

Michael F. Arrigo Curriculum Vitae

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Undergraduate Education and College Degree

The University of Southern California, Los Angeles, CA — Bachelor of Science, Business Administration, **1981**, Entrepreneur Program - management decision-making, leadership, marketing, financing of startups.

The University of California, Irvine — Studies in Economics, Inferential Statistics,¹ and Computer Science; multiple programming languages and software development methodologies and usability studies, 1976 to 1978.²



Postgraduate Courses, Training, Certificate Programs

Harvard Medical School, Cambridge, MA — **Clinical Bioethics and Risk Management**, certificate, **2018**³ - ethical, legal, technological issues in Medicine^{4,5,6,7} **AI and Precision Medicine** 2019; Privacy, prediction, precision medicine⁸ Addiction Medicine 2022⁹

Stanford Medical School, Palo Alto, CA — **Biomedical Informatics**, **2015**^{10,11} - biomedical systems, data, knowledge,¹² terminologies,¹³ rule-based systems, description logic, 'Artificial Intelligence in medicine,'¹⁴ ontologies and problem-solving methods,¹⁵ **Locating and using medical information in a digital age**, May 2019,¹⁶ evidence-based clinical decisions.¹⁷

Wharton School, University of Pennsylvania, Philadelphia, PA – **Board of Directors'** effective Governance of public companies, April 2023.¹⁸

Massachusetts Institute of Technology, Cambridge, MA - MIT Sloan School **Blockchain Technologies** blockchain-based ventures; crypto assets, cryptography, and cybersecurity, shared ledgers, Merckle trees,¹⁹ evaluating Initial Coin Offering (ICO) investments,²⁰ privacy, proof of work,²¹ mining, evaluation of over twenty crypto ventures with case studies. 2022²²

Ruling by the U.S. Court of Appeals, where Arrigo's Opinions were Adduced

See *U.S. v Mirando*; No., 17-50386; D.C. No. 2:16-cr-00215-PA-1 before Gould and Nguyen, Circuit Judges, and Marbley, U.S. District Judge, Southern District of Ohio,²³ U.S. Court of Appeals, Ninth Circuit partially **VACATED** and **REMANDED** sentencing; the Court made its decision, in part, after considering Arrigo's opinions in Defendant-Appellant brief 4/9/19.

Decision by the Office of Medicare Hearings and Appeals (OMHA) Before U.S. Administrative Law Judge where Arrigo's Opinions were Adduced

FULLY FAVORABLE decision. See *Appellant Dr. Eric Justin Brahlin OMHA Appeal No. 3-10749034046* before Robert S. Fisher, U.S. Administrative Law Judge. Judge Fisher stated,

“After considering the evidence and arguments presented in the record and at the hearing, the undersigned Administrative Law Judge (ALJ) enters a FULLY FAVORABLE decision in the appeal regarding ambulatory video electroencephalographic (EEG) monitoring (95951), on multiple dates of service,” based in part on “...Michael Arrigo offered sworn testimony on behalf of the appellant.” 12/6/22.

Federal Rulings Regarding Motions to Exclude Expert, Stipulations as Expert

1. Motion by the government prosecutor for more information **DENIED** - *UNITED STATES of AMERICA v Perez* Court Docket No. 3:20-cr-86 (M.D. Florida) (retained by counsel for criminal defendants S. Porter and J. Porter) in June 2022, U.S. District Judge Timothy J. Corrigan denied a motion from the prosecution for more information about Arrigo’s expert report, stating that the report met the requirements under Federal Rules of Criminal Procedure, Rule 16.²⁴
2. Motion to exclude **DENIED**^{25, 26} - *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.** (Retained by Relator) 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 ...**” 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...**” re: illegal kickbacks, 550-bed hospital system billing, physician billing compensation, skilled nursing, subacute care, psychiatric care, ambulance, Medicaid, Medicare fraud. Feb. 2018
3. Motion to exclude **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 and rebutting the prosecution’s applications of methods, statistically invalid sample sizes, improper extrapolation, consistency in applying regulatory guidance, clinical documentation, medical diagnosis codes, procedure codes, application of criteria to Medicare coverage

policies (i.e., Medicare Local Coverage Determinations (LCDs)), identification of duplicated or missing data in alleged \$30 million Medicare fraud case. When Defendant's opposition prevailed, the Government withdrew its Daubert challenge.

4. Parties **STIPULATED** that Arrigo is an expert – *Thomas Hammock v. Snoqualmie Casino* Civil Action No. SNO-CIV-2019-0918 Randy Doucet, Chief Judge SNOQUALMIE TRIBAL COURT October 23, 2020. Trial testimony. Opinions regarding historical and future medical coding, medical billing, customary and reasonable community charges for emergency ambulance transportation, diagnostic imaging, anesthesia, surgery center facility fees, orthopedic surgeon's fees, hospital inpatient stays, Diagnosis Related Groupings (DRGs).
5. Motion to exclude **DENIED** – MSPA CLAIMS 1, LLC, a Florida limited liability company, Plaintiff, v. TOWER HILL PRIME INSURANCE COMPANY, a Florida profit corporation, TOWER HILL CLAIMS SERVICE, LLC, a Florida limited liability company Defendants. CASE NO.: 1:18-cv-00157. Judge Allen C Winsor of the UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF FLORIDA, GAINESVILLE DIVISION. Motion pertained to class certification. Opinions, generally: educating the Court and the trier of fact regarding the Industry Standard data and processes that are followed by health plans and by the healthcare industry, especially those provided for by the HIPAA Privacy Rule, the ARRA HITECH Act of 2009 Safeguards, and the HIPA Standard for Disclosures for Judicial and Administrative Proceedings. Also, the Standards employed in the normal course of business processes with respect to electronic data for healthcare claims, payment, and insurance coverage and eligibility. Whether the industry Standard electronic data and processes used by the health insurance industry were adopted for Medicare Secondary Payer Act, Section 111 of the Medicare, Medicaid, and SCHIP²⁷ Extension Act of 2007 (MMSEA) Mandatory Insurer Reporting (MIR) for Non-Group Health Plans (NGHP) who are Responsible Reporting Entities (RREs),²⁸ Insurance subrogation, and Third-Party Liability (TPL). Whether Defendant is an RRE, implemented the data and process Standards that it is responsible for implementing as an RRE, and performed its duties as an RRE concerning an exemplar insured. Whether Plaintiff and Defendant also use those electronic Standards. Whether Plaintiff's discovery requests for the production of electronic class-wide data are reasonable based on the data that NGHPS must already maintain, whether based on the testimony of the PMK, Defendant's efforts

demonstrated the implementation of capabilities to meet the Standards, whether based on its implementation, Defendant can assert that it now cannot produce the requested information because it is ‘burdensome,’ ‘irrelevant,’ or that it is precluded from doing so because of HIPAA or other privacy standards.

6. Motion to exclude **DENIED** – *John D. Thomson v. HMC Group et al.* 2:13-CV-03273 U.S. DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA (Los Angeles) before U.S. District Judge Dolly M. Gee, December 1, 2015. (Retained by Plaintiff) Opinions regarding Intellectual Property; Copyright (260) and damages in the form of lost revenues to a copyright holder; opinions regarding hospital medical coding and billing, revenue codes, revenue attributable to Operating Rooms over a specified period applicable to the use or unauthorized use of a copyrighted architectural design for an operating room.
7. Motion to exclude **DENIED** as to exclusion but granted in part as to the scope of testimony²⁹ – *United States v. Ganesh and Belcher* Case No. 16-CR-00211-LHK (retained by Defendant Belcher) U.S. DISTRICT COURT, 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.”

State / Worker’s Comp Rulings Regarding Motions to Exclude Expert, Stipulations

8. A motion in Limine to preclude testimony and opinions of Arrigo **DENIED** subject to voir dire at trial. At trial, the Court admitted Arrigo as an expert in physician compensation - See Frank Giordano v Georgia De Toledo, Case no: FST-CV-18-6039157-S, Superior Court, J.D. of Stamford / Norwalk at Stamford, Connecticut, 6/20/2023.
 - a. Testimony regarding damages in the form of lost income for an interventional cardiologist who routinely performs various approaches of transcatheter aortic valve replacements (TAVR, e.g., CPT codes 33361, 33362, 33363, 33364, 33365, 33366, 33367, 33368, 33369)

- b. Utilization of Industry-Standard methods (e.g., Fair Market Value (FMV) of physician compensation using a comparison of physician productivity using work RVUs (wRVUs)), Medical Group Management Association (MGMA) industry benchmarking for similarly situated physicians by productivity, medical specialty, geography, number of years practicing medicine, on-call time, etc.
 - c. Lost compensation compared to similarly situated physicians in academic medical centers
 - d. National Institutes of Health (NIH) grants,
 - e. faculty tenure and level (e.g., instructor, assistant professor, associate professor, and professor),
 - f. income derived from teaching vs. practicing medicine).
9. Motion to exclude **DENIED** – See *KAITLYNN DERANI v. E.A., a minor child by and through JAMES TIMOTHY ALBI* Colorado Case Number: 2021CV30, District Court, Douglas County, Colorado. In a recent case in Colorado, the plaintiffs sought to exclude my testimony by alleging that I used insurance as a collateral source as the basis for my opinions in a personal injury case. I did NOT. The Court denied the motion to exclude my testimony. September 26, 2022, ruling of Jeffrey K. Holmes, District Court Judge
10. Parties **STIPULATED** that Arrigo is an expert – *Alikai Health, LLC v. Travelers*, WCAIS No. 8304084 MF-590085 COMMONWEALTH OF PENNSYLVANIA DEPARTMENT OF LABOR AND INDUSTRY BUREAU OF WORKERS' COMPENSATION, September 2020. Affirmed an expert by William J. Hall, a former Workers' Compensation Judge, and Certified Workers' Compensation Specialist as authorized by the Pennsylvania Supreme Court. Opinions re: Medicare payment mechanisms, National Coverage Determinations and LCDs for Durable Medical Equipment (DME) and

prosthetics, orthotics, and supplies (POS), usual customary and reasonable charges under workers' compensation in all 50 states, Federal Worker's Compensation, private payors.

11. Motion to exclude **DENIED** ³⁰ – *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). Defendants argued that a capitated Medicare Part C plan paid for Plaintiff's medical care, 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. Judge Williams states, "This value is generally determined by expert testimony."
12. Motion to exclude **DENIED** ³¹ - *Thomas McGuigan v. Source One, et al.*, Docket MER-L-2096-16 Superior Court of New Jersey, County of Mercer. (retained by Defendant) "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, and improper extrapolation.
13. Motion to exclude **DENIED** – *Higgs v. Plum Healthcare et al.* Case No. 34-2015-00186569-CU-PO-GDS SUPERIOR COURT OF THE STATE OF CALIFORNIA FOR THE COUNTY OF SACRAMENTO (retained by Defendant) Hon Richard K. Sueyoshi denied a motion to exclude Arrigo. Order from the bench. Opinions regarding electronic health record forensic audit, observation of opposing expert, Minimum Data Set 3.0 (MDS 3.0), and Resource Utilization Groups (RUGs) not a standard in the State of California for staffing (case mix hours, expected hours) for patient care, but rather for reimbursement, Medicaid (Medi-Cal) payment of Skilled Nursing Facilities based on per diem rates.
14. Motion to exclude **DENIED** ³² – *Marina Ascarate v. College Hospital Costa Mesa*; JAMS Ref. No. 1220059632, Hon. Rex Heeseman (Ret.) (ret. by Plaintiff) 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.

