee at conferences, roundtables, and webinars on healthcare industry regulations, data, and economic issues. *** See 18 addendums to this CV for specifics**.
- **Certified Ambulance Documentation Specialist** (CADS) National Academy of Ambulance Compliance, May 2018; trained in medical coding and billing.
- **HIPAA Business Associates,** Privacy and Security and EDI transactions, certified in HIPAA; June 2017, re-certification & training October 2019
- **HIPAA for Healthcare Workers** June 2017, re-certification & training October 2019
- State Privacy Standards including California Confidentiality of Medical Information Act (**CMIA**), Patient Access to Health Records Act (PAHRA), Insurance Information and Privacy Protection Act (IIPPA), Collection of Medical Information for Direct Marketing, and Shine the light Certification, May 2019
- **Medical coding and billing**, course work in compliance officer curriculum (see addenda).
- **National Patient Safety Goals,** 1, 2, 3, 6, 7 and **Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery,** October 2019

Programming languages education and knowledge

Structured Query Language (SQL), data quality Standards (normalization, Extract Transform Load or 'ETL'), database tools and statistical data models for economics and damages calculations. Prior work with Dr. Moshe Zloof, formerly of IBM Research labs and inventor of database query method(s) Query Be Example (QBE). Computer science education

included use of symbolic, compiled, and interpreted procedure and object oriented systems LISP, Fortran, Smalltalk virtual machines, PHP, Java, Ruby, and CSS/HTML/responsive web technology for mobile health as well as content optimization for Google Search Engine Optimization interactive debuggers, compilers, Basic, Pascal software development.

Industry Awards and Recognition

Arrigo, M. F. 2016 Nominee: Best Legal Blogs of 2016 for healthcare industry sector, No World Borders, Inc

Selected Quotations

(2019) The Wall Street Journal: ***New York City Has Been Releasing Burial Records of Fetal Remains—and Names of Women Linked to Them*** **Medical ethicists say publishing such information on Hart Island cemetery is an invasion of privacy that could cause harm** *https://www.wsj.com/articles/new-york-city-has-been-releasing-burial-records-of-fetal-remainsand-names-of-women-linked-to-them-11566420004*

(2018) ***Kaiser Health News*** *: Usual Customary and Reasonable Charges for medical procedures: https://khn.org/news/thats-a-lot-of-scratch-the-48329-allergy-test/*

(2018) ***National Public Radio****: Bill Of The Month: A $48,329 Allergy Test Is A Lot Of Scratch https://www.npr.org/sections/health-shots/2018//29/660330047/bill-of-the-month-a-48-329-allergy-test-is-a-lot-of-scratch*

(2016) ***Association of Healthcare Journalists****: HIPAA experts: No need to request a waiver after Orlando shooting https://healthjournalism.org/blog/2016/06/hipaa-experts-no-need-to-request-a-waiver-after-orlando-shooting/*

(2011, February 23) - **Wall Street Journal**: Is Switch to New Medical Coding System Health Care's Y2K Problem? *https://blogs.wsj.com/venturecapital/2011/02/22/it-companies-stand-to-gain-from-health-cares-y2k-problem/*

(2011, February 23) **Wall Street Journal**: IT Companies Stand To Gain From Health Care's 'Y2K' Problem *https://blogs.wsj.com/health/2011/02/23/is-switch-to-new-medical-coding-system-health-cares-y2k-problem/*

Publications

Arrigo, M. F. (2019) OIG Industry Guidance Sets Standards for Governance by Healthcare Industry Sector. Published November 12, 2019 https://noworldborders.com/2019/11/12/oig-regulatory-guidance-standards/

Arrigo, M. F. (2019) Pharmacy Benefit Managers - U.S. Pharmacy Distribution and Reimbursement System. Published February 4, 2019
https://noworldborders.com/2019/02/04/pharmacybenefitmanagerdrugprices/

Arrigo, M. F. (2018) Drug Pricing Expert and Classification Systems: drug classification systems and their impact the overall cost of health care. Published March 1, 2019
https://noworldborders.com/2018/03/01/drug-pricing-classification-systems/

Arrigo, M. F. (2017) American Health Care Act DOA. What Does it Mean for Medical Cost Litigation? Published March 24, 2017 https://noworldborders.com/2017/03/24/american-health-care-act-doa-medical-cost-litigation/

Arrigo, M. F. (2016) Strategic Financial Management for Healthcare Providers: Clinical Documentation Improvement and Accuracy as a Foundation Value Based Care. Peer review, review by clinical and business executives at Baptist Health (a large academic medical center). Healthcare Financial Management (HFMA). Published August 17, 2016. https://www.hfma.org/sfp/

Arrigo, M. F. (2015) Mobile Health, HIPAA Privacy and Security
Blackberry Sharpens Security with Good Technology Acquisition. Gov. Health IT.
http://www.govhealthit.com/blog/commentaryblackberry-sharpens-security-good-technology-acquisition

Arrigo, M. F. (2015) Five Interest-Piquing Trends at HIMSS15. Gov. Health IT.
http://www.govhealthit.com/news/5-interest-piquing-trends-himss15

Arrigo, M. F. (2014) Cloud and Mobile Convergence: The Regulatory View. Gov. Health IT.
http://www.govhealthit.com/blog/cloud-and-mobile-convergence-regulatory-view

Arrigo, M. F. (2011) ICD-10 financial impact vs. mortgage crisis? Gov. Health IT.
http://www.govhealthit.com/news/could-icd-10-have-big-financial-impact-mortgage-crisis

Arrigo, M. F. (2012) How a Flaw in the ACO Model Leaves Patients Out. Gov. Health IT.
http://www.govhealthit.com/news/how-flaw-aco-model-leaves-patients-out

Arrigo, M. F. (2012) 10 ICD-10 Regulation Myths Demystified. Gov. Health IT.
http://www.govhealthit.com/news/10-icd-10-regulations-demystified

Arrigo, M. F. (2012) Real-time location, mobile health gain traction. Gov. Health IT.
http://www.govhealthit.com/news/real-time-location-and-mobile-health-solutions-gain-traction-show-roi

Arrigo, M. F. (2013) 3 Top Priorities for CommonWell. Gov. Health IT.
http://www.govhealthit.com/news/3-top-priorities-commonwell

Arrigo, M. F. (2013) Commentary: ICD-10 Arrives Early, New Claims Form. Gov. Health IT. *http://www.govhealthit.com/news/commentary-icd-10-arrives-early-claims-CMS-coding-HIPAA-icd-9*

Arrigo, M. F. (2014) Increased Spending - Big Data, Cloud, mHealth Social. Gov. Health IT. *http://www.govhealthit.com/blog/increased-spending-and-savings-tap-big-data-cloud-mhealth-and-social*

Arrigo, M. F. (2014) Ebola: How cloud, mHealth, and ICD-10 could help. mHealth News. *http://www.mhealthnews.com/blog/ebola-how-cloud-mhealth-and-icd-10-could-help*

Arrigo, M. F. (2014) How Cloud and mHealth Ease Claims Processing (also coverage of Prior Authorization/Eligibility HIPAA EDI 270/271, referral EDI 278 transaction). Gov. Health IT. *http://www.govhealthit.com/news/how-cloud-and-mhealth-promise-ease-claims-processing*

Arrigo, M. F. (2014) How to Get Behavioral Health Codes Right. Gov. Health IT. *http://www.govhealthit.com/blog/how-get-your-behavioral-health-codes-right*

Lectures, Conference Speaking Engagements

- Presentation to Assistant U.S. Attorney, FBI, and OIG in Cincinnati, Ohio (March 2018) regarding Meaningful Use of Electronic Health Records, demonstration of electronic health records and patient data including diagnosis codes, medical procedure codes, computerized provider order entry, drug-drug interactions, clinical decision support, physician progress notes in compliance with 45 CFR 170.304 (E.H.R. software certifications, physician and hospital attestations), and certifications and second standard §170.314.
- Presentation to the Assistant U.S. Attorney, Southern District of New York (January 2018). Evaluation and Management (E&M) codes and appropriate usage based on complexity and severity of existing diagnosis codes rendered by physicians according to AMA guidelines.
- Presentation to the Assistant U.S. Attorney in Houston, Texas (October 2017) regarding professional components and technical components of CPT coding for 95951— monitoring for localization of cerebral seizure focus by cable or radio, 16 or more channel telemetry, combined electroencephalographic (EEG) and video recording and interpretation (e.g., for presurgical localization); each 24 hours.
- Presentation to the Assistant U.S. Attorney, FBI, and Office of the Inspector General (OIG) for HHS in Cincinnati, Ohio (November 2015) regarding Meaningful Use of Electronic Health Records in confidential qui tam false claims act investigation regarding 45 CFR 170.304 (E.H.R. software certifications, physician and hospital attestations), and certifications and second standard §170.314 electronic health record certifications—including electronic storage

and display of patient progress notes, patient diagnosis, patient clinical quality measures, smoking status, problem lists, drug-drug interactions, allergies, and computerized provider order entry.

