Regulatory Overview for Valuation Professionals

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Presenter Bio

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Mr. Zigrang is the co-author of the "*Adviser's Guide to Healthcare – 2nd Edition*" (AICPA, 2015), numerous chapters in legal treatises and anthologies, and peer-reviewed and industry articles such as: *The Guide to Valuing Physician Compensation and Healthcare Service Arrangements* (BVR/AHLA); *The Accountant's Business Manual* (AICPA); *Valuing Professional Practices and Licenses* (Aspen Publishers); *Valuation Strategies*; *Business Appraisal Practice*; and, *NACVA QuickRead*. Additionally, Mr. Zigrang has served as faculty before professional and trade associations such as the American Bar Association (ABA); the National Association of Certified Valuators and Analysts (NACVA); the American Society of Appraisers (ASA); Medical Group Management Association (MGMA); Physician Hospitals of America (PHA); the Institute of Business Appraisers (IBA); the Healthcare Financial Management Association (HFMA); and, the CPA Leadership Institute.

Presenter Bio

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She serves on the Editorial Board of NACVA's *The Value Examiner* and of the American Health Law Association's (AHLA's) *Journal of Health & Life Sciences Law*. Additionally, she is the Chair of the American Bar Association's (ABA) Young Lawyers Division (YLD) Health Law Committee and a YLD Liaison for the ABA Health Law Section's Membership Committee. She has previously presented before the ABA and NACVA.

Ms. Bailey-Wheaton is a member of the Missouri and Illinois Bars and holds a J.D., with a concentration in Health Law, from Saint Louis University School of Law.

Session Overview

- Tax Regulations
- Licensure, Certification, & Accreditation
- Fraud & Abuse Regulation
- Fraud & Abuse Enforcement
- Privacy Laws
- Other Federal Regulations
- The Patient Protection & Affordable Care Act

Tax Regulations

501(c)(3) Tax Exempt Organizations

- Importance of tax status:
  - Changes Federal tax burden
  - Changes State tax burden
  - Tax-exempt bond financing
  - Donations
  - Operations and governance
  - Intrinsic value of non-profit status

"Do Nonprofit Hospitals Pay Their Way?" By Michael A. Morrisey, Gerald J. Wedig, and Mahmud Hassan, Health Affairs, Vol. 15, No. 4, Winter 1996, p. 135; "Health Law: Cases, Materials and Problems" Barry R. Furrow, Thomas L. Greaney, Sandra H. Johnson, Timothy Stoltzfus Jost, Robert L. Schwartz, Erin C. Fuse Brown, Brietta R. Clark, Robert Gatter, Jaime S. King, and Elizabeth Pendo, Eighth Edition, St. Paul, MN, West Academic, 2018, p. 833.

501(c)(3) Tax Exempt Organizations

- Charitable organization qualification under 501(c)(3):
  - No benefit of earnings are allocated to any private shareholder or individual
  - No activities consist of influencing legislation
  - No participation in political campaigns or on behalf of political officials

"Exemption from tax on corporations, certain trusts, etc." 26 USC 501 2019; "REQUIREMENTS FOR TAX-EXEMPT STATUS UNDER CODE SEC. 501(C)(3)" Federal Tax Coordinator, FTC D-4006, Second Edition, 2019.

501(c)(3) Tax Exempt Organizations

- Qualification Tests:
  - *Organizational Test*: Corporate articles of incorporation limit activities to exempt purposes
  - *Operational Test*: The organization must be operated primarily for exempt purposes
    - Exempt purpose may be:
      - Charitable
      - Educational
      - Religious

"Chapter D-4006 Organizational Test for Tax-Exempt Organizations" Federal Tax Coordinator, FTC D-4006, Second Edition, 2019; "Operational Test for Tax-Exempt Organizations" Federal Tax Coordinator, FTC D-4014, Second Edition, 2019.

501(c)(3) Tax Exempt Organizations

- Community Benefit Standard:
  - "*Promote the health of a class of persons broad enough to benefit the community as a whole*"
  - Promoting health for the general benefit of the community if:
    - A governing board composed of the community
    - An open medical staff
    - Treatment of government-insured patients

Revenue Ruling 69-545, Internal Revenue Service, 1969; "The Failure of Community Benefit, John D. Colombo, Health Matrix, Vol. 15, Issue 29, 2005, p. 29-32; "Charitable purpose—Promotion of health community benefit" Health Law Practice Guide 35:5, American Health Lawyers Association, 2019.