Arbitration Rulings Regarding Motions to Exclude Expert, Stipulations as Expert

15. *ASM Medical Ventures v. Dr. Trinh*. AAA Case, California. Counsel for Defendant motioned to exclude Arrigo as an expert in corporate governance concerning disclosures of Related Party Transactions and the importance of the accuracy of financial statements for healthcare companies.³³ Based on Arrigo's prior experience leading a Sarbanes Oxley internal audit of a Fortune 100 public company, his familiarity with Public Company Accounting Oversight Board (PCAOB) guidance, and his current service as a member of the Board of Directors of a public company where he serves on the Audit Committee and as chair of the Compensation Committee, the motion to exclude Arrigo was DENIED by the arbitrator. August 18, 2023.
16. *Ramapo Anesthesiologists v. Origin Healthcare*. AAA Case, New Jersey. Counsel for Defendant submitted Arrigo as an expert without objection by Plaintiff; the arbitrator admitted Arrigo as an expert to provide testimony on May 19, 2023.
17. *Hughes v. Ancestry et al.* Motion to exclude **DENIED**. AAA Case 01-21-0004-8999 Brad I. Pearson, Arbitrator, 8/31/22, Kansas City, MO. (retained by Plaintiff). Opinions regarding FTC privacy rules pertaining to personal health records (PHRs), HIPAA privacy and security rules, Business Associates, identifiers in protected health information (PHI) hybrid-entities, and consent requirements for research required notice before sharing information without consent, including compound authorizations, de-identification standards, and limited data sets for research. Whether DNA is biometric information. Whether Centimorgans³⁴ are part of industry-Standards for determining the risk of re-identification. Whether a privacy policy that tells users that DNA is not personal information is deceitful. Whether privacy policies and procedures of Defendant met Standards.

18. Parties **STIPULATED** that Arrigo is an expert - *San Francisco Spine Surgeons v. Claim Works, LLC*. JAMS No. 1110018697 9/17/2017, Transcript Volume III. (retained by Defendant Claim Works) 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 the plaintiff to support assertions in their complaint, and industry-standard roles and responsibilities of providers, coders, and billing entities when not specifically provided for by the contractual agreement.

19. Motion to exclude **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. (retained by Defendant) 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 insured's benefits under state Medicaid and Affordable Care Act 'metal' plans provide, Federal Poverty Level (FPL) guidelines on insurance eligibility, out of pocket maximum (OOPM) costs to an insured.

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

In UNITED STATES OF AMERICA, Plaintiff-Appellee, v. MICHAEL MIRANDO, Defendant-Appellant, the Government's intended loss standard resulted in an increase in the level of sentencing guidelines from six to thirty. As a result, at the sentencing hearing, the lower court initially imposed a 97-month sentence, which was appealed.

Retained by Defendant to review Presentence Investigation Report under U.S. Sentencing Guidelines 26 (USSG) §2B1.1, evaluated using U.S. Sentencing Commission (USSC) methods, specialized knowledge, training, education, and experience. Prepared a rebuttal report in response to the methods: sample size, lack of comprehensive clinical documentation review, and 'intended loss' vs. 'actual loss' used by the Government.

My opinions were adduced as part of the Appellant's Opening Brief by James W. Spertus (CA SBN 159825), Attorney for the Defendant-Appellant, filed on April 4, 2018. As a result, the U.S. Court of Appeals "...**VACATED AND REMANDED**..." sentencing of the Defendant.

In the 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:

- “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 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 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 full reimbursement of the amount billed.” “...The district court abused its discretion when it concluded that the Government’s evidence met this ‘clear and convincing’ standard.

Rulings, Orders Re: Arrigo Opinions in Class Certifications

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

- CERTIFIED - *Jene 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 Defendant 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 (receiving a healthcare claim, adjudicating a claim [pay, pend, or deny], application of medical policies and coverage determinations], information technology with

respect to producing electronic claim data based on these Standards, storage, retrieval, and reporting.

Rulings – Motion for Summary Judgement where Arrigo Opinions were Considered

A California State judge denied Defendant's motion for summary judgment where counsel retained me for the Plaintiff in a California Confidentiality of Medical Information Act (CMIA) and HIPAA Privacy Breach Case. See J.K., KIRSTY KEILEN MATTHEW KEILEN v LAURA LEE KAISER; PETER HANS KAISER; JOHN MUIR HEALTH, Case No.: MSC19-00213, SUPERIOR COURT OF THE STATE OF CALIFORNIA IN AND FOR THE COUNTY OF CONTRA COSTA. ORDER AFTER HEARING ON MOTION FOR SUMMARY JUDGMENT OR SUMMARY ADJUDICATION FILED BY DEFENDANT JOHN MUIR HEALTH. My testimony, in part, discussed the Defendants did not meet the applicable standards for the safekeeping of medical information. I stated that technologies were commercially available and widely used by other hospitals from JMH's electronic health records vendor, Epic, before the breach in this case, which would have prevented or limited Nurse Kaiser's conduct. For example, Epic's privacy tool, "Break the Glass" has been available since 2014.

Rulings Re Arrigo Opinions - Trade Secret, Patent Infringement

Served as expert in support of a motion to dismiss a case involving, in part, alleged infringement of Trade Secrets. Below is a summary of the case and Arrigo's scope:

- DISMISSED with PREJUDICE – *Consortia Health Clinical Continence Services, LLC v. Sharda 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 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 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, the decision tree often dictates that the owner seek patent protection because a patent will provide greater protection.

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).

- While this was a State case, I applied Generally Accepted Standards to the analysis. *See* CV SUPPLEMENT 18 - Patent Statutes, Sub Parts, Rules, Case Law, Scope of Work as Technical and Damages Expert (1 of 4), *page 67*.

Certifications

1. Certified Professional Medical Auditor (CPMA) training; 3/20 to 5/20, 16.25 hours.³⁵
2. Medicare Fraud Waste and Abuse 9/21³⁶
3. Certification: HIPAA Privacy and Security Rules, Calif. Confidentiality of Medical Information (CMIA), Patient Access to Health Records Act (PAHRA), Insurance Information, Privacy Protection (IIPPA), Collection of Medical Information for Direct Marketing, Shine the light, 10/21/19³⁷
4. HEDIS Star Ratings, Risk Adjustment 11/19³⁸
5. Managing Ambulatory Surgical Ctr. Staff, 3/20³⁹
6. Certification: Joint Commission National Patient Safety Goals, 5/18/21⁴⁰
7. Certification: Ambulance Documentation Specialist, 5/18⁴¹
8. RAI MDS 3.0, RUG Skilled nursing assessment and data collection requirements.⁴²
9. Medicare Part B Appeals Process Overview⁴³
10. Medical coding for clinical pathology; recognizing specimen interference in clinical laboratories 9/21⁴⁴
11. Principles in addiction medicine.⁴⁵
12. Medicare Independent Diagnostic Test Facilities⁴⁶



Industry Awards and Recognition

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

Selected Quotations

(2023) **Kaiser Health** <https://kffhealthnews.org/news/article/new-york-bariatric-surgery-provider-patient-lawsuits-medical-debt/> Opinions regarding the usual customary and reasonable charges, coinsurance, co-pay, deductible, debt-collection practices, out-of-network payment agreements, for medical billing in cases involving bariatric surgery.

(2023) **ABC News 15 Television, Arizona.**” DOJ: Scottsdale Physicians Group may have ‘upcoded’ and ‘improperly admitted’ patients.” Interviewed regarding Medicare billing fraud. <https://www.abc15.com/news/local-news/investigations/doj-scottsdale-physicians-group-may-have-upcoded-and-improperly-admitted-patients>

(2022) **Forbes Advisor** <https://www.forbes.com/advisor/health-insurance/what-is-cobra-insurance/> Quoted regarding COBRA eligibility, thresholds requirements for employers as to COBRA coverage levels.

(2022) **Tech News World** <https://www.technewsworld.com/story/google-cloud-introduces-new-ai-powered-medical-imaging-suite-177173.html> Contacted by a journalist to provide opinions regarding Google’s New Artificial Intelligence-based Medical Imaging suite, the efficacy of the promised capabilities for various diagnostic imaging modalities such as CT Scan, MRI, etc. and by medical specialty, and the requirement of well-structured data to ensure the reliability of artificial intelligence based image recognition.

(2022) **Part B News.** (the article is only available behind a paywall for subscribers). “After Meta pixel HIPAA gaffe, check your online business associate agreements.” Quoted regarding Meta / Facebook practice of using “Meta pixel” that would, without the patients knowledge, make “an intimate receipt of the appointment request for Facebook.”

(2022) **USA Today / Milwaukee Journal Sentinel** <https://www.jsonline.com/in-depth/news/2022/01/26/prenatal-care-businesses-grow-under-cloud-fraud-infant-mortality/6111168001/> Opinions regarding Medicaid fraud, the Affordable Care Act and Essential Health Benefits such as prenatal care coordination, inducements to patients (Federal Beneficiary Inducement Statute (“BIS”) prohibiting an individual or entity from providing remuneration to patients who are eligible for Medicare or Medicaid benefits).

(2021) **Kaiser Health News** <https://khn.org/news/article/letters-of-protection-personal-injury-cases-surprise-bills/> Opinions regarding medical billing and ethical issues in personal injury cases involving orthopedic spine surgery, facility fees, surgeon's fees.

(2021) **The Daily Beast** <https://www.thedailybeast.com/the-sneaky-way-docs-and-lawyers-leave-patients-with-debt> Opinions regarding medical billing and ethical issues in personal injury cases involving orthopedic spine surgery, facility fees, surgeon's fees, Letters of Protection (LOP)

(2021) **Consumer Affairs.** <https://www.consumeraffairs.com/news/having-trouble-with-your-prescriptions-complaints-about-pbms-show-that-you-arent-alone-062221.html> **Having trouble with your prescriptions? Complaints about PBMs show that you aren't alone.** Provided opinions to a journalist regarding formulary exclusions and access to care.

(2021) – **Consumer Affairs.** <https://www.consumeraffairs.com/news/facebook-goes-all-in-on-covid-19-vaccination-tools-for-its-users-031621.html> **Facebook goes all-in on COVID-19 vaccination tools for its users.** Provided opinions to a journalist regarding privacy risks with Facebook, Federal Trade Commission Regulations of 'personal health records.'

(2021) – **NBC News Affiliate KPRC Houston** <https://www.click2houston.com> – COVID-19 Vaccine eligibility and medical ethics – Non-U.S. Citizens from Mexico, Argentina traveling to the U.S. to gain access to the vaccine. Commentary regarding medical ethics and bioethics decisions, the role of hospital ethics committees, American Medical Association ethical guidelines, Stark, Anti-kickback Statutes and inducements to provide care where Medicaid or Medicare is billed for COVID related care or vaccinations. County, State and Federal CDC guidelines regarding classification of patients (Phase 1A, Phase 1B, etc.), Texas Health and Human Services, Texas Department of State Health Services guidelines and protocols.