- Arrigo, M. (Speaker) (2015, November 2015) Medical Device Reimbursement, FDA, 510(k) FCC, and CMS regulatory disruption and opportunities under the Affordable Care Act, ICD-10, and HITECH Act. BioMed Device and Wireless Device Conference, San Jose, California.
- Arrigo, M. (Speaker) (2015, September 2015). Meaningful Use of Electronic Health Records, HIPAA Privacy and Security, and potential damages for breaches under the HITECH Act as a foundation for the International Classification of Diseases from the World Health Organization (ICD-10) — Discussion of risks and opportunities in these two regulations; discrete data, quality measures, medical codes: clinical documentation, clinical decision support, physician and patient engagement, HIPAA Privacy and Security, and revenue cycle. Wolters Kluwer Corporate event, presented to audience of over 800 participants.
- Arrigo, M. (Speaker) Wolters Kluwer 2015 webcast to over 800 pharmacists, re: medical coding and billing and correlations with drug indications based on new ICD-10 diagnosis codes. Letter of recommendation received from Wolters Kluwer events staff available upon request.
- Arrigo, M. (Speaker) (2015, January) JP Morgan Healthcare Conference, re: economic shifts due to changing standards in medical coding and billing. San Francisco, California.
- Arrigo, M. (Speaker) and Hartley, C. (2014) HIPAA Plain and Simple/HIPAA for Behavioral Health — Credible Behavioral Health E.H.R. Software Users Conference, Baltimore Maryland (18 March 2014) regarding 42 CFR Part 2 — privacy in behavioral health patient records, data segmentation requirements of The Substance Abuse and Mental Health Services Agency (SAMHSA) and the Health Resources and Services Administration (HRSA), which provides resources for Federally Qualified Health Centers (FQHCs). HITECH Act Information Safeguards, HIPAA Privacy Rule and HIPAA Security Rule, implementation of risk assessments by Covered Entities. HIPAA Omnibus Rule Overview, National Public Rule Making (NPRM) about privacy rights, and duties of Business Associates.

- Arrigo, M.F. (2014) Diagnostic and Statistical Manual of Disorders (DSM 5) and the International Classification of Diseases, version 10 (ICD-10) with respect to changing medical coding and billing standards. Discussion of changes in number of, and use of, diagnosis codes for anxiety disorders, autism spectrum disorders, mood-related disorders, schizophrenia, and drug abuse. Challenges in obtaining data; value in objectivity of the data. CMS guidance

regarding DSM IV vs. HIPAA Standard Transactions — Credible Behavioral Health E.H.R. Software Users Conference, Baltimore, Maryland (18 March 2014).

- Arrigo, M. (Speaker) (2014) Managed Care and Accountable Care for Behavioral Health. Risk adjustment and capitated payments and the intersection with Behavioral Health. Discuss populations who fit into ACOs who: (1) have a high-risk score under CMS' HCC risk adjustment model; (2) are considered high-cost due to having two or more hospitalizations each year; (3) are dually eligible for Medicare and Medicaid; National Association of State Mental Health Program Directors (NASMHPD) criteria §1115 (Statewide) Medicaid waiver using three separate ACO models. Seven more States were in the process of setting up their own Medicaid ACO programs, eligibility, and coverage determinations[5] — Credible Behavioral Health E.H.R. Software Users Conference, Baltimore, Maryland (18 March 2014).
- Arrigo, M. (Speaker), re: medical coding and billing webcast. HIMSS 2014, Orlando, FL.
- Arrigo, M. and Nichols J. MD — (Speakers) (2013, November). Claims Data, Clinical Data — Working Together to Improve Clinical Documentation for International Classification of Diseases from the World Health Organization (ICD-10). Discussion of healthcare data analytics methods, inpatient and outpatient procedure coding, comparison of record audit methods, and physician engagement strategies and audit results. Workgroup for Electronic Data Interchange (WEDI) National Conference, Washington D.C.
- Arrigo, M. (Speaker) Duke Life Health System (2013), Pittsburgh, Pennsylvania — Physician engagement for accuracy of medical coding using clinical concepts, and clinical documentation improvement for ICD-10.
- Arrigo, M. (Speaker) (2013, April 23). **The Perfect Storm in Healthcare** — How Disruptive Regulations and Technologies Create Risks and Opportunities for Medical Coding and Revenue Cycle Management. Affordable Care Act, ICD-10, CORE Operating Rules, HITECH Act Security and Meaningful Use, Best Practices Health IT, process improvement. **Scripps Healthcare Summit 2013. Lecture conducted from La Jolla, San Diego, California**.

- Arrigo, M. (Speaker) (2012, April 14). **The Perfect Storm in Healthcare** — How Disruptive Regulations and Technologies Create Risks and Opportunities for Medical Coding and Revenue Cycle Management. Affordable Care Act, ICD-10, CORE Operating Rules, and HITECH Act.

[5] Lead training for pharmacists, hospitals, physicians, health IT value-based care firms

American Academy of Professional Coders (AAPC) National Conference. Lecture conducted from Las Vegas, NV. http://news.aapc.com/icd-10-monitor-wish-i-were-in-las-vegas/

- Arrigo, M. (Speaker) American Health Information Management Association (AHIMA), re: medical coding and billing. 2013, New Orleans, Louisiana.
- Arrigo, M. (Speaker) (2012, June 14). ICD-10: Impact on Payment Reform. Wisconsin Medical Society. Lecture conducted from Madison, Wisconsin. http://bit.ly/16acIDy
- Arrigo, M. (Speaker) (2012, May). How ICD-10 and Payment Reform Will Change the Radiology Revenue Cycle. Radiology Business Management Association (RBMA), Orlando, Florida.
- Arrigo, M. (Speaker) (1994 - 1995). Impact of the Internet on medical and financial businesses, Loyola University, Los Angeles, California.
- Arrigo, M. (Speaker) (1994 - 1995). Impact of the Internet on medical and financial businesses, University of California, Irvine, California.

Professional Affiliations

- Medical Group Management Association (MGMA), 2009
- Health Information Management Systems Society (HIMSS) 2009
- American Academy of Professional Coders (AAPC) 2013
- American Health Information Management Association (AHIMA) 2013
- Workgroup for Electronic Data Interchange (WEDI) 2009
- Association for Clinical Documentation Improvement Specialists (ACDIS) 2017
- California Ambulatory Surgery Association (CASA), March 2019
- American Academy of Pain Medicine (AAPM), May, 2018
- American Society for Clinical Pathology (ASCP), June, 2016
- Information Systems Audit and Control Association (ISACA), January 2003
- National Alliance of Medical Auditing Specialists (NAMAS) (February 2018)
- American Society of Radiologic Technologists (October, 2019)
- **Contributor:** Strategic Financial Management Newsletter, Healthcare Financial Management Association;
- **Contributor:** Healthcare IT News, GovHealth IT, Mobile Health News, Financial Health News
- **Volunteer:** Children's Hospital Medical innovation committee

Legal Experience

(See Separate Document for List of Case Retentions & Opinions)

1. Three retentions by **U.S. Department of Justice** :
    i. Federal investigation into medical data, Health IT/E.H.R. stimulus funds, and False Claims Act (estimated value of $900 million).
    ii. Evaluation and management (E&M) coding and correlating diagnosis codes as to whether the patient condition met the AMA coding guidelines for medically necessary care; damages and loss calculations exceeding $40 million for large multi-site clinic provider.
    iii. Excessive billing practices of hospital
2. Three retentions in class actions regarding privacy and security breaches (over 30 million impacted patients / individuals), in plaintiff and defendant retentions as well as individual breach cases.
3. Four retentions in class actions regarding bad-faith insurance litigation, and failure to report Medicare insured data to CMS under the MMSEA Section 111 Standards for Required Reporting Entities (RREs) of the Medicare Secondary Payer Act (MSPA).
4. Three retentions involving toxicology and pathology billing and genetic testing; accuracy of records under the CLIA Standard.
5. Retained by defendant in alleged **trade secret and intellectual property disputes** regarding whether certain healthcare and medical processes, electronic solutions, diagnosis code and procedure codes were unique, protected and not commonly known in the industry. Work with defense counsel on discovery, prior art, education to the Court resulted in dismissal of case.

a. **Plaintiff, Defendant, and Relator retentions** cases involving the False Claims Act and Medicare fraud; retained in cases involving a total of over $80 million in fraud damages. Liability and damages expert and rebuttal expert in various phases of criminal and civil cases.

b. **Rebuttal expert to life care plans.** Testimony regarding benefits provided under the **Affordable Care Act, Americans with Disabilities Act, Health and Welfare Plans**, Medicare, State Medicaid, Medicaid expansion via Federal Poverty Level (FPL) calculations, household income, members in household, Minimum Essential Coverage (MEC) SSDI and other factors.

c. Served as expert consultant on seven **patent licensing, patent litigation, and intellectual property infringement matters** (five in healthcare, two in enterprise software and security).