Private Inurement and Benefit

- Private Inurement
  - Main question: what is the relationship between what the organization pays and what it receives?
  - Akin to a *per se* rule, requiring revocation or denial of exempt status with no exception
  - Only applies to "*insiders*"
    - Private shareholders or individuals having a personal and private interest in or opportunity to influence the activities of the organization from the inside
    - Staff physicians

"IRS Fact Sheet 2011-11: Tax-Exempt Organizations Participating in the Medicare Shared Savings Program through Accountable Care Organizations" Internal Revenue Service, October 20, 2011; American Campaign Academy v. Commissioner, 92 T.C. 1053, 1068 (1989); United Cancer Council, Inc. v. Comm'r, 165 F.3d 1173, 1176 (7th Cir. 1999); "The Scintilla of Individual Profit: In Search of Private Inurement and Excess Benefit" By Darryll K. Jones, Virginia Tax Review, Vol. 19, spring 2000, p. 576-578.

Private Inurement and Benefit

- Private Benefit
  - Applies to transactions with "*outsiders*" to the exempt organization
    - Limitation not prohibition
    - Not a *per se* rule
    - Entails a broader inquiry
      - Must weigh private benefits against the community benefit provided

Excess Benefit Transactions

- Excess Benefit Transaction (EBT): Any transaction in which an economic benefit is provided by a tax-exempt organization directly or indirectly to or for the use of a "*disqualified person*" (DQP)
- IRS imposes EBT tax beginning at 25% on DQPs
- Additional 10% automatically added to "*organizational managers*"
  - DQPs:
    - Person during 5-year period who had substantial influence over organization
    - Officers, directors, and their close relatives
    - Organizational managers
      - Individuals who can delegate or exercise administrative powers

"Taxes on excess benefit transactions" 26 U.S.C. § 4958; Definition of disqualified person, 26 C.F.R. § 53.4958-3.

Reasonable Compensation

- Despite IRS prohibitions against excess benefit transactions, compensation arrangements involving tax exempt organizations may include financial incentives if the arrangement involves "*reasonable compensation*"
- IRS Definition
  - The value of services provided
  - "*the amount that would ordinarily be paid for like services by the enterprises (whether taxable or tax-exempt) under like circumstances*."

In General Counsel Memorandum (GCM) 35638, published on January 28, 1974, the IRS stated that compensation arrangements involving shared savings related to quality improvements could be acceptable if they were at arm's length and were "*…a means of providing reasonable compensation to employees without any potential for reducing the charitable services or benefits otherwise provided…*" [emphasis added]. "Section 4958 Update" By Lawrence M. Brauer and Marvin Friedlander" in "2000 Exempt Organization (EO) CPE Text" Internal Revenue Service, 2000, p. 29. "Excess benefit transaction" 26 C.F.R. § 53.4958-4(b)(ii)(A) (2012).

Reasonable Compensation

- IRS Definition
  - Valuation standard -"*fair market value*"
    - i.e., "*the price at which property or the right to use property would change hands between a willing buyer and a willing seller, neither being under any compulsion to buy, sell or transfer property or the right to use property, and both having reasonable knowledge of relevant facts*"

"Excess benefit transaction" 26 C.F.R. § 53.4958-4(b)(ii)(A) (2012).

Reasonable Compensation

- IRS Definition
  - "*payments under a compensation arrangement are presumed to be reasonable...if the following conditions are satisfied*:
    - "*The compensation arrangement…[is] approved in advance by an authorized body of the applicable tax-exempt organization composed entirely of individuals who do not have a conflict of interest with respect to the compensation arrangement;*
    - *The authorized body obtained and relied upon appropriate data as to comparability prior to making its determination; and*
    - *The authorized body adequately documented the basis for its determination concurrently with making that determination*." [emphasis added]

"Excess benefit transaction" 26 C.F.R. § 53.4958-4(b)(ii)(A) (2012).

Licensure, Certification, & Accreditation

Licensure of Healthcare Facilities

- Intended to ensure that patients receive quality healthcare
- All 50 states require hospitals and skilled nursing facilities to be licensed
- Minimum requirements for licensing nursing home facilities vary little between states
- Most states require entities to meet practice standards set forth by Medicare as a condition of licensure, and Medicare requires state licensure as a condition of reimbursement

"State Licensure of Facilities" Thomson Reuters, June 2012. "Medicare and Medicaid Fraud and Abuse" By Alice G. Gosfield, 2012 Edition, Thomson Reuters, 2012, p. 31. "Agreements with States" 42 U.S.C. § 1395aa (2010). "Effect of Accreditation" 42 U.S.C. § 1395bb (2010).