(2021) **Cape Cod Times** <https://www.capecodtimes.com> – COVID-19 contact tracing proven effective by World Health Organization (WHO), Centers for Disease Prevention and Control (CDC); how does a substance use disorder clinic follow both epidemiological guidelines and HIPAA Privacy rule? Who can be notified (i.e., treating medical staff? non-treating medical staff? county, state health departments? public?) of a patient is known to have COVID?

(2020) – **KNX 1070 News Radio** – Emergency Medical Treatment and Labor Act (EMTALA) and California law AB-72 regarding balance billing, out-of-network care. October 22, 2020.

(2020) – **Inside Higher Ed** - Gag Order or Privacy Concern? When it comes to their students testing positive for COVID-19, professors say they have a right to know and share the information how they deem appropriate. Colleges want to keep those cases close to the vest. Quoted re: **HIPAA, FERPA** in higher education and student privacy.

<https://www.insidehighered.com/news/2020/08/31/colleges-want-professors-stay-mum-student-covid-19-cases>

(2020) **The Lund Report** - Moda Wins Supreme Court Case, insurers can collect the \$12 billion spent on so-called “risk corridors.” <https://www.thelundreport.org/content/moda-wins-supreme-court-case>

(2020) – **This is Reno** - How Reno is grappling with COVID-19 infectious disease <https://thisisreno.com/2020/03/podcast-how-reno-is-grappling-with-covid-19/> Patient privacy and how potential COVID-19 patients may impact first responders.

(2020) **Tech News World** - *Ask Siri if You Have the Coronavirus* <https://www.technewsworld.com/story/Ask-Siri-if-You-Have-the-Coronavirus-86587.html> and *New Website Aims to Help People Access COVID-19 Testing* <https://www.technewsworld.com/story/86573.html> Discussion regarding infectious disease diagnostic tools

(2020) **The Capitol Forum** Vol. 8, No. 76 March 2 - *Natera: Company Using Incorrect Billing Codes to Inflate Insurance Cost, According to Billing Experts* <https://thecapitolforum.com>

(2020) **New England Psychologist** - *Feds investigate data breach at Maine’s Sweetser*. HIPAA Privacy and Security Issues, measures to prevent hacking and improper uses and disclosures of protected health information, required investigations and reporting to HHS Office of Civil Rights. <https://www.nepsy.com/articles/feds-investigate-data-breach-at-maines-sweetser/>

(2019) **Fortune.com** - *Electronic Health Records Creating a 'New Era' of Health Care Fraud, Officials Say the federal government funneled billions in subsidies to software vendors and some overstated or deceived the government about what their products could do, according to whistleblowers.* <https://fortune.com/longform/electronic-health-records-fraud/>

(2019) **Kaiser Health News** – *Electronic Health Records Creating a 'New Era' of Health Care Fraud* <https://khn.org/news/electronic-health-records-creating-a-new-era-of-health-care-fraud-officials-say/>

(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. Patient privacy concerns, Federal and New York State privacy Standards
<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**: *That's A Lot of Scratch: The \$48,329 Allergy Test 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/>

(2015) **Medical Economics**: *The ICD-10 transition: Avoiding revenue disruptions*
<https://www.medicaleconomics.com/health-law-policy/icd-10-transition-avoiding-revenue-disruptions/page/0/4>

(2014) **eCommerce Times**: *Accenture Tapped to Doctor Healthcare.gov*
<https://www.ecommercetimes.com/story/79783.html>

(2011) **Healthcare IT News - ICD10Watch**: 3 lessons Canadian healthcare can teach us about ICD-10 implementation <https://www.icd10watch.com/blog/3-lessons-canadian-healthcare-can-teach-us-about-icd-10-implementation>

(2011) - **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) **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

Publications included both articles that were written and published by independent media outlets and on the corporate website.

Published by Independent Media Outlets

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. (2016) CMS Merit-Based Incentive Payment System (MIPS) in 60 Day Comment Period, Sunset of Meaningful Use. <https://noworldborders.com/2016/05/12/cms-merit-based-incentive-payment-system-mips-60-day-comment-period/>

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) *Easing the Pain of Prior Authorizations*. *Healthcare Finance*

<https://www.healthcarefinancenews.com/blog/easing-pain-prior-authorization>

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. (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>

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. (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. (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>

Published by Corporate Website

Arrigo, M.F. (2022) Could Russia Use Borderless Blockchain Cryptocurrency to Circumvent Sanctions? How are blockchain transactions logged? Are there ways to control blockchain transactions centrally? What are some of the privacy challenges with blockchain? Could Russia elude western sanctions using cryptocurrency? What are the impediments to replacing established currency such as the U.S. dollar with cryptocurrency? What are Asset-backed tokens? What else are we not considering in this debate? Where will future crypto-economic innovation come from?

<https://noworldborders.com/2022/03/06/could-russia-use-borderless-blockchain-cryptocurrency-to-circumvent-sanctions/>

Arrigo, M.F. (2022) Healthcare crypto-economics and blockchain models for the future.

Medicalchain business model, unique use of tokens and blockchain, crypto-economics adoption in healthcare. <https://noworldborders.com/2022/01/10/healthcare-crypto-economics-and-blockchain-models-for-the-future/>

Arrigo, M. F. (2021) Laboratory CPT codes and pathology CPT codes include services primarily reported to evaluate specimens obtained from patients (body fluids, cytological specimens, or tissue specimens obtained by invasive/surgical procedures) in order to provide information to the treating physician. This information, coupled with information obtained from history and examination findings and other data, provides the physician with the background upon which medical decision making is established. Published October 4, 2021.

<https://noworldborders.com/2021/10/04/laboratory-cpt-codes/>

Arrigo, M. F. (2021) The Medicare, Medicaid and SCHIP Extension Act (MMSEA) of 2007 contains mandatory insurer reporting in Section 111 for “Non-Group Health Plans” or NGHPs. NGHPs liability insurance (including [self-insurance governed by ERISA](#)), no-fault insurance and workers’ compensation. Published November 4, 2021.

<https://noworldborders.com/2021/11/04/mmsea-paid-act-smart-act/>

Arrigo, M. F. (2021) NSA Provides Guidance to Mitigate VPN Vulnerabilities to Hackers. Published April 15, 2021. <https://nowworldborders.com/2021/04/15/nsa-provides-guidance-to-mitigate-chinese-and-russian-hacking/>

Arrigo, M. F. (2021) Do Risk Corridors Help Health Plan Beneficiaries? The U.S. Supreme Court ruled on three cases brought by four insurers over whether insurers are entitled to \$12.3 billion in unpaid risk corridors payments from 2014 to 2016. The reactions to the ruling mostly fell along political party lines. This article presents questions and objective data to consider. Published March 2, 2021. <https://nowworldborders.com/2021/03/02/do-risk-corridors-help-health-plan-beneficiaries/>

Arrigo, M. F. (2021) California Knox-Keene Act HMO Regulations re: Out-of-Network Under EMTALA and ERISA. Published February 28, 2021

Arrigo, M. F. (2021) Genetic Testing Ethics Privacy Anti-Discrimination: Rapidly Developing Regulatory Landscape. Published February 5, 2021 <https://nowworldborders.com/expert-witness/hospital-safety-expert/genetic-testing-ethics-privacy-anti-discrimination/>

Arrigo, M. F. (2021) Use of Telemedicine During a Public Health Emergency. Published January 14, 2021 <https://nowworldborders.com/2021/01/14/use-of-telemedicine-during-a-public-health-emergency/>

Arrigo, M. F. (2021) Hospice Care for Medicare Medicaid Tricare Beneficiaries. Published January 10, 2021 <https://nowworldborders.com/2021/01/10/hospice-care/>

Arrigo, M. F. (2020) HIPAA and HITECH Act Serve as Cybersecurity Recognized Security Practices. Published December 26, 2020. <https://nowworldborders.com/2020/12/26/hipaa-and-hitech-act-serve-as-cybersecurity-standards-for-healthcare/>

Arrigo, M.F. (2019) How healthcare can benefit from blockchain. Cost of verification, cost of networking, the last mile problem, trusted governance. <https://nowworldborders.com/2019/11/15/how-healthcare-can-benefit-from-blockchain/>

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. (2019) *Pain Management, Addiction Medicine Coding, Billing Expert Provides Guidance to Comply with Medical Necessity, Medical Coding, Medical Billing and Controlled Substances Act Requirements* - <https://noworldborders.com/expert-witness/pain-management-and-addiction-medicine-coding-and-billing-expert/>

Arrigo, M.F. (2019) *Medicare 2020 Skilled Nursing Facility PPS Final Rule - The Centers for Medicare & Medicaid Services (CMS) has issued the federal fiscal year (FFY) 2020 final rule for the skilled nursing facility prospective payment system (SNEPPS). CMS' Patient Driven Payment Model (PDPM) will be effective October 1, 2019*. <https://noworldborders.com/2019/10/02/medicare-2020-skilled-nursing-facility-pps-final-rule/>

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. (2017) *Telehealth Visits Show Growth in Benefits for Insureds*. Telehealth means and methods as well as coding for enhancing healthcare, public health and health education. <https://noworldborders.com/2017/05/30/telehealth-growth-insureds/>

Arrigo, M.F. (2011) *Skilled Nursing Resource Utilization Group (RUG) Classifications*. <https://noworldborders.com/2011/08/09/skilled-nursing-resource-utilization-group-classifications/>

Lectures, Presentations, Conference Speaking Engagements

- Arrigo, M. (Speaker) (February 2022) – Medicare LCD modernization LCD Development for genetic tests, genetic test panel coding and coverage challenges, genetic sequencing in panels, one-to-many data mapping, ACCE criteria (Analytic validity, Clinical validity, Clinical utility, Ethical, legal, and social implications), Palmetto GBA unique identifiers through the DEX™ Diagnostics Exchange Registry, healthcare privacy Standards (HIPAA and The Genetic Information Nondiscrimination Act (GINA)), genetic test coverage determinations, commercial payor edits, case study: what can go wrong in payor provider litigation? Fraud and false claims act matters.
- 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 the 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) 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 an audience of over 800 participants.
- Arrigo, M. (Speaker) Wolters Kluwer 2015 webcast to over 800 pharmacists: 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 medical coding and billing standards. 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 and use of diagnosis codes for anxiety disorders, autism spectrum disorders, mood-related disorders, schizophrenia, and drug abuse. Challenges in obtaining data; value in the 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 determinations⁵ — 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). Discuss 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. 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/>

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

- 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

- Information Systems Audit and Control Association (ISACA), January 2003 to 2007
- 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 – 2012
- 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
- National Alliance of Medical Auditing Specialists (NAMAS) (February 2018)
- American Society of Radiologic Technologists (October 2019)
- American Association of Nurse Assessment Coordination (AANAC), (December 2019)
- **Contributor:** Strategic Financial Management Newsletter, Healthcare Financial Management Association;
- **Former contributor:** Healthcare IT News, GovHealth IT, Mobile Health, Financial Health News

- **Volunteer:** Children's Hospital Medical innovation committee

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 / Petition able Matters in Ex-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 – business applications of blockchain technology. Specialized interest and communication with faculty and students regarding shared ledgers and cryptography for electronic healthcare using blockchain.⁴⁷
- **American Society for Clinical Pathology** – Recognizing Specimen Interferences in the Clinical Laboratory – 9/19/21
- **American Society for Clinical Pathology** – Medical coding for lab, clinical pathology⁴⁸ – 9/19/21
- **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; updated 2021.