d. Retained by former RAND Economists and Health IT firm for testimony before **Federal Trade Commission** involving anti-trust and access to clinical data, which impacted billing and revenue cycle.

e. Retained in five **white-collar crime cases**, alleged fraud valued at over $10 million each; loss calculations and/or damages based on intended and actual loss.

f. **Audits of medical coding** trends, clinical documentation, coding intensity, correlation of coding, and **medical decision complexity to medical diagnosis codes; use of natural language processing, encoders, computer assisted coding and medical concepts** integrated with electronic health records for closing gaps in coding; use of best practices **SQL database analytics** and **data quality assessments**.

g. Federal, State, written testimony in expert reports, depositions, and court appearances re: **ACA**, **HIPAA**, medical coding and billing, usual customary and reasonable cost of care, Medicaid Expansion, Medicaid waivers for disabled insureds, respite care, attendant care, home health charges and benefits (HHRGs, RAPs, LUPA, levels of clinical and other severity, OASIS assessments), SSI, SSDI, Qualified Income Trusts (QITs), and ACA Qualified Health Plans, ERISA/Taft-Hartley Trusts, subsidies, rates and actuarial value.

h. Engaged by plaintiffs, class action attorneys, relators, defendants with experience across payors (including Medicare, Medicaid, social security, workers' compensation, private insurance/health plans, ERISA/Taft-Hartley plans), providers (including hospital systems, physician groups, FQHCs, ASCs, IDTFs), patients, and healthcare IT (*see* Attachments for experience in various medical specialties).

i. Fraud data and documentation evaluations including physical therapy, orthopedics, ambulance transportation records review and eligibility for dialysis, and dialysis charges.

j. User of eDiscovery tools such as *Relativity* and *Concordance* for document discovery work, structured methods, and data normalization using SQL Server and Extract, Transform, and Load (ETL) to review large case files with over 50,000 pages in complex litigation

Non-Litigation Consulting in Healthcare, Software, Financial Services

2007 to Present **- No World Borders** – I lead a healthcare data, regulatory, and economic consulting firm as Managing Partner. Our business provides advisory services on disruptive health care regulations for hospitals, insurance companies, self-insured employers, and health IT companies and investors.

Summary of Accomplishments and Experience

I work with hospital systems, physician groups, and health IT companies, health plans, investors, and law firms. I was selected as an expert for a landmark Federal Trade Commission case regarding healthcare data, regulations, and economics. I currently serve as managing partner of No World Borders. I am:

- A writer and speaker quoted in the Wall Street Journal, and a regular speaker with published works as an expert in the field.
- Prepared by a leading litigation firm in Rule 702, including applying scientific or specialized knowledge Federal rules (702(a)); facts (702(b)); application of principles and methods (702(c)); application of criteria, principles, methodology, and test methods (amended in *Daubert*, 2000 — (702(d)) before FTC Commissioner.
- An advisor to value-based care companies, including Medicare Advantage and Medicare Shared Savings Accountable Care Organizations.
- Led investor diligence on over $8 billion in healthcare merger and acquisition transactions.
- Trained in clinician, coder, medical billing, claims, E.H.R, hospital and practice management software, and regulatory, usual, customary and reasonable (UCR) medical and prescription charges. Application of Inpatient Prospective Payment System (IPPS), Outpatient Prospective Payment System (OPPS), and Medicare Physician Fee Schedules (MPFS) Part A, Part B, Physician Fee Schedules, U.S. standard wage indices, geographic adjustment factors (GAFs), market charges comparisons (where no collateral source rule is at issue), and market reimbursement by health, auto, and liability payors.
- Opinions on over $2 billion in medical reimbursements for inpatient facilities (inpatient prospective payment system or IPPS and DRGs, ICD-9) and ambulatory (non-facility using CPT codes).

Regulatory Consulting - Health Care Provider and Healthcare I.T. Firms

I competed for, won, and led these among other account engagements where large global firms were also bidding on the business:

- **Duke Life Point Academic Medical Center, Pittsburgh —** *ACO, ICD-10, Revenue Cycle Strategy; HCC risk adjustment for Medicare Advantage. Evaluate over $1 billion in healthcare claims for risk adjustment, audit quality using RADV methods, and clinical documentation coding quality. Evaluate Meaningful Use compliance risk with respect to storage and security of discrete data from medical records, data conversion strategies, and analytics strategies.*
- **Advisory to E.H.R., Accountable Care Organizations, practice management IT companies** *— manage a team that has advised over 100 companies on Meaningful Use, Medicare Advantage, ACA, and ICD-10 regulations. Ambulatory, acute care – MU1, MU2, DSM-5, CPT, ICD-9, ICD-10, clinical documentation, HIPAA, Clinical Quality Measures, and CA Civil Code §56.*
- **Nemours Children's Hospital, Orlando, Florida —** *Meaningful Use of Electronic Health Records, HIPAA transactions for claims processing, and HIPAA secure clinical and physical plant data interoperability strategy of clinical and healthcare claims data using enterprise web services solutions. Sharing of data in emergencies between clinical staff and security to protect pediatric patients.*
- **Credible, Inc. a leading behavioral health electronic health record software vendor —** Advised regarding compliance with HIPAA Privacy and Security in general and specific privacy and security rules for the Behavioral Health specialty, International Classification of Diseases version 10 versus Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition (DSM 5), Accountable Care Organizations, and Managed Care for Behavioral Health.

Regulatory Consulting - Health Plan, Self-Insured Employers

I lead a company that competed for, won, and led these among other account engagements where large global firms were also bidding on the business:

- **Walmart, top 5 employer globally —** Advised regarding ERISA Plans, Taft-Hartley Trusts, Minimum Essential Coverage, HIPAA insurance claims transactions, CORE operating rules,

ICD-10, and Affordable Care act business and regulatory issues, underlying systems, and process issues for the largest self-insured employer in the world.

- **National Home Health Care Efficiency and Electronic Records company —** Advised regarding revenue model, including home health resource groups (HHRGs), costs and technology adoption, regional adjustments, levels of clinical severity and supplies needs for home health and long-term care, Skilled Nursing Facility populations, and businesses to develop a new home health agency technology solution that manages labor efficiencies and deployments.
- **Excellus Blue Cross Blue Shield** — Rochester, New York. Lead consulting engagement to remediate health plan enrollment process and TriZetto Facets Claims system. Rescue project from off-budget, off-plan, and restore to on-time, on-budget.

- **Blue Cross Blue Shield/Triple – S** (Salud Puerto Rico) — Lead implementation of TriZetto QNXT claims system including all process models, software implementation, and project management office.
- **Preferred Care – Florida —** Medicare Advantage HEDIS 5-Star Ratings, provider network clinical data, Utilization Management, Coordination of Benefits, Case Management and claims processing, chart review quality audits and analytics, risk adjustment using HCC and ICD-9 coding, RADV audit methods, and RAPS file analytics.
- **United Healthcare, Florida —** Medicare Advantage HEDIS 5-Star Ratings, provider network clinical data, Utilization Management, Coordination of Benefits, Case Management and claims processing using HCC and ICD-9 coding, RADV audit methods, and RAPS file analytics.
- **Public Employees Health Plan, Salt Lake City, Utah —** Advised and assessed re: new medical coding and medical policy management remediation to comply with ICD-10, which impacts medical policy plan design, actuarial processes, covered amounts, utilization management, eligibility, referrals, covered amounts, and other factors.
- **Regence BlueCross BlueShield, Seattle, Salt Lake, Portland** — HITECH Act, HIPAA 5010, ICD-10 processes, DRGs, Ambulatory claims, Ancillary Services, and IT architecture to enable these capabilities which impacts medical policy plan design, actuarial processes, covered amounts, utilization management, eligibility, referrals, covered amount calculations.
- **TennCare – Tennessee Medicaid and TN Insurance Exchange eligibility**
- ***Citra Health Solutions, Jacksonville FL*** *— Advisor to CEO. Advised leadership regarding value-based care, HIPAA privacy and security, meaningful use, and strategic partnerships and*

acquisitions for Medicare Advantage and Accountable Care market. Focus on value-based pricing, Medicare Advantage Risk Adjustment using HCCs; population health, patient and physician engagement, and quality reporting.

- ***Alliance Family of Companies*** — Advised regarding regulatory compliance for EEG telehealth and EKG medical coding and billing, payor reimbursement, fair market value of medical directors using MGMA guidelines, professional fee and technical fee components of medical billing, Medicare Administrative Contractor, and private payor coverage determinations.

Investor Diligence — $8 billion in Health IT M&A transactions

Selected as advisor regarding investor diligence on large healthcare mergers and acquisitions.