Medicare & Medicaid Certification of Healthcare Facilities

- Must meet the eligibility requirements for program participation, including certification of compliance with the Conditions of Participation (CoP)
  - Based on a survey conducted by a state agency on behalf of CMS
- Organization must be “deemed” to satisfy the health and safety standards component of the Medicare certification process to be certified

“Facts about federal deemed status and state recognition” The Joint Commission, 2018, https://www.jointcommission.org/-/media/tjc/idev-imports/topics-assets/facts-about-federal-deemed-status-and-state-recognition/federal_deemed_status_12_12_181pdf.pdf(Accessed 10/8/20).

Accreditation of Healthcare Facilities

- Granted by private authorities – not legally mandated
- Some states accept certain accreditation as a basis for full or partial licensure as part of an effort to reduce duplicative hospital inspections

"Problems in Health Care Law, Ninth Edition" By Robert D. Miller, Burlington, MA: Jones and Bartlett, 2006, p. 59-66.

Accreditation Bodies

The Joint Commission

- Provides accreditation for:
  - Behavioral health centers
  - Critical access hospitals
  - Nursing care centers
  - Perinatal Care
  - Office-based surgery centers
  - Disease-specific care
  - Healthcare staffing
  - Home care
  - Hospitals
  - Laboratory services

American Osteopathic Association

- Accrediting body for osteopathic healthcare facilities and medical schools

"State Recognition Details" The Joint Commission, http://www.jointcommission.org/state_recognition/state_recognition_details.aspx?ps=25 (Accessed 10/8/20); "About the AOA" American Osteopathic Association, 2020, https://www.osteopathic.org/inside-aoa/about/Pages/default.aspx (Accessed 10/8/20).

Accreditation Bodies

National Committee on Quality Assurance (NCQA)

- Accrediting body for managed care plans

Accreditation Association for Ambulatory Health Care (AAAHC)

- Evaluates federally qualified health centers (FQHCs), office-based surgery centers, ASCs, and now hospitals

"About NCQA" National Committee for Quality Assurance, http://www.ncqa.org/about-ncqa (Accessed 10/8/20); "Accreditation" Accreditation Association for Ambulatory Health Care, Inc., 2020, https://www.aaahc.org/en/accreditation/ (Accessed 10/8/20); "About AAAHC" Accreditation Association for Ambulatory Health Care, 2020, https://www.aaahc.org/about/ (Accessed 10/8/20).

Individual Professional Licensure

- Every state requires licensure of all allopathic (M.D.) and osteopathic (D.O.) physicians
  - Candidates required to submit proof of completion of the graduate medical education and passage of examinations verifying that "*the physician is ready and able to practice competently and safely in an independent setting*"
- National Practitioner Data Bank
  - Established by Health Care Quality Improvement Act of 1986
  - Requires state licensing boards to report disciplinary action taken against a licensed professional in regards to his/her professional competence and professional conduct
  - Hospitals required to periodically check database for each member of their medical staff

"State Medical Boards: Future Challenges for Regulation and Quality Enhancement of Medical Care" By James N. Thompson, Journal of Legal Medicine, Vol. 33, no. 9, January-March 2012, p. 94.

Board Certification

- The American Board of Medical Specialties (ABMS) is a nationally-recognized non-profit organization made up of 24 Member Boards that oversee physician specialty certification in the U.S.
  - Today most, if not all, physicians are considered specialists
  - Medical specialty certification in U.S. is a voluntary process
  - Board Certification demonstrates a physician's exceptional expertise in a particular specialty and/or subspecialty of medical practice