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.

Selected Legal Experience

(See Separate Document for List of Case Testimony. The list below is not comprehensive)

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 (\$155 million settlement).
 - 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 re: inpatient stay of trauma patient
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 the defendant in alleged **trade secret and intellectual property disputes** regarding whether certain healthcare and medical processes, electronic solutions, diagnosis codes, and procedure codes were unique, protected, and not commonly known in the industry. Work with defense counsel on discovery, prior art, and education to the Court resulted in the dismissal of the case.
 - a. **Plaintiff, Defendant, and Relator retentions** cases involving the False Claims Act and Medicare fraud; retained in cases involving 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. A 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, and 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 healthcare regulations for hospitals, insurance companies, self-insured employers, health IT companies, and investors.

May 2022 to Present - **MSP Recovery / Life Wallet** - Member of the Board of Directors, member of the audit committee, member of two special committees, and chair of the compensation committee for MSP Recovery, a leading healthcare data analytics and Medicare Secondary Payer Act (MSPA) recovery company whose stock is publicly traded.

Summary of Accomplishments and Experience

I work with hospital systems, physician groups, 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 the 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 of 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 Providers 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 advising 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 five self-funded, self-insured employer globally** — *Advised regarding ERISA Plans, Taft-Hartley Trusts, Minimum Essential Coverage, HIPAA insurance claims transactions, CORE operating rules regarding real-time eligibility and transaction Standards, coordination with Third-Party Administrator (TPA), Blue Advantage / Blue Cross Blue Shield of Arkansas, ICD-10, and Affordable Care Act, systems and processes topology for eligibility, business and regulatory issues, underlying systems, and process issues for the largest self-insured employer in the world.*
- **National Home Health Care and Post-Acute Care (SNF) 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 using Resident Assessment Instruments (RAI), Minimum Data Set 3.0, Resource*

Utilization Groups (RUGs), and Hierarchical Condition Categories (HCCs) to develop a new Skilled Nursing and home health 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 process models, software implementation, and project management office; required bilingual team to perform modeling and implementation.
- **Preferred Care – Florida** — Medicare Advantage HEDIS 5-Star Ratings, risk adjustment (HCC codes), 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, p risk adjustment (HCC codes), 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.*

- **National Independent Diagnostic Testing Facility** — Advised regarding regulatory compliance for EEG telehealth and EKG medical coding and billing, payor reimbursement, fair market value (FMV) of medical directors using MGMA and other industry guidelines, professional fee and technical fee components of medical billing, Medicare Administrative Contractor, and private payor coverage determinations.

Investor Diligence — \$8 billion in Healthcare IT, Clinical, and Crypto asset M&A transactions

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

- **Special Purpose Acquisition Company (SPAC)** – pre-acquisition diligence of blockchain crypto-asset-based storage business.
- **Special Purpose Acquisition Company (SPAC)** – pre-acquisition diligence of blockchain distributed ledger identity management venture
- **Special Purpose Acquisition Company (SPAC)** – Initial Coin Offering (ICO) business offering review.
- **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 the 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

While working as a management consultant at Abbott Labs, Medical Optics Division (formerly Advanced Medical Optics, now owned by J&J), for the Regulatory Affairs Department, I led the FDA Compliance initiative for global complaint handling which was rolled out in the U.S., U.K., EU, and Asia). This pharmacovigilance solution supported compliance with the 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. Subsequently, I led the hardware and software development team through IQ/OQ/PQ process.⁴⁹

Prior Experience, Non-Litigation Consulting Work

October 2003 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 - President & CEO (Erogo, / (Citrix Systems licensor) 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 Requirements for Business Associates in 2000 – 2003.*

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 1994 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;

1987 to 1994 - 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 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),⁵⁰ First product manager for the Lotus / Microsoft / Ashton-Tate SQL Server, a joint venture to implement SQL Server on personal computers and servers (Windows NT and IBM OS/2 Systems) after its success as a Unix-based relational database. Examined competitors; the first commercial implementations of SQL from 1979 to 1992, including the Relational Software (now Oracle) first commercially available implementation of SQL, Oracle V2 for the Digital Equipment Corp (DEC) VAX minicomputer.

Supplemental Material Available Upon Request

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<i>Arrigo, M. F. (2020) HIPAA and HITECH Act Serve as Cybersecurity Recognized Security Practices. Published December 26, 2020. https://noworldborders.com/2020/12/26/hipaa-and-hitech-act-serve-as-cybersecurity-standards-for-healthcare/</i>	20
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NOT RETAINED

Health Care Processes – Health Plans

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

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

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

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

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).

Additional Experience with Providers by 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

CV SUPPLEMENT 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	TBD

	for glycemic control compared with standard clinical practices.	
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	\$300

	engagement modules; evaluation of patent portfolio.	
Confidential	Independent Diagnostic Testing Facility (IDTF) that provides EEG and EKG services	\$250
	Total Enterprise Value	\$8.0 Billion +

CV SUPPLEMENT 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 SUPPLEMENT 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 21 st 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 SUPPLEMENT 5 - Meaningful Use / Promoting Interoperability 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.

Eight of the Top Ten Electronic Health Record Companies —

- Allscripts,
- Athenahealth,
- Cerner,
- eClinicalWorks,
- Epic,
- McKesson,
- Meditech,
- NextGen.

Assessed five mid-tier E.H.R. and smaller E.H.R. companies and practice management systems including AdvancedMD, Kareo, and Modernizing Medicine, with respect to Meaningful Use, HIPAA, and Information Safeguards compliance. Prior retention by U.S. DOJ pertaining to a particular E.H.R. and the False Claims Act; retained by Defendant/owner of E.H.R. and a hospital re: False Claims Act; presentation on E.H.R. to U.S. OIG and FBI.

Meaningful Use (MU) (now called “Promoting Interoperability”) 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 care⁵¹ (TOC), 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 SUPPLEMENT 5 - Meaningful Use of Electronic Health Records, Workflows, Physician Experience Optimization (2 of 3)

Leadership of Team with the Following Qualifications

- Served as a resource to Access Hospitals for U.S. HHS for hospital E.H.R. implementations across the country
- Experienced training the implementation process for Regional Extension Centers; co-chaired the committee that built the curriculum
- 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/YE AR	ASSIGNMENT
Certified electronic health record Technology (CEHRT) certification testing and audits	2014 to present	1. Advise E.H.R. companies on HITECH Act requirements for CEHRT, proctor and test preparation using ONC test scripts. 2. Audit / prosecution and audit defense of eligible hospitals, eligible providers in DOJ / ONC / CMS / HHS / OIG investigations
Johnstown PA	2013 – 2014	ICD-10 Transition review of Allscripts, Epic systems for Duke LifePoint, / Conemaugh Health system and processes
Confidential Client Zachary, LA	Apr 13 – Sep 14	<u>CPOE, RXM, E-Prescribe implementation for Magic 5.66 site.</u> Built all PHA and RXM dictionaries including all Order Strings. Primary resource for system preparation and workflow recommendations.
Confidential Client CO	Oct 12 – Mar 13	<u>CPOE building & support.</u> 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.
Confidential Client Galway, Ireland	Jul 12 -Aug 12	<u>MEDITECH Magic Optimization.</u> Pharmacy Assessment and recommendations. Remediation. NPR for MM, PHAMM, PHA)
Confidential Client Newburg, NY	Apr 12 – Jun 12	<u>Magic 5.66 RXM and CPOE assessment, recommendations, and remediation.</u> Build support. Workflow assessment and recommendations. Med Reconciliation NPR (ADM, NUR, PHA)
Confidential Client Arlington, TX	Jan 10 - Mar 10	<u>Pharmacy module training for new pharmacy director.</u> Included MEDITECH, Pyxis, module integration, billing process reformat.
Confidential Client Arlington, TX	Jul 09 – Sep 09	<u>Remote module support.</u> Problem analysis / remediation. Dictionary work, NPR report writing for PHA, ADM, BAR, SCH, Rules
Confidential Client Memorial Hospital Ventura, CA	Jun 08 – Jan 09	<u>Magic to Client Server Migration:</u> (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
Confidential Client Fredericksburg, TX	Nov 06 – Dec 06	<u>Clinical Workflow Assessment</u> - Workflow review and recommendations. Dictionary rebuild, MEDITECH Task completion, NPR Label reformat. EMAR/BMV project lead.
Confidential Client New Mexico	Oct 06 – Nov 06	<u>PHA Workflow & Billing Assessment</u> – Performed on-site dictionary and workflow review for PHA, BAR, AP, GL. Provided written assessment and recommendations for multidisciplinary problems; Remediation.
Confidential Client Texas	May 06 – Sep 06	<u>EMAR/BMV Installation</u> - Project Manager

Confidential Client MO	Jan 06 – May 06	<u>EMAR/BMV Installation</u> - Created a "closed loop" pharmacy where every step in the medication cycle is scanned. Coordinated with project manager, nursing analyst
Confidential Client Arizona	Nov 05 – Dec 05	<u>Pharmacy Expansion</u> : Assess and support pharmacy for the opening of an additional hospital for a corporation.
Confidential Client Arizona	Jun 05 – Nov 05	<u>EMAR/BMV Install</u> Pharmacy Analyst for multidisciplinary team. Build, testing, medication stock preparation. QA/Metric validation.
Confidential Client Illinois	Mar 05 – Jun 05	<u>New MEDITECH Installation</u> – Clinical module dictionary build, testing, training. go live support.
Confidential Client CA	May 04 – Oct 04	<u>EMAR/BMV Installation</u> - Assessment, preparation of Clinical dictionaries, bar coding pharmacy stock, project management. User go-live support. Forms and label
Confidential Client 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 Patient access to records via web or mobile portal

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

Merit-Based Incentive Payment System (MIPS):

As the meaningful use program transitioned to a focus on promoting interoperability, the Merit-based Incentive Payment System (MIPS) is one way to participate in the Quality Payment Program (QPP), a program authorized by Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). The program describes how Medicare reimburses MIPS-eligible clinicians for Part B-covered professional services and rewards them for improving the quality of patient care and outcomes. The **Merit-Based Incentive Payment System (MIPS)** determines the Medicare payment adjustments. Using a composite performance score, eligible clinicians (ECs) may receive:

1. a payment bonus,
2. a payment penalty,
3. no payment adjustment.