- **London PE Firm —** pre-IPO cloud security business for healthcare.
- **Kleiner Perkins Caufield & Byers, Silicon Valley** — work with founding partners of VC that funded Google, Netscape, Amazon, Amgen, Intel, and Sun Microsystems on largest cloud healthcare investment *in Medicare Advantage and Accountable Care population health management and analytics.*
- **NY PE Firm** - Liability insurer and compliance with **Medicare Medicaid SCHIP Extension Act of 2007** (**MMSEA**) reporting as provided for in Section 111.
- **NY PE Firm** – diligence on $500 million acquisition of Medicare Administrative Contractor (MAC) electronic data connectivity and services company. Evaluate financial projections and growth potential, capabilities regarding claims status, new EDI standards, medical policy plan design, actuarial processes, covered amounts, utilization management, eligibility, referrals, covered amount calculations, and other factors.
- In-Network and Out of Network medical charges, **340B Drug discount provider.**
- **Attachment available detailing transaction experience**

Medical Device, Pharmaceutical Regulatory Compliance

Abbott Labs, Medical Optics Div. (formerly Advanced Medical Optics) — Regulatory Affairs, FDA Compliance — led global complaint handling rollout (US, UK, EU, Asia) of pharmacovigilance solution supporting FDA Adverse Event reporting rules to FDA Adverse Event Reporting System (FAERS), National Drug Codes (NDCs), HCPCS, formularies, and health insurance coverage determinations for pharmaceuticals. Consultant to Optics division

on global FDA Adverse Event reporting system and pharmacovigilance system for medical devices and pharmaceuticals.

Led hardware and software development team through IQ/OQ/PQ process (IQ stands for Installation Qualification. OQ is Operational Qualification and PQ is Performance Qualification for FDA approval for medical device.

Prior Experience, Non-Litigation Consulting Work

October 2002 to February 2007 — **First American/CoreLogic — SVP eCommerce —** *Banking solutions for $8 billion firm. Led one of the largest, most complex Sarbanes Oxley IT audits in the U.S., according to attorneys and accounting firm. Led rollout of single platform eCommerce solution to integrate Wells Fargo, JP Morgan Chase, Bank of America,* transactions for mortgage loan origination (credit, valuation, tax, flood, title), closing, and securitization. Member of industry Standards committees regarding document authenticity and eSign standards Mortgage Industry Standards Maintenance Organization (MISMO), the Mortgage Electronic Registration System (MERS),responsible for integrating the Fannie Mae electronic note (eNote), security instrument and application, hybrid paper-electronic mortgages which uses the e-Sign 21 C.F.R. Part 11 ("Part 11") and Uniform Electronic Transactions (UETA) Standards.

2002 to October 2003 — Fidelity — SVP eCommerce — Banking solutions, $12 billion firm. Met eCommerce deadline for roll out of new electronic appraisal network, responsible for roll out of electronic eCommerce exchange for financial services products consumed by mortgage loan originators.

May 2000 to 2002 — Citrix Systems — President & CEO (Erogo, a SaaS Cloud medical and internet billing company). *Built cloud SaaS internet medical billing company from $500k to $10 million in revenue and investment by Citrix.* Contracted as HIPAA Business Associate with healthcare providers at the outset of HIPAA Requirement for Business Associates in 2000 – 2003.

June 1997 to October 1999 to 2000 ***Axway/Worldtalk, (Acquired by Tumbleweed Communications)*** Silicon Valley — VP Marketing for a secure email and Cloud/Internet of Things (IoT) rules-based interoperability company.

June 1997 to October 1999 — **Heidrick & Struggles, Silicon Valley** — President & CEO**, LeadersOnline** — Hired by premier executive search firm to *build and lead an online recruiting business to diversify and assist with IPO. Set strategy, acquired assets, and led launch of Internet*

recruiting business as portion of IPO prospectus (S-1) and road show with Goldman Sachs, adding $100 million to market cap of Heidrick at IPO.

September 1992 to 1997 —Oracle, HP, Symantec, Intel - Served as management consultant to Hewlett Packard on their web services strategy for enterprise clients; developed internet content joint venture partnerships between Oracle and media companies; and Corporate Development. Led IP licensing strategy and partnerships between Symantec and Intel (online software distribution), derivative works negotiations; assisted attorneys in software knowledge domain; served as Vice President of Marketing and Channel Sales for an object-oriented software development tool company; built team and helped grow company to a $50 million acquisition.

Ashton-Tate, Borland, Cincom Systems / Parc Place — Silicon Valley, Southern California, Boston — roles from Product Manager, VP Marketing and Channel Sales. Built a company from $2 million to $50 million buyout, owner of $350 million P&L and brand relaunch, turnaround. Led product requirements, worked with customers and engineering teams, developed branding, managed public relations, advertising and research firms. Launched advertising campaigns in Wall Street Journal and other publications for largest database software brand. Conducted product research for branding including qualitative focus groups and quantitative research for branding and brand confusion (Squirt test and Eveready test), [21] survey designs to avoid confusion, address segments, avoid confusion (test cell, control cell).

Supplemental Attachments Available Upon Request

CV ATTACHMENT 1 - HEALTHCARE TRANSACTIONS AND PROCESSES

CV ATTACHMENT 2 - PRIVATE PAYOR, ACO, IDN, MEDICARE (PART A, B, C, D), HEALTH IT EXPERIENCE

CV ATTACHMENT 3 - INVESTOR TRANSACTIONS AND DILIGENCE

CV ATTACHMENT 4 - AFFORDABLE CARE ACT, MEDICAID, SOCIAL SECURITY, INSURANCE EXCHANGE, BENEFITS DETERMINATION (1 OF 2)

CV ATTACHMENT 4 - AFFORDABLE CARE ACT, MEDICAID, SOCIAL SECURITY, INSURANCE EXCHANGE, BENEFITS DETERMINATION (2 OF 2)

CV ATTACHMENT 5 - MEANINGFUL USE OF ELECTRONIC HEALTH RECORDS, WORKFLOWS, PHYSICIAN EXPERIENCE OPTIMIZATION (1 OF 3)

CV ATTACHMENT 6 - HEALTHCARE BUSINESS TRANSACTIONS, SUPPORTING HIPAA X12

CV ATTACHMENT 7 - REVENUE CYCLE MANAGEMENT, CLINICAL DOCUMENTATION AND CODING PROCESSES

CV ATTACHMENT 8 – DRUG PRICING PRACTICES USING ANALYTICS TO IDENTIFY - UCR (FAIR MARKET VALUE) IN PHARMACEUTICAL PRICING

CV ATTACHMENT 9 - HIPAA PRIVACY RULE AND HIPAA SECURITY RULE, HITECH ACT INFORMATION SAFEGUARDS AND STATE STATUTES

CV ATTACHMENT 10 - RURAL HEALTH CENTERS (RHCS), CRITICAL ACCESS HOSPITALS (CAHS), FEDERALLY QUALIFIED HEALTH CENTERS (FQHCS)

CV ATTACHMENT 11 - CLINICAL DOCUMENTATION, CODING, BILLING, REGULATORY AND REIMBURSEMENT, FRAUD PREVENTION, AND SAFETY TRAINING

CV ATTACHMENT 12 - MEDICAL/LABORATORY TEST FEES

CV ATTACHMENT 13 - AMBULANCE, TRAUMA ACTIVATION FEES, ANESTHESIOLOGY

CV ATTACHMENT 14A –SAFETY POLICIES FOR HEALTHCARE PROVIDERS - CERTIFICATION REVIEW PROCESSES GUIDELINES AND JOINT COMMISSION STANDARDS:

CV ATTACHMENT 14B – NATIONAL PATIENT SAFETY GOALS DEFINED BY THE JOINT COMMISSION, ELEMENTS OF PERFORMANCE TO MEET GOALS FOR THE PURPOSES OF AUDITING POLIES & PROCEDURES

CERTIFICATION OCTOBER 2019

CV ATTACHMENT 15 - MEDICAL DEVICES, PHARMACEUTICAL 510(K) PREMARKET SUBMISSIONS, ADVERSE EVENTS

CV ATTACHMENT 16A – PAIN MANAGEMENT PRACTICES AND OPIOID PRESCRIBING UNDER FEDERAL CONTROLLED SUBSTANCES ACT AND STATE LAWS, OPIOID REVERSAL AND MEDICATION ASSISTED TREATMENT (MAT) AND CLINICAL RESEARCH / CLINICAL TRIALS DATA FORENSICS

CV ATTACHMENT 16B – PAYOR DATA AND COVERAGE DETERMINATIONS, MEDICATION-ASSISTED TREATMENT FOR ALCOHOL AND OPIOID USE DISORDERS AND OF MEDICATION FOR THE REVERSAL OF OPIOID OVERDOSE

CV ATTACHMENT 16C – PAYOR DATA AND COVERAGE DETERMINATIONS, GENERIC AND BRAND NAME DRUGS, ORPHAN DRUGS, FORMULARIES, PHARMACY AND THERAPEUTICS (P&T) COMMITTEES, COVERAGE TIERS

CV ATTACHMENT 17 - DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, SUPPLIES (DMEPOS)

CV ATTACHMENT 18 - PATENT STATUTES, SUB PARTS, RULES, CASE LAW, SCOPE OF WORK AS TECHNICAL AND DAMAGES EXPERT (1 OF 4)

CV ATTACHMENT 19 – MEDICARE MEDICAID SCHIP EXTENSION ACT OF 2007 REPORTING UNDER SECTION 111

CV ATTACHMENT 20 – EEG AND TELEMEDICINE FOR PRIMARY CARE AND THE NEUROLOGY SPECIALTY

CV ATTACHMENT 21 – AMBULATORY SURGICAL CENTER FACILITY FEES, EXCLUSIONS

CV ATTACHMENT 22 - CLINICAL LABORATORY IMPROVEMENT AMENDMENTS OF 1988 (CLIA) CERTIFICATIONS AND CLIA COMPLIANCE TO MAINTAIN CERTIFICATION

CV ATTACHMENT 23 – LABORATORY BILLING, REFERENCE LABS, MOLECULAR PATHOLOGY, TOXICOLOGY

CV ATTACHMENT 24 – CERTIFIED COMPLIANCE OFFICER TRAINING

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.)