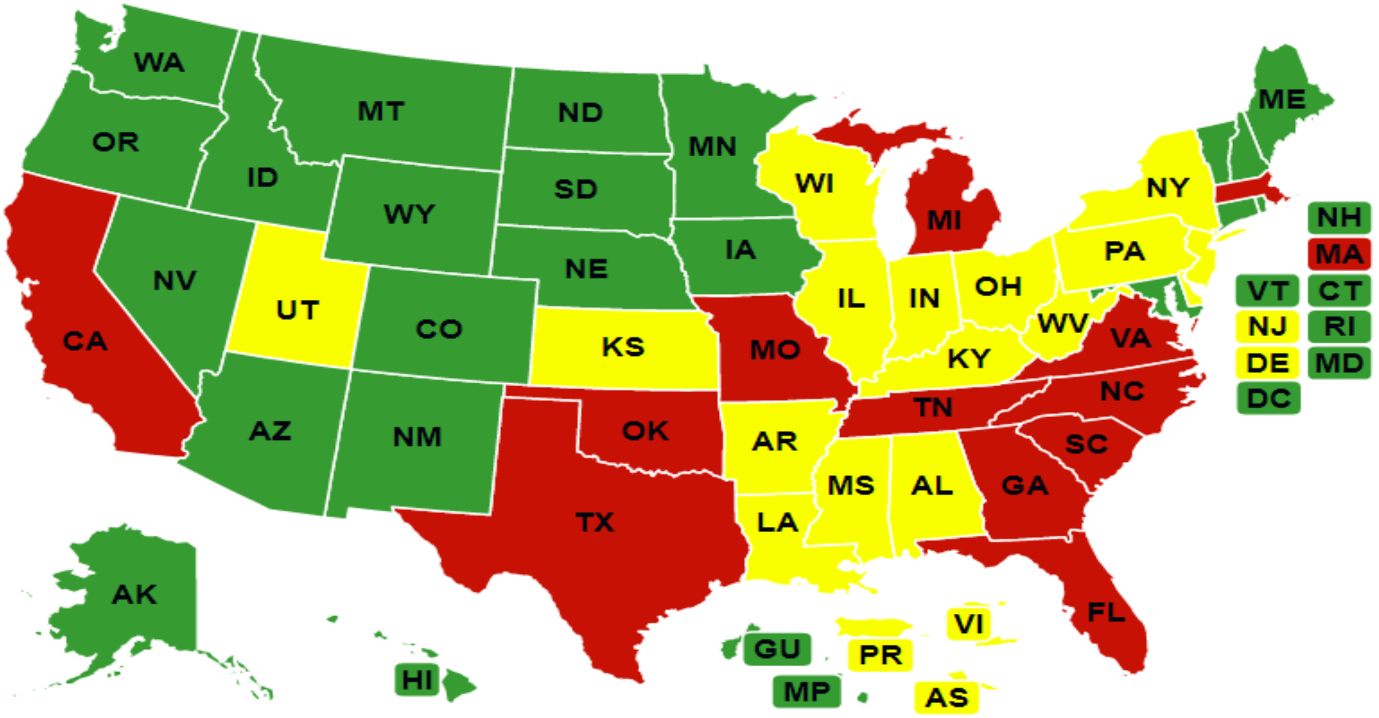
"Frequently Asked Questions" American Board of Medical Specialties, 2017, https://www.abms.org/about-abms/faqs/ (Accessed 12/15/17); "A Trusted Credential" American Board of Medical Specialties, 2020, http://www.abms.org/board-certification/a-trusted-credential/ (Accessed 10/8/20).

Nonphysician Scope of Practice

- Predicted shortage of primary care physicians as the population grows and millions of individuals become newly insured
- One proposed solution – Expand laws regarding the scope of practice of nurse practitioners and physician assistants
  - Allow them to provide a wider range of services
- In considering changes to licensure and scope-of-practice requirements, state legislatures will weigh physician shortage problems

"Nurse Practitioners and Primary Care" Health Policy Brief, Health Affairs, October 25, 2012, p.1.

Nonphysician Scope of Practice Nurse Practitioners (NPs)



Green: Full practice authority of NPs without physician oversight
Yellow: Reduced practice authority requiring some oversight
Red: Restricted practice authority with significant physician oversight

"State Practice Environment" American Association of Nurse Practitioners. 2020, https://www.aanp.org/advocacy/state/state-practice-environment (Accessed 10/8/20).

Licensure Waivers & Suspensions during COVID-19

- State suspensions/waivers of:
  - Some/all practice agreement requirements for advanced practice clinicians (APCs)
  - Requirements that physicians/APCs be licensed in the state in which they are providing services (so long as they are licensed in another state)
- Federal waivers of telemedicine requirements – Allows healthcare professionals to provide an expanded list of telehealth services to (new or established) patients (across state lines) no matter the patient's location

Licensure of Health Insurance Plans

- State laws require insurers and insurance-related businesses to be licensed before selling products/services
- Insurers who fail to comply with regulatory requirements are subject to license suspension or revocation
  - States may exact fines for regulatory violations
- Fundamental reason for government regulation – to protect American consumers
  - Insurance is more heavily regulated than other types of business because of the complexity of the contracts

"State Insurance Regulation" National Association of Insurance Commissioners and the Center for Insurance Policy and Research, 2011, p. 1-3. "Office-Based Anesthesia and Surgery: Creating a Culture of Safety" By Fred E. Shapiro and Richard D. Urman, American Society of Anesthesiologists, Vol. 75 no. 8, August 2011, p. 14.