CV SUPPLEMENT 6 - Healthcare Business Transactions, Supporting HIPAA X12

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

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

1. Health Care Eligibility Benefit Inquiry and Response – EDI 270/271

2. Health Care Claim Status Request/Response – EDI 276/277
3. Health Care Services Request for Review/Response (Prior Auth.) – EDI 278
4. Payroll deductions for premiums – EDI 820
5. Benefit enrollment and maintenance – EDI 834
6. Health Care Claim: Payment/Advice – EDI 835,
7. Health Care Claim: institutional, professional/dental –
 - a. EDI 837I /P /D, 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 SUPPLEMENT 7 - Revenue Cycle Management, Clinical Documentation and Coding Processes
Lead team that implements hospital system assessments for ICD-10 and CPT coding compliance and quality, including:

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

Patient intake
Patient assessment
Documentation of care
Insurance coverage determination
Discharge activities
Provider communications
Referrals
Prior authorizations
Coding
Charge capture, super bills

Billing
Revenue collection
Vendor impacts
EHR and other system readiness to support clinical documentation improvement
IT plans
Impact on concurrent initiatives
Reporting
Quality improvement efforts
Payor readiness and processes; medical policy assumptions for contracting
Institutional Review Board (IRB) impact review for ICD-10
Data warehouse and business intelligence “retooling” of analytics required
National Correct Coding Initiative (NCCI), Modifiers, Bundling and Unbundling Criteria According to Centers for Medicare and Medicaid

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

- Re-Defining AWP
- % Factor
- NDC price reporting
- Mark-Ups & Price Spreads
- Backroom Processor Schemes
- Rebate Schemes
- Flat, Access, Market Share
- Rebates
- “Brand” and “Generic”
- Formulary Steering
- Pre-Authorization Schemes
- Clinical Rules & Protocols
- Mail-Order
- Leveraging Captive Facility

- Multiple MAC Lists
- Drug Switching
- Drug Repackaging
- Fraudulent Plan Design
- Zero Cost Scripts
- Higher Than Logic
- Pocketing Refunds, Reversals, and Returns
- Payor Account Crediting
- Specialty Drug Issue

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

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

Researcher, clinical trials and pharmaceutical consultant publications (confidential client).

CV SUPPLEMENT 9 - HIPAA Privacy Rule and HIPAA Security Rule, HITECH Act Information Safeguards and State Statutes

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.
24. HHS Guidance: Hybrid Entities.⁵²

CV SUPPLEMENT 10 - Rural Health Centers (RHCs), Critical Access Hospitals (CAHs), Federally Qualified Health Centers (FQHCs) Standards

1. Section 10501(i)(3)(B) of the Affordable Care Act
 2. Rural Health Clinics Act (P.L. 95-210)
 3. Section 330 of the Public Health Service Act is the section of federal statute that creates and authorizes the Health Center Program. It gives the [Bureau of Primary Health Care](#) (BPHC) the authority to make grant awards to eligible entities and outlines the requirements that health centers must meet in order to be eligible for these awards. [Health center look-alikes](#) are also subject to these requirements.
 4. The section 330 statute was most recently revised in February 2018 as part of the Bipartisan Budget Act.
- 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 Public Health Service (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))

1 0 .	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))
1 1 .	Collaborative Relationships	(Section 330(k)(3)(B) of the PHS Act and 42 CFR Part 51c.303(n))
1 2 .	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)
1 3 .	Billing and Collections	(Section 330(k)(3)(F) and (G) of the PHS Act)
1 4 .	Budget	(Section 330(k)(3)(D), Section 330(k)(3)(I)(i), and 45 CFR Part 74.25)
1 5 .	Program Data Reporting Systems	(Section 330(k)(3)(I)(ii) of the PHS Act)
1 6 .	Scope of Project	(45 CFR Part 74.25)
1 7 .	Board Authority	(Section 330(k)(3)(H) of the PHS Act and 42 CFR Part 51c.304)
1 8 .	Board Composition	Subsection (g), (h), (i), or (p). (Section 330(k)(3)(H) of the PHS Act and 42 CFR Part 51c.304)
1 9 .	Conflict of Interest Policy	(45 CFR Part 74.42 and 42 CFR Part 51c.304(b)).

CV SUPPLEMENT 11 - Clinical Documentation, Coding, Billing, Regulatory and Reimbursement, Fraud Prevention, and Safety Training

1. National Correct Coding (NCCI) claims edits, September 2012.
2. Ambulance billing and trauma activation; State, Federal CDC trauma criteria and clinical documentation Standards, Glasgow Coma scale, September 2012.
3. NAAC **Certified Ambulance Documentation Specialist (CADS)** May 2018.
4. Home health agencies Home Health Resource Groups (HHRGs), OASIS episodes of care.
5. Behavioral health, November 2013.⁵³
6. Cardiology, November 2013.

7. Family practice and internal medicine, November 2013.
8. Obstetrics, November 2013.
9. Oncology, November 2013.
10. Urology, November 2013.
11. Orthopedics, November 2013.
12. General Surgery, and Dental, November 2013.
13. Plastic Surgery, November 2013.
14. HCC, risk adjustment, November 2013.⁵⁴
15. DRG calculations, ICD-10, IPPS, OPPS payment systems, November 2013.⁵⁵
16. Diagnostic Imaging & Nuclear Medicine (PET-Scans), September 2014.⁵⁶
17. Medical Auditing, including focus on anesthesiology, pathology, evaluation management, radiology, chemotherapy, psychotherapy, physical therapy, modifiers, and medical necessity. November 2015.⁵⁷
18. Dermatopathology diagnosis relevant to medical specialty, 2016.
19. Dietetics and Nephrology, insulin DME billing for diabetes, December 2015, AHIMA.
20. Liens, balance billing, subrogation seminar, 2014.
21. Affordable Care Act “metal” plans, Medicaid expansion, Federal Poverty Level guidelines on cost of care, 2014.
22. Coding and reimbursement for Pain Management, December 2015; outpatient physical, occupational, and speech therapy, ambulance and non-emergency transportation, January 2016.⁵⁸
23. 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 2016.⁵⁹
24. HIPAA Privacy and Security test certification, HIPAATraining.com; June 2017.

25. 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.
26. Urology and toxicology screening guidelines training, In-Office Urine Drug Testing: Avoid Investigations and Audits, January 23, 2018.⁶⁰ Certified Professional Coder curriculum, 10,000 Series Integumentary⁶¹ System, February 25, 2018.⁶²
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, 2018.⁶³
28. Certified Professional Coder curriculum, Endocrine System and Nervous System, June 2018

CV SUPPLEMENT 12 - Medical/Laboratory Test Fees and Billing

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); patient identification errors
 - 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.

5. Categories of codes and tests:

- | | |
|--|--|
| 1. Organ or Disease Panels | 9. Immunology ⁷³ |
| 2. Drug Testing (presumptive, ⁶⁴
definitive, ⁶⁵ therapeutic ⁶⁶) | 10. Transfusion Medicine ⁷⁴ |
| 3. Evocative / Suppression Testing ⁶⁷ | 11. Microbiology ⁷⁵ |
| 4. Consultations / Clinical Pathology ⁶⁸ | 12. Cytopathology ⁷⁶ |
| 5. Urinalysis ⁶⁹ | 13. Cytogenic Studies ⁷⁷ |
| 6. Molecular pathology ⁷⁰ | 14. Surgical Pathology ⁷⁸ |
| 7. Chemistry ⁷¹ | 15. In Vivo ⁷⁹ |
| 8. Hematology and Coagulation ⁷² | |

CV SUPPLEMENT 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 and Documentation Standards

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 Subjective,

Objective, Assessment, and Plan (**SOAP**), **DRAATT** (**D** – Dispatch information, **R** – Response, **A** - Arrival, **A** – Assessment, **T** – Treatment, **T** – Transport), 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 SUPPLEMENT 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 Events⁷:

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,

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.

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

CV SUPPLEMENT 14B – National Patient Safety Goals Defined by the Joint Commission, Elements of Performance to Meet Goals for the Purposes of Auditing Policies & 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

PC.02.02.01 EP 1, PC.02.02.01 EP 2 - During transitions of care, there must be a process in place to ensure coordination of care among care providers – also referred to as "hand off communication". "The hospital has a process to receive or share patient information when the patient is referred to other internal or external providers of care, treatment, and services" and "The hospital's process for hand-off communication provides for the opportunity for discussion between the giver and receiver of patient information. Note: Such information may include the patient's condition, care, treatment, medications, services, and any recent or anticipated changes to any of these."

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

MM.04.01.01 EP 8 - Conducting a risk assessment allows organizations to identify risk points associated with these processes, and to ensure that such processes do not include any summary (blanket) orders for resuming medication. A proactive risk assessment (sometimes referred to as an FMEA) examines a process in detail, including sequencing of events, actual and potential risks, and failure or points of vulnerability. Risk points are then prioritized through a logical process, then process improvements - based on the actual or potential impact (that is, criticality) on quality and safety – are implemented to reduce or

eliminate risk. The introductory section of the Leadership (LD) chapter provides an example of a proactive risk assessment model that an organization may use. However, this specific approach is not mandated as there are other risk assessment tools available that may better meet the needs of the organization.

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

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

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

- I. 510(k) premarket submissions to FDA to demonstrate that device is to be marketed as safe and effective—that is, substantially equivalent to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to Premarket Approval (PMA):
- II. Device predicates as it pertains to FDA approval for a specific purpose:
- intended use;
 - technological characteristics vs. predicate;
 - technological characteristics and the information submitted to FDA;
 - does not raise new questions of safety and effectiveness;
 - demonstrates that device is at least as safe, effective as predicate.
- III. Audits of healthcare providers and claims with respect to approved devices matched to medically necessary procedures:
- a. Frequencies and bandwidths applicable to cardiac and brain diagnostic monitoring (ECG, EKG, EEG) and applicable medical procedure codes
 - b. Independent Diagnostic Testing Facility form CMS-855B (device inventories)
 - c. CPT codes matched to devices, procedure billing timelines
- IV. Performance Qualification (PQ), IQ (Installation Quality), Operational Qualification (OQ)
- a. Led embedded systems software team
 - b. Coordinated regulatory affairs work, liaison regarding IQ/OQ/PQ validation process as provided for in 21 CFR part 11
- V. Triage process for FDA Event Reporting System (FAERS) compliant complaint handling
- a. Pharmaceuticals and devices
 - b. Led implementation of a global pharmacovigilance complaint handling system

CV SUPPLEMENT 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, Evzio (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 SUPPLEMENT 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 the 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 Disorder Treatments, charges, and eligibility determinations:

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)

Elements of Collaborative Practice Agreements for Nurse Practitioners (NPs) and other clinicians in various Jurisdictions under Physician Supervision, e.g.:

- Scope of practice, for example:
 - i. Psychiatric diagnostic evaluations to assess for and determine psychiatric illness, and diagnoses that can be made (e.g., mood and anxiety disorders, psychotic disorders, disruptive behavior, developmental disorders, eating disorders, delirium, and dementia, substance use disorders, and personality disorders).
 - ii. Requesting and interpreting lab and other diagnostic procedures, such as EKGs, to rule out medical etiology for psychiatric illness or other medical conditions, and to assist in diagnosis and monitoring for adverse effects from medications.
 - iii. Request assessments/evaluations, as needed, to confirm or support diagnoses or guide treatment, including but not limited to psychological and educational testing; speech/language, vision, and hearing assessment; neurological evaluation; or referral to their primary care physician.
 - iv. Prescriptive Authority.
 - v. Drug categories that may and may not be prescribed by the NP (including controlled (II-V), legend, and over-the-counter drugs)
- Practice protocols
- Physician consultation
- Record review
- Resolution of disagreements

CV SUPPLEMENT 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:⁸⁰

- 1. Tier 1: generic drugs
- 2. Tier 2: preferred brand-name drugs
- 3. Tier 3: non-preferred brand-name drugs (Gocovri)⁸¹
- 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 **formulary 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 SUPPLEMENT 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 SUPPLEMENT 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. and foreign.
- b. Exceptions §102(b), disclosures
 - c. Common ownership under joint research agreements §102(c)
 - d. Patents and published applications as effective prior art §102(d)
3. Non-obviousness (*see* U.S.C. §112)
- a. General §112(a) including the written description, manner and process of making and using, terminology, skill level, and the best mode contemplated by the inventor or joint inventor...
 - b. Conclusion §112(b) – conclusion distinctly claiming subject matter...
 - c. Form §112(c) written in independent or multiple dependent form...
 - d. Reference in dependent forms §112(d) a dependent form reference to the limitation of subject matter...
 - e. Reference in multiple dependent forms §112(e) concerning multiple dependent forms, a reference to more than one claim previously set forth...