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, Miami (now owned by United Healthcare), as well as Independent Diagnostic Testing Facilities (IDTFs).

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.	Confidential
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	**$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. Coordinated with project manager, 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 por

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. Standards for:
    a. user dashboards, clinical desktops,
    b. face sheets, patient charts,
    c. checkout workflow; orders,
    d. progress notes,
    e. CMS guidelines,
    f. review of systems (types),
    g. business intelligence,
    h. clinical decision support workflows;
8. Team rehearsals for audits, E.H.R. 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

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

- 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).

Prior work in drug coverage determinations and medical policies of Medicare, Medi-Cal, and private insurers.

Researcher, clinical trials and pharmaceutical consultant publications.

Leader of a team that assesses and advises HIPAA Covered Entities Regarding Standards and implementation of Privacy, Security, HITECH Act, including:

HIPAA Privacy Rule and HIPAA Security Rule Standards for PHI:

1. **"**Administrative Safeguards"
2. **"**Physical Safeguards"
3. **"**Technical Safeguards"
4. Organizational Policies and Procedures and Documentation Requirements
5. "Breach" under the Privacy Rule, including but not limited to 45 C.F.R. § 164.402.
6. "Breach Notification for Unsecured Protected Health Information" Section 13402(f) of the HITECH Act - content requirements for the breach notice … **(**4) a brief description of what the covered entity involved is doing to investigate the breach, mitigate the harm to individuals, and to protect against any further breaches…"
7. "Business Associate," "Covered Entity," under the Privacy Rule, including but not limited to 45 C.F.R. § 160.103.
8. "Designated Record Set" under the Privacy Rule, including but not limited to 45 C.F.R. § 164.501.
9. "Disclosure" under the Privacy Rule, including but not limited to 45 C.F.R. § 160.103.
10. "De-Identification Standard" including § 164.514(b)(1) Expert Determination and §164.512(b)(2) Safe Harbor, removal of 18 identifiers
11. "Electronic Protected Health Information" or "ePHI" under the Privacy Rule, including but not limited to 45 C.F.R. § 160.103.
12. Four-factor breach / risk assessment as part of HIPAA Omnibus Rule
13. "Individual" under the Privacy Rule, including but not limited to 45 C.F.R. § 160.103.
14. "Minimum Necessary" under the Privacy Rule, including but not limited to 45 C.F.R. §§ 164.502(b) and 164.514(d).
15. "Privacy Rule" Standards for Privacy of Individually Identifiable Health Information at 45 C.F.R. Part 160 and Part 164, Subparts A and E.
16. "Protected Health Information" or "PHI" in 45 C.F.R. §§ 160.103 and 164.501, and is the information created or received by BA.
17. "Required by Law" in 45 C.F.R. § 164.103.
18. "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.
19. "Sanction Policy" (see §164.308(a)(1)(ii)(C))adjusts the disciplinary action based on and investigation of the severity of the violation (intent) and patient impact (harm) for pre-2013 breaches, and 2013 HIPAA Omnibus Rule standards 'the recipient of the PHI; and whether the PHI was actually acquired or viewed;' which provide specific guidance regarding potential patient harm assessments. (see 'Four factor risk assessment')
20. "Security Rule" 45 C.F.R. Part 160 and Part 164, Subparts A and C.
21. "Subcontractor" under the Privacy Rule, including but not limited to 45 C.F.R. § 160.103.
22. "Unsecured Protected Health Information or PHI" under the Privacy Rule, including but not limited to 45 C.F.R. § 164.402.
23. "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.[22]
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.[23]
14. DRG calculations, ICD-10, IPPS, OPPS payment systems, November 2013.[24]
15. Diagnostic Imaging & Nuclear Medicine (PET-Scans), September 2014.[25]
16. Medical Auditing, including focus on anesthesiology, pathology, evaluation management, radiology, chemotherapy, psychotherapy, physical therapy, modifiers, and medical necessity. November 2015.[26]
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.[27]

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.[28]

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.[29]

26. Certified Professional Coder curriculum, 10,000 Series Integumentary[30] System, February 25, 2018.[31]

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.[32]

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 Standards 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 14A –Safety Policies for Healthcare Providers - Certification Review Processes Guidelines and Joint Commission Standards:

Health Care Medication Management, Drug Interaction Best Practices Materials and Staffing Services Certification, Personnel File Review, Risk Management Joint Commission Standards [6] which are designed in part to avoid Sentinel Events[7]:

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

[6] 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.

[7] 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 14B – National Patient Safety Goals Defined by the Joint Commission, Elements of Performance to Meet Goals for the Purposes of Auditing Polies & Procedures
Certification October 2019

Goal 1 - Improve the accuracy of patient identification

NPSG.01.01.01 - Use at least two patient identifiers when providing care, treatment, and services.
NPSG.01.03.01 - Eliminate transfusion errors related to patient misidentification

Goal 2 - Improve the effectiveness of communication among caregivers

NPSG.02.03.01 - Report critical results of tests and diagnostic procedures on a timely basis

Goal 3 - Improve the safety of using medications.

NPSG.03.04.01 - Label all medications, medication containers, and other solutions on and off the sterile field in perioperative and other procedural setting
NPSG.03.05.01 - Reduce the likelihood of patient harm associated with the use of anticoagulant therapy.
NPSG.03.06.01 - Maintain and communicate accurate patient medication information

Goal 6 - Reduce the harm associated with clinical alarm systems.

NPSG.06.01.01 - Improve the safety of clinical alarm systems

Goal 7 - Reduce the risk of health care–associated infections.

NPSG.07.01.01 - Comply with either the current Centers for Disease Control and Prevention (CDC) hand hygiene guidelines or the current World Health Organization (WHO) hand hygiene guidelines.

NPSG.07.03.01 - Implement evidence-based practices to prevent health care–associated infections due to multidrug-resistant organisms in acute care hospitals (applies to, but is not limited to, epidemiologically important organisms such as methicillin- resistant Staphylococcus aureus (MRSA), Clostridium difficile (CDI), vancomycin-resistant enterococci (VRE), carbapenem-resistant enterobacteriaceae (CRE), and other multidrug-resistant gram-negative bacteria).

NPSG.07.04.01 - Implement evidence-based practices to prevent central line–associated bloodstream infections (short- and long-term central venous catheters and peripherally inserted central catheter (PICC) lines).

NPSG.07.05.01 - Implement evidence-based practices for preventing surgical site infections.

NPSG.07.06.01 - Implement evidence-based practices to prevent indwelling catheter-associated urinary tract infections (CAUTI).

Goal 15 - The hospital identifies safety risks inherent in its patient population.

NPSG.15.01.01 - Identify patients at risk for suicide

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 and devices
b. Led implementation of a global pharmacovigilance complaint handing system

CV ATTACHMENT 16A – Pain Management Practices and Opioid Prescribing under Federal Controlled Substances Act and State Laws, Opioid Reversal and Medication Assisted Treatment (MAT) and Clinical Research / Clinical Trials Data Forensics

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. **Controlled Substances Act Compliance Audits**
   a. Audit Protocol Development Methodology
   b. Goals in Reviewing a Pain Management Practice
   c. Physician Prescribing Analytics
   d. Examine Prescribing Volume and Days of Supply per Patient
   e. Diagnoses of population and medical necessity of opioids
   f. Initial Patient Intake and Examination
   g. Formulation of Treatment Plan
   h. Pain Management Agreement
   i. Re-Assessment
   j. Objective Measures and Corrective Action
   k. State PDMP Database Checks
   l. Toxicology / Drug Screening
   m. Titration / Weaning
   n. Termination
   o. PEG Screening Tool
   p. Objective tools to describe pain levels in patients based on CDC and other standards
   q. DOJ Diversion Control Division CSA Guidelines
   r. Medical Necessity and the CSA
   s. The Practitioners Manual, Section IV – Record Keeping
   t. The Practitioners Manual, Section V – Valid Prescription Requirements
   u. The Practitioners Manual, Section VI – Opioid Addiction Treatment Programs