Fraud & Abuse Regulation

The Anti-Kickback Statute (AKS)

- A felony for any person to "*knowingly and willfully*" solicit or receive, or to offer or pay, any "*remuneration*," directly or indirectly, in exchange for the referral of a patient for a healthcare service paid for by a federal healthcare program
  - Affordable Care Act – "*With respect to violations of [the Anti-Kickback Statute] a person need not have actual knowledge of this section or specific intent to commit a violation of this section*"
- Punishable by up to five years in prison and/or criminal fines up to $25,000

"Criminal Penalties for Acts Involving Federal Health Care Programs" 42 U.S.C. § 1320a-7b(b); "Patient Protection and Affordable Care Act" Public Law 111-148, 124 STAT. 119 (March 23, 2010), p. 1008.

AKS Safe Harbors

- HHS has authority to create a list of payment and business practices that are guaranteed to not be considered as kickbacks, bribes, or rebates under Medicare and Medicaid
- Shields arrangements from regulatory liability and protects transactional arrangements unlikely to result in fraud or abuse
  - Intended to "*permit physicians to freely engage in business practices and arrangements that encourage competition, innovation and economy*"

"Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions" Department of Health and Human Services, Federal Register, Vol. 54, No. 13 (January 23, 1989), p. 3088.

List of Safe Harbors

- Investment Interests
- Space Rental
- Equipment Rental
- Personal Services and Management Contracts and Outcomes-Based Payment Arrangements
- Sale of a Practice
- Referral Services
- Warranties
- Discounts
- Employees
- Group Purchasing Organizations (GPOs)
- Waiver of Beneficiary Coinsurance and Deductible Amounts
- Increased Coverage, Reduced Cost-Sharing Amounts, or Reduced Premium Amounts Offered by Health Plans
- Price Reductions Offered to Health Plans
- Practitioner Recruitment
- Obstetrical Malpractice Insurance Subsidies
- Investments in Group Practices
- Cooperative Hospital Service Organizations (CHSO)
- Ambulatory Surgery Centers (ASCs)
- Referral Agreements for Specialty Services
- Price Reductions Offered to Eligible Managed Care Organizations

"Exceptions" 42 C.F.R. § 1001.952(a)-(x).

List of Safe Harbors, continued

- Price Reductions Offered by Contractors with Substantial Financial Risk to Managed Care Organizations
- Ambulance Replenishing
- Federally Qualified Health Centers (FQHCs)
- E-Prescribing Items and Services
- Electronic Health Records
- FQHCs and Medicare Advantage Organizations
- Medicare Coverage Gap Discount Program
- Local Transportation
- Point-of-Sale Reductions in Price for Prescription Pharmaceutical Products NEW
- PBM Service Fees NEW
- Care Coordination Arrangements to Improve Quality, Health Outcomes, and Efficiency NEW
- Value-Based Arrangements with Substantial Downside Financial Risk NEW
- Value-Based Arrangements with Full Financial Risk NEW
- Arrangements for Patient Engagement and Support to Improve Quality, Health Outcomes, and Efficiency NEW
- Cybersecurity Technology and Related Services NEW
- ACO Beneficiary Incentive Program NEW

"Exceptions" 42 C.F.R. § 1001.952(a)-(x).

Stark Law

- Federal prohibition against physician self-referral
- Prohibits physicians from referring Medicare or Medicaid patients to an entity for Designated Health Services (DHS) if the physician, or an immediate family member, has a financial relationship with that entity

"Health Care Fraud and Abuse: Practical Perspectives" Edited by Linda A. Baumann, Washington, DC: American Bar Association, 2002, p. 52. "Limitation on certain physician referrals." 42 U.S.C. § 1395nn(a) (2012). "Prohibition on certain referrals by physicians and limitations on billing." 42 C.F.R. § 411.353 (2015).

Designated Health Services

List of Designated Health Services
Clinical laboratory services
Physical therapy, occupational therapy, and outpatient speech-language pathology services
Radiology and certain other imaging services
Radiation therapy services and supplies
Durable medical equipment and supplies
Parenteral and enteral nutrients, equipment, and supplies
Prosthetics, orthotics, and prosthetic devices and supplies
Home health services
Outpatient prescription drugs
Inpatient and outpatient hospital services

"Financial Relationships Between Physicians and Entities Furnishing Designated Health Services" 42 C.F.R. § 411.351 (October 1, 2011).