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

- a. 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^{82 83}

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 SUPPLEMENT 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 SUPPLEMENT 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 SUPPLEMENT 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 SUPPLEMENT 21 – Ambulatory Surgical Center Facility Fees, Exclusions, Medical Necessity, Usual Customary and Reasonable Charges

Regulatory and Structural Issues regarding ASCs:

- Whether ASCs are traditionally subject to Stark Law, federal Anti-Kickback Statute (AKS) as well as state laws regarding physician ownership and referral and the Standards that apply to ASCs as opposed to what the law requires
- 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 inclusion criteria⁸⁴ including:

Medicare, industry guidance, and other accreditation organizations and requirements, types of care, e.g.:

- | | | |
|---|--|-------------------------------------|
| 1. Nursing | surgical | supervision of |
| 2. Technician and related services | procedure | the |
| 3. Diagnostic or therapeutic services or items directly related to the provision of a | 4. Administrative, recordkeeping and housekeeping items and services | services provided by an anesthetist |
| | 5. Operating surgeon's | 6. Drugs |
| | | 7. Biological |
| | | 8. Surgical dressings |
| | | 9. Supplies |

- | | | |
|--|--|-------------------------|
| 10. Splints | surgical | 14. Some |
| 11. Casts | procedures | anesthetic |
| 12. Appliances and equipment that are directly related to the provision of | 13. Anesthesia materials and implants, including intraocular lenses (IOLs) | agents |
| | | 15. Biologics |
| | | 16. Radiologic services |

CV SUPPLEMENT 21A – Fair Market Value (FMV) Physician Compensation of Physicians and Medical Directors in IDTFs, ASCs, Hospitals and other Settings by Medical Specialty

1. Usual and customary administrative duties
2. Objective measures for accountability an at-risk compensation
3. Stipends
4. Hourly rates
5. Service Line Co-Management Arrangements as a Stark or Anti-Kickback Statute Compliant Alternative to Hourly Compensation for Medical Directors with Base Fee and Quality Oriented Incentive Fees
6. Hourly thresholds
7. Percentage of surgical procedures
8. Fair market value exceptions
9. Issues with equity compensation
10. Compensation stacking
11. Examination of other income sources
12. Analysis of other payment which may be interpreted by OIG as ‘inducements’ to refer
13. Sunshine act payments
14. Standards regarding accounting for administrative tasks
15. Duties at Intersection with Medical Staff Bylaws, Medical Executive Committee (MEC)
16. Analysis of cardiology and cardiology subspecialty physician compensation, psychiatry compensation, orthopedic surgeon compensation, pediatric physician compensation and other specialties.

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

1. CLIA Certificates and CLIA numbers.⁸⁵
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.colabio.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 steps 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.^{86, 87, 88}

CLIA training and proficiency testing (PT)⁸⁹ regarding:

- a. Laboratory Quality Assurance,
- b. the [College of American Pathologists](http://www.cap.org)' (CAP) accuracy-based proficiency testing (PT),
- c. PT quality requirements issued by the [Centers for Medicare and Medicaid Services](http://www.cms.gov) (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 test⁹⁰

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

“The Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) brought further enhancements and participation incentives to the Critical Access Hospital program. **The majority of the provisions relating to CAHs offered increased financial incentives for becoming a CAH.** [emphasis added] This new law expanded the categories of services for which CAHs are reimbursed on a reasonable cost basis. They include:

- Skilled nursing facility services provided in swing beds
- On-call emergency room physicians not present on the premises, not otherwise furnishing physician services, and not on call or at any other facility
- Ambulance services if the CAH is the only supplier of ambulance services within a 35-mile drive of the hospital
- Outpatient laboratory services”⁹¹

Lab Payments to Critical Access Hospitals

Reasonable cost reimbursement for outpatient laboratory tests was made retroactive to the passage of the Balanced Budget Refinement Act of 1999. Prior to the BBRA’s passage, CAHs received cost-based reimbursement for outpatient laboratory services. However, a drafting error in BBRA changed the reimbursement methodology to the fee schedule. Additionally, **BIPA restated that coinsurance, deductible, co-payment, or any other beneficiary cost sharing did not apply to clinical diagnostic laboratory services** [emphasis added] furnished as an outpatient Critical Access Hospital service.⁹²

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.”⁹³

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

81443 - Genetic testing for severe inherited conditions (panel), which bundles several CPT codes per 2019 guidelines. Definition of panel tests. Example 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.

CV SUPPLEMENT 23b – Dental Billing, ADA Policies and Guidelines

Prior expert work in billing disputes, elder abuse, provider biller and provider payer disputes, usual customary, reasonable charges, appropriate dental billing practices and coding including but not limited to:

<u>CDT</u>	<u>Description</u>
D0150	Comprehensive Oral Evaluation
D0210	Intraoral Complete Series
D2750	Crown - porcelain fused to high noble metal
D2999	Unspecified restorative procedure, by report
D3320	Endodontic therapy, premolar tooth (excluding final restoration)
D3331	Treatment of root canal obstruction; non-surgical access In lieu of surgery.
D4341	Periodontal scaling and root planning - four or more teeth per quadrant
D4999	Unspecified periodontal procedure, by report
D6240	Pontic - porcelain fused to high noble metal
D6750	Crown - Porcelain - High Noble metal
D7210	Surgery Extraction Erupted Tooth
D7953	Bone replacement graft for ridge preservation
D9210	Local anesthesia not in conjunction with operative or surgical procedures

D9310	Consultation - diagnostic service provided by dentist or physician other than requesting dentist or physician
JP, JO	Qualifiers, (permanent or supernumerary dentition; entire oral cavity, mandibular arch, etc.)
Additional EDI 837D and ADA Claim Data:	
	1. Area of the Oral Cavity and the Tooth Anatomy code sets (Entire, maxillary, mandibular, quadrant)
	2. Tooth surface (Mesial, occlusal, distal, incisal, lingual, buccal, facial / labial)
	3. Tooth Number
ADA Policies regarding Ethics and practice compliance with ADA policies	
ADA Policies regarding prior authorization and practice compliance with ADA policy	
Medicare local coverage determinations / commercial policy - medical and dental procedures	

CV SUPPLEMENT 24 – Certified Compliance Officer Training, Certified Professional Medical Auditor Training (CPMA)

Auditing Standards

1. Audit methodologies and communicating audit results
2. Documentation of medically necessary care (and documentation by those who can determine a diagnosis, appropriateness of medical specialty to perform procedure, etc.)
3. Telehealth (virtual encounter by physician or ancillary staff, audio only, audio & video, patient portal use, specific telemedicine codes such as 99441 5-10 minutes, G2012 – brief evaluation, 98966 – 510 minutes by ancillary staff, etc.)
4. Anesthesia, e.g., modifiers indicating personally performed by anesthesiologist (professional fee claim), CRNA, medical direction and supervision, monitoring, etc.
5. Surgery Auditing Guidelines, Surgery Documentation, modifiers, operative notes, deciphering operative notes
6. National Correct Coding Initiative and Unbundling Audits, EPSU Modifiers (Separate encounter, separate practitioner, separate structure, unusual, non-overlapping service) as alternative to Modifier 59
7. Integumentary System (measurement of lesions, method of removal e.g., biopsy, excision, shaved, pathology results, malignant vs. benign, intermediate, and complex repair separately reported, Mohs Surgery, Repairs of lacerations)
8. Musculoskeletal – E&M included in surgical procedure exploration and diagnosis as part of therapeutic procedure, global fees and included components such as application of cast, bills for supplies, separate billing of radiological services
9. Respiratory – e.g., bronchoscopy procedures, endoscopy,

10. Cardiovascular, e.g., vascular family, 1st order, second order, third order catheterization in the vascular family, “Appendix L” selective versus non-selective catheters, central venous access, catheter placement, tunneled versus non-tunneled catheters, with and without port or pump, PICC, insertion vs. repair vs. replacement vs. removal
11. Gastrointestinal – correct quadrant for abdominal pain, endoscopy procedures, hot forceps, snare, brushing removal techniques, hernias (location, type, strangulated, incarcerated, reducible, use of mesh, incisional vs. laparoscopic repair)
12. Genitourinary (genital and urinary) Documentation, e.g., male vs. female specific codes, MUEs, OB vs. Non-OB (GYN), result of delivery, successfully hysterectomy
13. Nervous System, e.g., specificity regarding approach technique for spine, brain, cervical, thoracic, lumbar, pain levels as well as acute vs. chronic, V00-Y99 codes for causation (accidents),
14. Ophthalmological e.g., specialized evaluation and management codes “(920...)” modifiers for unilateral / bilateral or specified laterality, eyelids (E1...E4), type of extraction for cataracts, muscular for strabismus surgery⁹⁴
15. Auditory, e.g., diagnosis for otitis media, use of laterality modifiers, general or local anesthesia
16. Radiology, and pathology, lab services, e.g., professional (pro fee, modifier 26), technical component (‘tech fee’) modifier, unbundling checks, orders, location electronically stored, scanned, reads (CMS payments), over reads (radiology views films for quality rather than interpretation), payment to professional who performs the read / interpretation
17. Pathology and Laboratory e.g., qualitative (substance found), quantitative, how much of substance in documentation, organ or disease-oriented panels, “when only a portion of a test panel is performed, report each separately, rather than the panel.” Specific challenges with lack of specificity in CPT codes where one genetic sequencing could be performed, or multiple genetic sequences could be performed that are associated with a single CPT code. Typical acceptable modifiers (91, repeat clinical diagnostic lab, multiple tests, same day, same patient; 90-reference laboratory; QQ – waived CLIA status, e.g., waived tests QW not required to be provided by CLIA Lab); gross and microscopic examination of specimens for code ranges; Bill Type (TOB) 141, 147, non-patient referred tests, specimen collection, handling, conveyance;
18. Immunizations, e.g., Type of vaccination / immunization, injection /administration site, person administering, documentation of rout of admin, lot numbers.