2. **State Treatment with Opioid Patient Agreements and compliance**, toxicology protocols, State prescription drug management programs (PDMPs)

3. **Data Analytics competencies:**
   a. Human Data Science analytics regarding use of Naloxone, Narcan, Evizio (high-risk / low-risk populations)
   b. Patient access data, utilization reviews, abuse patterns
   c. Medicare, Medicaid and private payor coverage determinations and claims analytics
   d. **FAERS** Adverse Event reports (see Attachment 15) and National Addictions Vigilance Intervention and Prevention Program (**NAVIPPRO)** Addiction Severity Index (ASM-MV), Comprehensive Health Assessment for Teens (**CHAT**), **RADARS** Opioid Treatment and Survey of Key Informants Programs (**OTP** and **SKIP**, respectively), Treatment Episode Data Set (**TEDS**) admission-based census that includes data from facilities that receive public funds
   e. **BARDA** - Biomedical Advanced Research and Development Authority HHS ASPR, the Technical Resources, Assistance Center, and Information Exchange (**TRACIE**)

4. **Clinical Trials Research Data Forensics (CDISC)**
   a. Organize (SEND)
   b. Plan (PRM)
   c. Collect (CDASH)
   d. Organize (SDTM)
   e. Analyze (ADaM)
5. **Clinical Trials covered by CMS**
   a. ICD-9, ICD-10 diagnosis codes
   b. Modifiers for procedure codes
   c. Coverage criteria

CV ATTACHMENT 16B – Payor Data and Coverage Determinations, Medication-Assisted Treatment for Alcohol and Opioid Use Disorders and of Medication for the Reversal of Opioid Overdose

Expertise in analysis of prescribing data, data standards, distribution and Coverage Determinations by payors, Guidance from the Substance Abuse and Mental Health Services Administration SAMHSA:

Prior Speaking Engagements re Behavioral Health and Substance Abuse:

See list of presentations to Behavioral Health / substance abuse specialists in main body of C.V.

Drug Utilization Data and Coverage Determinations:

- Fee for Service Medicaid plan
- Medicaid managed care organizations (MCOs)
- Medicare (Local Coverage Determinations or LDCs retired and active during applicable date(s) of service
- Commercial Medical Policies (over 15 across 60 payors) such as ultra-rapid detoxification (UROD)
- Presence or absence of diagnosis, diagnosis codes and other indications for medically necessary care determinations

Drug Classification Systems:

- HCPCS codes for drugs,
- drug classification systems (published author with prior experience in compounding pharmacies – see C.V. attachment 8),
- DOJ investigations of data standards for ePrescribing and E.H.R.s

Alcohol Use Disorder Medications:

1. Acamprosate calcium (oral) (Campral)
2. Disulfiram (oral) (Antabuse)
3. Naltrexone (oral)
4. Naltrexone (extended-release injectable) (Vivitrol)

Opioid Use Disorders:

1. Buprenorphine (sublingual)
2. Buprenorphine (subdermal/implant) (Probuphine)
3. Buprenorphine (extended-release injectable) (Sublocade)
4. Buprenorphine/ naloxone (oral, Bunavail [buccal], Suboxone [sublingual], Zubsolv [sublingual])
5. Methadone (oral) (Dolophine)
6. Naltrexone (oral)
7. (extended-release injectable) (Vivitrol)

CV ATTACHMENT 16C – Payor Data and Coverage Determinations, Generic and Brand Name Drugs, Orphan Drugs, Formularies, Pharmacy and Therapeutics (P&T) Committees, Coverage Tiers

1. Insurance Coverage Requirements
    a. Prior treatment with inexpensive Amantadine IR required first
    b. Prior authorization required
    c. Orphan drug status provides tax incentives but in the end is problematic for payors
        i. Orphan drug and reformulated generic immediately puts drug on radar with health plans to scrutinize for cost
        ii. Orphan drug / media public policy state concern for drugs not considered novel e.g. (Immediate release ("IR") vs. Extended release ("ER"))
2. Payer four-tier structure in formularies, in which the higher the tier the higher the patient cost-sharing:[33]
        1. Tier 1: generic drugs
        2. Tier 2: preferred brand-name drugs
        3. Tier 3: non-preferred brand-name drugs (Gocovri)[34]
        4. Tier 4 ("specialty tier") for so-called specialty drugs: specialty drugs are defined by the Centers for Medicare and Medicaid Services as therapeutic agents costing more than $600 per patient per month.

3. Formulary time to market
    a. Impact on payor acceptance – time to formulary impacts payor coverage
    b. Impact on e-prescribing if not in formulary for physicians when using E.H.R.

4. Clinical trials studies diligence, consultant publications and resultant f**ormulary composition** offered by a health plan payer based on medications that a panel of independent medical experts on pharmacy and therapeutics **(P&T)** committee select based on evidence of the drug's IR v. ER (e.g. pharmacokinetics), efficacy and price.

5. AMA committee methods to determine if a drug receives a new HCPCs code based on criteria such as 'significant therapeutic distinction.'

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

Generally familiar with 280 classifications of HCPS usual customary and reasonable charges, and classifications of DMEPOS, 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…

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 [35] [36]

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), and E.H.R. data forensics
        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), Revenue Codes, Place of Service Codes (POS)
- Outpatient Prospective Payment System (OPPS)
- Usual Customary and Reasonable Charges

ASC facility fees and exclusion criteria including:

- Medicare, industry guidance, and other accreditation organizations and requirements
- Types of care, e.g.:
  1. Nursing
  2. Technician and related services
  3. Diagnostic or therapeutic services or items directly related to the provision of a surgical procedure
  4. Administrative, recordkeeping and housekeeping items and services
  5. Operating surgeon's supervision of the services provided by an anesthetist
  6. Drugs
  7. Biological
  8. Surgical dressings
  9. Supplies
  10. Splints
  11. Casts
  12. Appliances and equipment that are directly related to the provision of surgical procedures
  13. Anesthesia materials and implants, including intraocular lenses (IOLs)
  14. Some anesthetic agents
  15. Biologics
  16. Radiologic services

CV Attachment 22 - Clinical Laboratory Improvement Amendments of 1988 (CLIA) Certifications and CLIA Compliance to Maintain Certification

1. CLIA Certificates and CLIA numbers.[37]
2. CLIA Certification types
    a. Certificates of waiver,
    b. Certificate for Provider-Performed Microscopy Procedures (PPMP),
    c. Certificate of Registration,
    d. Certificate of Compliance, Certificate of Accreditation during the relevant dates.
3. CLIA Accreditation organizations:
    a. Commission on Office Laboratory Accreditation (COLA), www.cola.org
    b. College of American Pathologists (CAP), www.cap.org
    c. The Joint Commission (TJC), www.jointcommission.org
    d. American Association of Blood Banks (AABB), www.aabb.org
    e. American Association for Laboratory Accreditation (A2LA), www.a2la.org
    f. American Osteopathic Association, www.osteopathic.org
    g. American Soc. for Histocompatibility and Immunogenetics (ASHI), www.ashi-hla.org
    h. CMS, or CMS via any State agency

CLIA and HIPAA – Accuracy and Authentication for Reporting Lab Test Results

Reasonable and objective measures used to ensure the accuracy, reliability and timeliness of clinical laboratories' test results including but not limited to **authentication process** used to determine that requests for records can be identified as belonging to that patient.[38, 39, 40]

CLIA training and proficiency testing (PT) [41] regarding:

a. Laboratory Quality Assurance,
b. the College of American Pathologists' (CAP) accuracy-based proficiency testing (PT),
c. PT quality requirements issued by the Centers for Medicare and Medicaid Services (CMS) and the dates of any training or testing.
d. laboratory's enrollment in PT
e. A copy of the notification to HHS of approved enrollment program for each specialty, subspecialty, and analyte or test [42]

Bill Type of Bill (TOB) 141 and related types, modifiers, CPT codes, customary billing practices

Beginning in calendar year (CY) 2014, payment for most laboratory tests (except for molecular pathology tests) is packaged under the Outpatient Prospective Payment System (OPPS). The general rule for OPPS hospitals is laboratory tests should be reported on a 13x TOB. There are limited circumstances described below in which hospitals can separately bill for laboratory tests. For these specific situations the Centers for Medicare & Medicaid Services (CMS) expanded the use of the 14x TOB to allow separate billing and payment at CLFS rates for hospital outpatient laboratory tests.

Molecular pathology described by CPT codes in the ranges of 81200 through 81383, 81400 through 81408, and 81479 are not packaged in the OPPS and should be billed on a 13X type of bill." [43]

For example, for the following molecular pathology tests:

81200 - ASPA (aspartoacylase) (e.g., Canavan disease) gene analysis, common variants (e.g., E285A, Y231X)

81301 - Microsatellite instability analysis (e.g., hereditary non-polyposis colorectal cancer, Lynch syndrome) of markers for mismatch repair deficiency (e.g, BAT25, BAT26), includes comparison of neoplastic and normal tissue

Typical modifiers:

- **90** Reference (outside) laboratory: when laboratory procedures are performed by a party other than the treating or reporting physician, the procedure may be identified by adding modifier 90
- **59** Distinct procedural service: under certain circumstances, it may be necessary to indicate that a procedure or service was distinct or independent from other non-e/m services performed on the same day.

OIG compliance guidance

- Corporate Integrity Agreements, (CIAs) and Certification of Compliance Agreements (CCAs)
- Supplemental Compliance Program Guidance for Nursing Facilities (73 Fed. Reg. 56832; September 30, 2008)
- Compliance Program Guidance for Nursing Facilities (65 Fed. Reg. 14289; March 16, 2000)
- Draft Compliance Program Guidance for Recipients of PHS Research Awards (70 Fed. Reg. 71312; November 28, 2005)
- NSTC Launches Government-Wide Initiative Based on OIG Draft Guidance for HHS Research Grants (June 7, 2006)
- Supplemental Compliance Program Guidance for Hospitals (70 Fed. Reg. 4858; January 31, 2005)
- Compliance Program Guidance for Hospitals (63 Fed. Reg. 8987; February 23, 1998)
- Compliance Program Guidance for Pharmaceutical Manufacturers (68 Fed. Reg. 23731; May 5, 2003)
- Compliance Program Guidance for Ambulance Suppliers (68 Fed. Reg. 14245; March 24, 2003)
- Compliance Program Guidance for Individual and Small Group Physician Practices (65 Fed. Reg. 59434; October 5, 2000)
- Compliance Program Guidance for Medicare+Choice Organizations (64 Fed. Reg. 61893; November 15, 1999)
- Compliance Program Guidance for Hospices (64 Fed. Reg. 54031; October 5, 1999)
- Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics, and Supply Industry (64 Fed. Reg. 36368; July 6, 1999)
- Compliance Program Guidance for Third-Party Medical Billing Companies (63 Fed. Reg. 70138; December 18, 1998)
- Compliance Program Guidance for Clinical Laboratories (63 Fed. Reg. 45076; August 24, 1998)
- Compliance Program Guidance for Home Health Agencies (63 Fed. Reg. 42410; August 7, 1998)
- IG Remarks
- Compliance Program Guidance for Hospitals (63 Fed. Reg. 8987; February 23, 1998)
- Supplemental Compliance Program Guidance for Hospitals (70 Fed. Reg. 4858; January 31, 2005)

[1] I found that most of the healthcare rationing doctrine focused on ensuring the poor and improving access to care, and that if these were not done then the only other solution was removing waste based on the assumption

that we have a fixed budget to work with. What was not included in academic treatises a recognition that it is also imperative to detect and reduce fraud to free up resources to deliver medical care to those who need it.

[2] "Distributive justice in its modern sense calls on the state to guarantee that everyone is supplied with a certain level of material means. **Samuel Fleischacker** argues that guaranteeing aid to the poor is a modern idea, developed only in the last two centuries. Earlier notions of justice, including Aristotle's, were concerned with the distribution of political office, not of property. It was only in the eighteenth century, in the work of philosophers such as Adam Smith and Immanuel Kant, that justice began to be applied to the problem of poverty. To attribute a longer pedigree to distributive justice is to fail to distinguish between justice and charity." Source: A Short Story of Distributive Justice - https://www.hup.harvard.edu/catalog.php?isbn=9780674018310 Fleischacker explains how confusing these principles has created misconceptions about the historical development of the welfare state. Socialists, for instance, often claim that modern economics obliterated ancient ideals of equality and social justice. Free-market promoters agree but applaud the apparent triumph of skepticism and social-scientific rigor. Both interpretations overlook the gradual changes in thinking that yielded our current assumption that justice calls for everyone, if possible, to be lifted out of poverty. By examining major writings in ancient, medieval, and modern political philosophy, Fleischacker shows how we arrived at the contemporary meaning of distributive justice.

[3] Research regarding rights violations and how they negatively affect access to health services and supported implementation. (See An Assessment of Human Rights-Based Approaches to Health Knowledge, Attitudes, and Practices Among Centers for Disease Control and Prevention Locally Employed Staff). The World Health Organization (WHO) posits that human rights standards and principles—such as participation, accountability, equality and non-discrimination—can be integrated into all aspects of public health practice, including assessment and analysis, priority setting, program planning and design, implementation, and monitoring and evaluation. (See WHO, A human rights based approach to health. Available at https://www.who.int/hhr/news/hrba_to_health2.pdf).

[4] "Despite the common sense appeal of increasing quality transparency, the macro level data suggest that the reality of public reporting initiatives has fallen short of the promise. For example, several empirical studies show that the launch of Hospital Compare website and other efforts to increase quality transparency have not resulted in tangible improvements in outcomes (see, e.g., Ryan et al. (2012), DeVore et al. (2012), Smith et al. (2012), Fung et al. (2008), and Hibbard (2008)). The simplest explanation for this is that the reality of public reporting has not yet caught up with the promise. empirical studies such as Dranove et al. (2003) and Dranove and Sfekas (2008) have found evidence that patients do respond to quality information of the type provided through public reporting initiatives…" "…the calibration of our model with CMS data suggests a quality transparency level of about 53% in 2008…" (See Can Public Reporting Cure Healthcare?
The Role of Quality Transparency in Improving Patient-Provider Alignment). I noted that these treatises ignored state and federal laws that require reporting of some conditions or outcomes such as infectious disease or adverse events.

[5] I noted that some faculty unilaterally expanded the role of their ethics treatises from values of patient autonomy, nonmaleficence, beneficence, justice, and veracity to public, fiscal, and legal policy. For example, faculty and community ethics members associated with Harvard recommended, "…or the minimum health care that an undocumented and uninsured immigrant can obtain, can be raised from the current EMTALA / Community Health Care models to include ongoing medical treatments for some chronic conditions." Essentially, this proposal means treat all uninsured illegal aliens with full medical care regardless of whether they are citizens or have insurance. (See ACCESS TO MEDICAL CARE for UNDOCUMENTED and

UNINSURED IMMIGRANTS A Response to a Request for Community Input, A report for the Harvard Ethics Leadership Group by the Community Ethics Committee."

[6] "Over 22 million patients in the U.S. live with rare genetic diseases for which there are no FDA-approved treatments. Over 3.5 million of these patients are children who will die before the age of five. While genome sequencing can help diagnose these patients, it is far too long and costly to develop treatments for their orphan diseases through usual forms of scientific and pharmaceutical investment. Case studies discuss the scientific and ethical challenges facing single-patient (N=1) trials, as well as the opportunities presented by this entrée into what may be termed "hyper-personalized medicine."

[7] 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.

[8] Computational manipulation of knowledge is an important, and often under-appreciated, aspect of biomedical Data Science. The first Data Science initiative from the US National Institutes of Health was entitled "Big Data to Knowledge (BD2K)." The main emphasis of the more than $200M allocated to that program has been on "Big Data;" the "Knowledge" component has largely been the implicit assumption that the work will lead to new biomedical knowledge. However, there is long-standing and highly productive work in computational knowledge representation and reasoning, and computational processing of knowledge has a role in the world of Data Science. Knowledge-based biomedical Data Science involves the design and implementation of computer systems that act as if they knew about biomedicine. See NLM Knowledge based biomedical data science. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6171523/

[9] Examples included methods to use controlled terminology that "…enhances the process of identifying patients who are potentially eligible for clinical trials of experimental therapies in a clinic that is limited by the existence of a singular clinical trial coordinator. Effective implementation of such a system requires the development of a meaningful controlled medical terminology that satisfies the needs of a diverse community of providers all of who contribute to the health care process…" https://www.ncbi.nlm.nih.gov/pubmed/8591141

[10] Logic and Artificial Intelligence Stanford Encyclopedia of Philosophy. https://plato.stanford.edu/entries/logic-ai/

[11] Much of the Stanford faculty's treatises compare knowledge reuse to software code reuse. Ontology examples were presented for web search engines, etc. (see Modern Architectures for Intelligent Systems: Reusable Ontologies and Problem-Solving Methods), https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2232188/pdf/procamiasymp00005-0083.pdf however the complexity of mapping codes, for example such as ICD-10 CM or ICD-10 PCS to meaning is much more challenging.

[12] MedlinePlus in contrast to National Library of Medicine, Google Scholar and PubMed
[13] The PICO process (or framework) is a mnemonic used in evidence based practice (and specifically Evidence Based Medicine) to frame and answer a clinical or health care related question. The PICO framework is also used to develop literature search strategies, for instance in systematic reviews. The PICO acronym stands for

- P – Patient, Problem or Population
- I – Intervention
- C – Comparison, control or comparator
- O – Outcome(s) (e.g. pain, fatigue, nausea, infections, death)

[14] inferential statistics (one of the two main branches of statistics. Inferential statistics use a random sample of data taken from a population to describe and make inferences about the population)
[15] Technically, Granted in Part, Denied in part. See C.V. end note 2. Partial grant of motion was not due to expert qualifications but based on procedural issues and the Court's determination of what was admissible.