19. Psychiatry, e.g., psychiatric diagnostic interview, with or without medical services, psychotherapy face to face time minutes, MD / DO / NP guidelines on prescriptions (“drug management” or “medical management”)
20. Infusions, e.g., hydration, therapeutic, chemotherapy, local anesthesia, IV start and stop, access to catheter or port, flush, standard tubing, syringes, and supplies, drugs administered at the time they start infusion or injection, hydration, therapeutic, prophylactic, diagnostic injections, administration technique e.g., Push, infusion, injection.
21. Physical Therapy, e.g., documentation of total treatment time, or beginning and end time, physician order, modality, unattended (billed or unbilled) activities
22. Evaluation and management coding, e.g., documentation of patient condition and complexity medical decision making, and other elements such as:
23. impact of electronic health records on medical documentation,
24. 1995 (focus on number of elements of exam) and 1997 (number of elements and ‘bullets’ completed) guidelines;
25. unit of time attained when mid-point is passed,
26. distinct procedures performed during time-based service (e.g., CPR during critical care),
27. the time spent performing should not be included in time-based service.
28. Date of service as start date, midnight spanning E&M,
29. E&M levels, (a) History, Exam, Medical Decision Making, and (b) nature of presenting problem, counseling, coordination of care, time, extended HPI (with at least four elements, i.e., quality, location, duration, context, modifying factors and severity, associated signs and symptoms.
30. Subjective, Review of system (ROS, i.e., Constitutional, eyes, ear/nose/mouth/throat, cardiovascular, respiratory, gastrointestinal, genitourinary, musculoskeletal, integumentary, neurological, psychiatric, endocrine, hematologic/lymphatic, allergic/immunologic), past family social history (PFHS, Inc. current medications, past surgeries and illnesses/injuries, family events such as hereditary). Documentation of organ systems (8)
31. Minimum of 8 (eight) organ systems must be documented to qualify for comprehensive. 1997 general multi-system and single organ

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)

CV SUPPLEMENT 25 – Blockchain Technologies

CV SUPPLEMENT 26 – Corporate Governance

¹ 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)

² principles of computer science and programming in five languages (BASIC, compiled UCSD Pascal, FORTRAN, LISP, COBOL, the impact of computers on society), 1978 (transferred to U.S.C. to complete undergraduate work).

³ **Clinical Bioethics and Risk Management**, certificate, **2018**. Ethical, legal, technological issues in medicine: genetics, privacy, opioids for pain management, patient autonomy, access to information for informed decisions, healthcare rationing, distributive justice, human rights in health, public reporting of outcomes. **Can AI Accelerate Precision Medicine?** 2019. Values, privacy & prediction in individualized³ treatments.

⁴ 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.

⁵ principles of distributive justice: (1) to each person an equal share, (2) to each according to need, (3) to each according to effort, (4) to each according to free market conditions, (5) to each so as to maximize overall usefulness. Rousseau's writings principally explore routes to achieving and protecting freedom: the first is a political one aimed at constructing political institutions that allow for the co-existence of free and equal citizens in a community where they themselves are sovereign; the second is a project for child development and education that fosters autonomy and avoids the development of the most destructive forms of self-interest. However, though Rousseau believes the co-existence of human beings in relations of equality and freedom is possible, he is consistently and overwhelmingly pessimistic that humanity will escape from a dystopia of alienation, oppression, and unfreedom. Kant wrote that human beings are equals under and through the moral law. All share the dignity of humanity. All are ends in themselves. All are owed respect; none may be subject to others' arrogance or contempt. But Kant also says that human beings attain personal worth through fulfillment of the moral law. A morally good person has an inner worth lacking in others. Those whom we regard as morally good elicit our respect; we attribute dignity to them because of their morality.

⁶ 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).

⁷ “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.

⁸ “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.”

⁹ Trauma, Self-Medication, description of co-morbidities and data in population health Integrating Pharmacotherapy and Behavioral Therapy in Treating Patients with Substance Use Disorders; Hub & Spoke Buprenorphine; Brain Science behind Adverse Childhood Experiences (ACE's): The Increased Risk for Substance Use and the Path to Resiliency

¹⁰ 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. Stanford Tuition Record available.

¹¹ Focus: modeling biomedical systems, data, knowledge processing in biomedicine, controlled terminologies, knowledge representation, rule-based systems, description logic, (components of ‘Artificial Intelligence in medicine,’) building systems with ontologies and problem-solving methods, BIOMEDIN 210 course. Locating

and using medical information in a digital age, May 2019: Curating digital health care information non-technical data sources, evidence-based practice cycles for clinical decisions, PICO framework, certificate, 2019.

¹² 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/>

¹³ 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>

¹⁴ Logic and Artificial Intelligence Stanford Encyclopedia of Philosophy.
<https://plato.stanford.edu/entries/logic-ai/>

¹⁵ 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.

¹⁶ MedlinePlus in contrast to National Library of Medicine, Google Scholar and PubMed

¹⁷ Course at test administered via Stanford University School of Medicine; certificate. 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)

¹⁸ Approximately 35 hours of classroom time, office hours discussions and case studies

¹⁹ Source: Rubin, Naik, Subramanian. Merkelized Abstract Syntax Trees. “Merkle trees are data structures that can be used to efficiently verify the integrity of the data they store.” See <https://www.mit.edu/~jlrubin/public/pdfs/858report.pdf>

²⁰ Merkle tree is a data structure that is used in computer science applications. In bitcoin and other cryptocurrencies, Merkle trees serve to encode blockchain data more efficiently and securely.

²¹ A popular approach to decentralize a blockchain requires *miners* to elongate the longest chain via proof-of-work. This requires a lot of computational effort from the miners, which ultimately translates into high energy consumption and very high transaction costs. Discussions regarding trust, committees, and governance.

²² Certificate can be verified here: <https://mitsloan.credential.getsmarter.com/3ec1d3de-243a-4c99-ad32-bbeld11delcb> Course focus (1) **Crypto economics**, and crypto assets, e.g., the study investment criteria, ways to create viable business models in blockchain, defensible differentiation areas, creation of intellectual property vs. open source unprotected innovation, initial coin offerings (ICOs), securities regulations and standards such as the Howey test, network bootstrap methods, building incentives using tokens, cost of identity verification, cost of networking, private blockchain networks, edge of network security, privacy and security concerns of shared ledgers, trusted governance running on the internet, last mile problems and solution research to solve the last mile problem; self-sovereign identity (SSI), and non-fungible tokens (NFTs). (2) **Technology considerations**, e.g., (e.g., cryptography, mining and cost of mining coins, token engineering, shared ledgers, differences between bitcoin and Ethereum)

²³ “The honorable Algenon L. Marbley, United States District Judge for the Southern District of Ohio, sitting by designation.”

²⁴ Information provided by retaining counsel and based on a transcript of the judges remarks. I have not been provided with the ruling at the time that this ruling was added to my C.V. on July 14, 2022. The transcript of the judges remarks provides, “as to whether the report itself is deficient under Rule 16, I find that it is sufficient, and, therefore, I’m denying the government’s motion for additional expert disclosure regarding defense expert Arrigo”

²⁵ Technically, Granted in Part, Denied in part. See C.V. end notes. Partial grant of motion was not due to expert qualifications but based on procedural issues and the Court’s determination of what was admissible.

²⁶ 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.”

²⁷ The State Children's Health Insurance Program (**SCHIP**) is designed to provide insurance coverage for children whose families earn too much to qualify for Medicaid, but who cannot afford private coverage. Unlike

Medicaid, funding for SCHIP is capped and both spending and the number of children covered by the program are much less than Medicaid. Much like Medicaid, each state is given the freedom to determine the design of its CHIP program, including eligibility groups, benefit packages, payment levels for coverage, and administrative and operating procedures. More information on individual state plans is available on the Centers for Medicare and Medicaid Services (CMS) Web site. See also

<https://www.asha.org/practice/reimbursement/medicaid/SCHIP/#:~:text=The%20State%20Children's%20Health%20Insurance,who%20cannot%20afford%20private%20coverage>. States may have varying eligibility rules,

but in most states, uninsured children under the age of 19 whose families earn up to \$36,200 a year (for a family of four) are eligible. SCHIP provides coverage for:

- doctor visits
- immunizations
- hospitalizations
- emergency room visits

²⁸ See CMS Mandatory Insurer Reporting (NGHP) <https://www.cms.gov/Medicare/Coordination-of-Benefits-and-Recovery/Mandatory-Insurer-Reporting-For-Non-Group-Health-Plans/Overview>

²⁹ 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."

³⁰ 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.

³¹ 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.

³² 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.

³³ According to the SEC, "'Related Party Transaction' means any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which (i) the Company or any of its subsidiaries is or will be a participant, and (ii) any Related Party has or will have a direct or indirect interest. See

<https://www.sec.gov/Archives/edgar/data/1437517/000101054917000418/ex142.htm#:~:text=%22Related%20Party%20Transaction%22%20means%20any,a%20direct%20or%20indirect%20interest>

³⁴ A centimorgan (abbreviated cM) is a unit of measure for the frequency of genetic recombination. One centimorgan is equal to a 1% chance that two markers on a chromosome will become separated from one another due to a recombination event during meiosis (which occurs during the formation of egg and sperm cells). On average, one centimorgan corresponds to roughly 1 million base pairs in the human genome. (Source: National Human Genome Research Institute, genome.gov)

³⁵ Course and test administered via **National Alliance of Medical Auditing Specialists (NAMAS)**, certificate, received only after completing 16.25 hours of instruction with tests.

³⁶ Course and test administered via HIPAAExams Included but not limited to Healthcare Fraud Statute, False Claims Act (FCA), Anti-Kickback Statute (AKS), Stark Law, Civil Monetary Penalties Law (CMPL), Exclusion Statute; certificate

³⁷ Course and test administered via HIPAAExams

³⁸ In person; RISE Health conference, Carlsbad CA.

³⁹ Course and test administered via California Ambulatory Surgery Association; 5 CEUs; Medical Staff Bylaws, The Credentialing Process and Common Pitfalls, Managing the Compromised Physician; Fair Hearing, 805 Reporting and Consequences, Medical Director Roles and Responsibilities.

⁴⁰ Joint Commission Content, course and test administered via HIPAAExams; certificate. 2018; re-cert 5/18/21

⁴¹ Certified Ambulance Documentation Specialist (CADS) National Academy of Ambulance Compliance. On site, Washington State, one day program with test.

⁴² Course and test administered via American Association of Post Acute Care Nursing (AANAC) update of The Resident Assessment Instrument/Minimum Data Set (RAI/MDS) is a comprehensive assessment and care planning process used by the nursing home industry since 1990 as a requirement for nursing home participation in the Medicare and Medicaid programs; certificate

⁴³ Course and test administered via Medicare Administrative Contractor First Coast

⁴⁴ Course and test administered via American Society for Clinical Pathology; 9/19/2021; certificate

⁴⁵ Course and test administered via American Society of Addiction Medicine

⁴⁶ Federal Standards for IDTFs including § 410.33 Independent diagnostic testing facility physician fee schedule, place of service (e.g., technical component and professional components), supervising physician, non-physician personnel, ordering of tests, multi-state entities, application certification Standards. February, 2022; CEU certificate.