[16] Technically, based on procedural circumstances, the Motion was granted in part, denied in part, based on procedural grounds, not the expertise or methods of the Expert (in that Judge Lew's ruling permitted Arrigo to give testimony and found that his specialized knowledge and methodology were sound, but precluded Arrigo from stating how many hours a physician might have spent performing specific procedures). "Relator fails to allege in the Amended Complaint that Dr. Khossoussi was unable to work the time he billed to Medicare. Further, Dr. Khossoussi argues that Mr. Arrigo's opinions regarding the possibility of Dr. Khossoussi working the time he billed are unfounded and irrelevant to Relator's remaining claims. Because Relator has failed to offer any opposition to these arguments, any opposition is waived."
[17] The Court permitted Arrigo to give testimony. GRANTED prosecution's motion only pertaining to preclude testimony Arrigo may give regarding state of mind, or billing error rates, GRANTED production of non-privileged documents and DENIED production of privileged documents. "The Court notes that although Arrigo may not use the CMS guidance to provide a definition of fraud, Arrigo may refer to the CMS guidance to discuss the CMS's targeting of Belcher."

[18] Denied subject to voir dire. Opposing counsel never called their expert after Arrigo's deposition testimony stating that Defendant's expert methods were flawed. Therefore, Arrigo not called as he was designated as a rebuttal expert to Defendant's expert and there was no voir dire. The case was settled before trial.

[19] As explained by retaining counsel who was present for the hearing on motions to exclude: With regard to the motions to exclude, the Judge denied the motion to bar Arrigo's report/testimony. Concerning the amended reports, the Judge ruled it would be unfair to allow plaintiff (opposing party to Arrigo's retention) to revise his report to add another category of damages and another year of historical collection rates after the DED. So their amended report was stricken. In the interest of fairness the Judge struck Arrigo's amended expert report but allowed his original December 2018 report, and said that Arrigo can testify as to any supplemental information or stylistic-type amendments. But he did not believe Arrigo needed an amended report to do that. While we don't agree with the holding, it is a good development as plaintiff cannot increase damage calculation, or introduce 2011 historical collection rates.

[20] A sixth opinion regarding a physician named as a Defendant recanted his earlier statements was precluded but the reason stated is that both litigants stipulated to this as a fact.
[21] In a standard Eveready format, a respondent is first shown an exemplar,(Context can convey information that consumers use in making source determinations. With point of purchase surveys, therefore, "the closer the survey context comes to marketplace conditions, the greater the evidentiary

weight it has," McCarthy, 3, § 32:163, which often requires displaying actual products, packaging and other source indicia that consumers would encounter at the point of sale), and a photograph or advertisement of defendant's branded product (With post-sale confusion, context (adjacent competitive products, signage, etc.) is irrelevant and would give the respondent information not typically available in a post-sale encounter. See Gateway, Inc. v. Companion Prods., Inc., 68 U.S.P.Q.2d 1407, 1420 (D.S.D. 2007) ("Post-sale confusion is particularly relevant in this case because . . . [a]fter Cody Cow is purchased, the point of sale materials are removed by the purchaser, and [have] no 'confusion obviating effect'"). Accordingly, photographs or videos that fairly reproduce what a respondent would see post sale may be easier to control (and afford greater certainty as to what respondents see) than actual displays that a field service may fail faithfully to execute in a shopping center interviewing booth. See Hermès Int'l v. Lederer de Paris Fifth Ave. Inc., 50 F. Supp. 2d 212, 222 (S.D.N.Y. 1999) approving a post sale stimulus showing a "Kelly bag (as carried by a woman walking at a distance of four feet)."

[22] 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.

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

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

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

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

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

[28] Health Care Incentives Improvement Institute, HC3i.

[29] Health Care Incentives Improvement Institute, HC3i.

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

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

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

[33] Blue Cross Blue Shiled of Michigan How do Drug Tiers Work? Page Last Updated Thu Aug 09 16:23:33 EDT 2018 / Y0074_Jul19BCBSMBCNWeb CMS Accepted 07062019. See https://www.bcbsm.com/medicare/help/understanding-plans/pharmacy-prescription-drugs/tiers.html

[34] Formulary Navigator https://client.formularynavigator.com/Search.aspx?siteCode=5972287365&targetScreen=3&drugBrandListBaseKey=gocovri%2B137%2Bmg%2Bcapsule%252cextended%2Brelease

[35] 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

[36] John R. Thomas, Claim Re-Construction: The Doctrine of Equivalents in the Post-Markman Era Georgetown University Law Center

[37] **Medicare Claims Processing Manual Chapter 16 - Laboratory Services**

***(Rev. 4299, 05-03-19)* 70.4 - CLIA Numbers (Rev. 1, 10-01-03) A3-3628.2.D**

The structure of the CLIA number follows:

Positions 1 and 2 contain the State code (based on the laboratory's physical location at time of registration);

Position 3 contains the letter "D"; and

Positions 4-10 contain the unique CLIA system assigned number that identifies the laboratory. (No other laboratory in the country has this number.)

Initially, providers are issued a CLIA number when they apply to the CLIA program.

[38] CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports Final Rule, Centers for Medicare & Medicaid Services (CMS), HHS; Centers for Disease Control and Prevention (CDC), HHS; Office for Civil Rights (OCR), HHS.

[39] CLIA Program and HIPAA Privacy Rule; Patients' Access to Test Reports Final Rule, Centers for Medicare & Medicaid Services (CMS), HHS; Centers for Disease Control and Prevention (CDC), HHS; Office for Civil Rights (OCR), HHS. At "**IV. Provisions of the Final Regulations**"

[40] HIPAA Privacy Rule at § 164.524(c)(3)(ii). Subject to certain conforming amendments, this final rule retains the CLIA regulatory provision that requires the release of test reports only to authorized persons, to the persons responsible for using the test reports, and to the laboratory that initially requested the test.

[41] **§493.15 Laboratories performing waived tests.**

(a) *Requirement.* Tests for certificate of waiver must meet the descriptive criteria specified in paragraph (b) of this section.

(b) *Criteria.* Test systems are simple laboratory examinations and procedures which—

(1) Are cleared by FDA for home use;

(2) Employ methodologies that are so simple and accurate as to render the likelihood of erroneous results negligible; or

(3) Pose no reasonable risk of harm to the patient if the test is performed incorrectly.

(c) *Certificate of waiver tests.* A laboratory may qualify for a certificate of waiver under section 353 of the PHS Act if it restricts the tests that it performs to one or more of the following tests or examinations (or additional tests added to this list as provided under paragraph (d) of this section) and no others:

(1) Dipstick or Tablet Reagent Urinalysis (non-automated) for the following:

(i) Bilirubin;

(ii) Glucose;

(iii) Hemoglobin;

(iv) Ketone;

(v) Leukocytes;

(vi) Nitrite;

(vii) pH;

(viii) Protein;

(ix) Specific gravity; and

(x) Urobilinogen.

(2) Fecal occult blood-non-automated;

(3) Ovulation tests—visual color comparison tests for human luteinizing hormone;

(4) Urine pregnancy tests—visual color comparison tests;

(5) Erythrocyte sedimentation rate—non-automated;

(6) Hemoglobin—copper sulfate—non-automated;

(7) Blood glucose by glucose monitoring devices cleared by the FDA specifically for home use;

(8) Spun microhematocrit; and

(9) Hemoglobin by single analyte instruments with self-contained or component features to perform specimen/reagent interaction, providing direct measurement and readout.

(d) *Revisions to criteria for test categorization and the list of waived tests.* HHS will determine whether a laboratory test meets the criteria listed under paragraph (b) of this section for a waived test. Revisions to the list of waived tests approved by HHS will be published in the Federal Register in a notice with opportunity for comment.

(e) Laboratories eligible for a certificate of waiver must—

(1) Follow manufacturers' instructions for performing the test; and

(2) Meet the requirements in subpart B, Certificate of Waiver, of this part.

[57 FR 7139, Feb. 28, 1992, as amended at 58 FR 5221, Jan. 19, 1993; 82 FR 48773, Oct. 20, 2017]

[42] §493.801 Provides specific requirement to enroll in the CLIA Program:

"Condition: Enrollment and testing of samples.

Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.

(a) *Standard; Enrollment.* The laboratory must—

(1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart.

(2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; and

(ii) For those tests performed by the laboratory that are not included in subpart I of this part, a laboratory must **establish and maintain the accuracy of its testing procedures, in accordance with §493.1236(c)(1).** [emphasis added]" [42]

This Standard applies to all tests except waived tests. Waived tests do not include genetic tests

[43] Medicare Administrative Contractor Palmetto GBA, CMS Manual System Pub 100-04 Medicare Claims Processing
https://www.palmettogba.com/palmetto/providers.nsf/vMasterDID/9FRR7A4285?open