⁴⁷ First portion Nov ‘19; second portion post pandemic resumed December ‘21

⁴⁸ American Society for Clinical Pathology; 9/19/2021

⁴⁹ IQ stands for Installation Qualification OQ is Operational Qualification and PQ is Performance Qualification

⁵⁰ 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).”

⁵¹ Transitions of Care (TOC) are embodied in both the ARRA HITECH Act of 2009 from technology implementation standpoint in Core Objective in Meaningful Use Stage 2 (see https://www.healthit.gov/sites/default/files/resources/transitions_of_care_toc.pdf) and Admit Discharge Transfer (ADT, see <https://www.healthit.gov/sites/default/files/onc-beacon-lg1-adt-alerts-for-toc-and-care-coord.pdf>), but in Joint Commission Standards of policies and procedures. For example, “PC.02.02.01 During transitions of care, there must be a process in place to ensure coordination of care among care providers – also referred to as “hand off communication”. The following requirements are found in the Provision of Care (PC) chapter of the accreditation manual: PC.02.02.01 EP 1 states “The hospital has a process to receive or share patient information when the patient is referred to other internal or external providers of care, treatment, and services” and

PC.02.02.01 EP 2 states "The hospital's process for hand-off communication provides for the opportunity for discussion between the giver and receiver of patient information. Note: Such information may include the patient's condition, care, treatment, medications, services, and any recent or anticipated changes to any of these." "Conducting a risk assessment allows organizations to identify risk points associated with these processes, and to ensure that such processes do not include any summary (blanket) orders for resuming medication (see MM.04.01.01 EP 8). A proactive risk assessment (sometimes referred to as an FMEA) examines a process in detail, including sequencing of events, actual and potential risks, and failure or points of vulnerability. Risk points are then prioritized through a logical process, then process improvements - based on the actual or potential impact (that is, criticality) on quality and safety – are implemented to reduce or eliminate risk. The introductory section of the Leadership (LD) chapter provides an example of a pro-active risk assessment model that an organization may use. However, this specific approach is not mandated as there are other risk assessment tools available that may better meet the needs of the organization."

⁵² HHS Guidance. "A [covered entity](#) that qualifies as a hybrid entity, meaning that the entity is a single legal entity that performs both covered and non-covered functions, may choose whether it wants to be a hybrid entity. If such a covered entity decides not to be a hybrid entity then it, and all of its components, are subject to the Privacy Rule in its entirety. Therefore, if a researcher is an employee or workforce member of a covered entity that has decided not to be a hybrid entity, the researcher is part of the covered entity and is, therefore, subject to the Privacy Rule. "

<https://www.hhs.gov/hipaa/for-professionals/faq/315/when-does-a-covered-entity-have-discretion-to-determine-covered-functions/index.html>

⁵³ 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.

⁵⁴ Used in Medicare Part C (Medicare Advantage "MAO"), Accountable Care (ACO) organizations.

⁵⁵ Training delivered by MD, board-certified orthopedic surgeon who advised CMS in all 50 States.

⁵⁶ Training delivered by Radiology Certified Coder (RCC), Certified Interventional Radiology Cardiovascular Coder (CIRCC), and Certified Professional Coder (CPC) credentialed instructor.

⁵⁷ American Academy of Professional Coders (AAPC).

⁵⁸ Training delivered by National Association of Rehabilitation Providers (NARP) trainer.

⁵⁹ Health Care Incentives Improvement Institute, HC3i.

⁶⁰ Health Care Incentives Improvement Institute, HC3i.

⁶¹ Pertaining to, or composed of, an integument such as [skin](#). Source: Dorland's Medical Dictionary.

⁶² American Academy of Professional Coders (AAPC) Certified Professional Coder (CPC) curriculum.

⁶³ Non-Covered Services provider education — Noridian Healthcare Services, LLC.

⁶⁴ According to ASCP: Identifies possible use or non-use of drug; Any specimen type; urine, blood, oral fluid

⁶⁵ According to ASCP: Qualitative or quantitative: identifies possible use or non-use of a specific drug and metabolites; Any specimen type; urine, blood, oral fluid

⁶⁶ According to ASCP: Quantitative: Specimen typically is whole blood, serum, plasma, cerebrospinal fluid

⁶⁷ According to ASCP: Evocative or suppression agents are administered by a physician and codes are used to report the

laboratory component of the overall testing protocol, e.g., 80400 ACTH stimulation panel; for adrenal sufficiency. The panel must include Cortisol.

⁶⁸ According to ASCP: 80500 – 80502 Clinical pathology consultation rendered by a pathologist in response to a

physician request; Requirements: Requested by the patient's attending physician; Must relate to a test result that lies outside clinically significant norm or expected range; Requires medical interpretation by the pathologist; Written report must be provided for the patient's medical record

⁶⁹ According to ASCP: 81000 – 81099 including Clinical testing of urine constituents with coding dependent on testing method (Automated vs non automated; with or without microscopy); includes test codes for urine pregnancy, specific analyte, and total volume measurement

⁷⁰ According to ASCP: 81105 - 81479 (four sections involving analysis of nucleic acid (DNA, RNA) to detect variants in genes that may indicate: Germline condition - constitutional disorder; Somatic condition – neoplasia; Histocompatibility antigens. Based on specific gene(s) being analyzed and includes all analytic services (e.g., cell lysis, nucleic acid stabilization, extraction); all analyses are qualitative unless otherwise noted; Tier 1, Tier 2, genomic sequencing; multianalyte assay by algorithmic analysis (MAAAs analyze multiple biomarkers using proprietary algorithm to generate risk score). Example: 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, if performed

⁷¹ According to ASCP: Specimen may be any source unless stipulated in code descriptor 84165 Protein; electrophoretic fractionation and quantitation, serum, 84166 electrophoretic fractionation and quantitation, other fluids with concentration (e.g., urine, CSF)

⁷² According to ASCP: 85002 – 85999 Hematology codes (85004 - 85049) describe variations of specific component(s) and methodology(s) used to obtain measurements of component parts of a complete blood count (CBC); Red blood cell count (RBC); White blood cell count (WBC); Hemoglobin (Hgb) Coagulation codes (85130 – 85999 describe variations of specific component(s) and methodology used to measure blood clotting abilities; Clotting factors, such as factor 7; Clotting inhibitors; Heparin assay

⁷³ According to ASCP: 86000 – 86804 Immunology tests the components of the immune system whether immunity from disease, the immune response (allergy), or the development of antibodies to oneself (autoimmune) Allergen specific tests, such as cat dander, oak pollen, or dust mites; Antibody-specific tests; Exposure to certain disease, such influenza, mumps, or rubella

⁷⁴ According to ASCP: 86805 – 86999, Procedures for testing blood antigens and antibodies for blood transfusions during/after surgery or for testing mother/baby compatibility; procedure codes for infusion of blood products such as fresh frozen plasma, platelets, white cells and red cells

⁷⁵ According to ASCP: 87003 – 87999 Presumptive testing is the identification of colony morphology, growth on selective media, Gram stains or up to 3 tests (e.g., catalase, oxidase, indole); Definitive testing is the ID of genus or species that requires tests (e.g., biochemical panel. If additional studies to ID the organism involve the use of molecular probes, nucleic acid sequencing or immunologic techniques, codes 87140 - 87158 should be used. Molecular diagnostic codes 81105 to 81408 are not to be used in combination with or instead of the procedures represented by codes 87140 - 87158.

⁷⁶ According to ASCP: 88104- 88199 - Use of specialist diagnostic techniques to examine individual cells extracted from tissues to determine the cause and nature of a disease; Codes are separated by procedures: Cervical or vaginal cytopathology- 88141, 88155,88164-88167,88174-88175; Cytopathology of fluids, washings, and brushings - 88104-88121; Cytopathology of fine needle aspirates - 88172-88177; Flow cytometry - a technique used to analyze the physical and chemical characteristics of particles (cells) in a fluid as it passes through at least one laser; 88182 - 88189

⁷⁷ According to ASCP: 88230 – 88299 The study of how chromosomes relate to cell behavior; Samples include tissue, blood, and bone marrow; Cells are grown in the lab to look for changes in chromosomes, including broken, missing, or extra chromosomes; Changes in certain chromosomes may be a sign of a genetic disease or condition or some types of cancer; May help diagnose a disease or condition, plan treatment, or find out how well treatment is working

⁷⁸ According to ASCP: 88300 – 88399 Gross and microscopic (G&M) examination of specimens for abnormalities - 88300-88309 Specimen is defined as tissue or tissues

that is/are submitted for individual and separate attention, requiring individual examination and pathologic diagnosis 88300 " ... is used for any specimen that in the opinion of the examining pathologist can be accurately diagnosed without microscopic examination" 88302 " ... is used when [G&M] examination is performed to confirm identification and absence of disease" 88304 - 88309 "describe all other specimens requiring [G&M] and represent additional levels of physical work" Ancillary services - 88311-88388; Special stains; intraoperative consultations

⁷⁹ According to ASCP: 88720 – 88749 Transcutaneous procedures – measures analyte through the skin rather than using blood specimen; Used mostly for fetal monitoring; Bilirubin; Hemoglobin; Carboxyhemoglobin – Measurement of carbon monoxide; Methemoglobin - Abnormal form of oxygenated hemoglobin that cannot deliver oxygen to the tissues

⁸⁰ Blue Cross Blue Shield 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>

⁸¹ Formulary Navigator <https://client.formularynavigator.com/Search.aspx?siteCode=5972287365&targetScreen=3&drugBrandListBaseKey=gocovri%2B137%2Bmg%2Bcapsule%252cextended%2Brelease>

⁸² David L. Schwartz, Explaining the Demise of the Doctrine of Equivalents, 26 Berkeley Tech. L.J. 1157 (2011). Available at: <http://scholarship.law.berkeley.edu/btlj/vol26/iss2/6>

⁸³ John R. Thomas, Claim Re-Construction: The Doctrine of Equivalents in the Post-Markman Era Georgetown University Law Center

⁸⁴ <https://med.noridianmedicare.com/web/jeb/specialties/asc>

⁸⁵ **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.

⁸⁶ 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.

⁸⁷ 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**”

⁸⁸ 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.

⁸⁹ **§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;

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- (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]

⁹⁰ §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]⁹⁰

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

⁹¹ Texas Department of Rural Affairs and Texas Healthcare Trustees. Texas Critical Access Hospital Trustee Resource Guide. www.tdra.state.tx.us and

<https://www.texasagriculture.gov/Portals/0/forms/ER/Texas%20CAH%20Trustee%20Resource%20Guide.pdf>

⁹² Texas Department of Rural Affairs and Texas Healthcare Trustees. Texas Critical Access Hospital Trustee Resource Guide. www.tdra.state.tx.us and

<https://www.texasagriculture.gov/Portals/0/forms/ER/Texas%20CAH%20Trustee%20Resource%20Guide.pdf>

⁹³ Medicare Administrative Contractor Palmetto GBA, CMS Manual System Pub 100-04 Medicare Claims Processing

<https://www.palmettogba.com/palmetto/providers.nsf/vMasterDID/9FRR7A4285?open>

⁹⁴ Strabismus surgery loosens or tightens eye muscles changing the alignment of the eyes relative to each other.

<https://aapos.org/glossary/strabismus-surgery>

NOT RETAINED