Stark Law Exceptions

- Any financial relationship between a healthcare entity and a physician providing DHS must fall within an exception to be legally permissible
- Promotes practice integration and protects arrangements where there is little risk of abuse
- 41 exceptions to Stark that fall under 3 categories:
  - Exceptions that apply to *both* ownership/investment interests and compensation arrangements
  - Exceptions that apply *only* to ownership/investment interests
  - Exceptions that apply *only* to compensation arrangements

"Health Care Fraud and Abuse: Practical Perspectives" Edited by Linda A. Baumann, Washington, DC: American Bar Association, 2002, p. 106; 42 C.F.R. §§ 411.355-411.357. "Limitations on certain physician referrals" 42 U.S.C. § 1395nn(a)-(e) (2012).

Provider Self-Referral Disclosures under Stark

- ACA required CMS to create *Self-Referral Disclosure Protocol* (SRDP)
- Financial incentives to providers to self-disclose *actual* or *potential* Stark violations
- CMS settled 335 violations of the Stark Law from 2011-2019
- OIG established a distinct Self-Disclosure Protocol for violations of AKS in 1998, and revised the Self-Disclosure Protocol in April 2013

"Self-Referral Disclosure Protocol" Centers for Medicare & Medicaid Services, http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self_Referral_Disclosure_Protocol.html (Accessed 10/8/20). "Self-Referral Disclosure Protocol Settlements" Centers for Medicare & Medicaid Services, http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Self-Referral-Disclosure-Protocol-Settlements.html (Accessed 10/8/20). "Self-Disclosure Information" Office of Inspector General, U.S. Department of Health and Human Services, http://oig.hhs.gov/compliance/self-disclosure-info/index.asp (Accessed 10/8/20). "Updated OIG's Provider Self-Disclosure Protocol" Office of Inspector General, U.S. Department of Health and Human Services, https://oig.hhs.gov/compliance/self-disclosure-info/files/Provider-Self-Disclosure-Protocol.pdf (Accessed 10/8/20).

Differences Between AKS and Stark Law

	AKS	Stark Law
Referrals	From anyone	From a physician
Items/Services	Any items/services	Designated health services
Intent	Willful action, but no actual knowledge of violation required	No intent required Intent required for civil monetary penalties for knowing violations
Penalties	Criminal and civil penalties	Civil penalties only
Exceptions	Voluntary safe harbors	Mandatory exceptions
Federal Health Care Programs	All	Medicare/Medicaid

"Comparison of the Anti-Kickback Statute and Stark Law" Health Care Fraud Prevention and Enforcement Action Team (HEAT), Office of Inspector General (OIG), http://oig.hhs.gov/compliance/provider-compliance-training/files/StarkandAKSChartHandout508.pdf (Accessed 10/8/20).

Stark/AKS Waivers during COVID-19

- March 30, 2020 – HHS waived certain Stark Law requirements (subject to certain conditions)
  - Effective March 1, 2020, through the end of the national emergency
- April 3, 2020 – The OIG similarly waived certain Anti-Kickback Statute requirements (subject to certain conditions)
  - Effective April 3, 2020, through the end of the national emergency

Stark/AKS Finalized Rule Changes

- November 2020 – HHS OIG and CMS finalized rule changes to AKS and Stark, respectively, to modernize the laws
- Changes are intended to:
  - Address changing reimbursement system
  - Reduce regulatory barriers
  - Promote care coordination

False Claims Act (FCA)

- An organization is liable when it "*knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval*," to the U.S. government
- Punitive law in nature
- Civil and criminal penalties
- Also for "*Qui Tam*" relators to bring actions on behalf of the government
- State may have its own false claim law

"The Federal False Claims Act" 31 USC § 3729-3733.

Fair Market Value Definition

General	Rental of Equipment	Rental of Office Space
The value in an arm's-length transaction -	The value in an arm's-length transaction -	The value in an arm's-length transaction -
	Of rental property for general commercial purposes (not taking into account its intended use)	Of rental property for general commercial purposes (not taking into account its intended use)
Consistent with the general market value of the subject transaction	Consistent with the general market value of the subject transaction	Consistent with the general market value of the subject transaction

General Market Value Definition

- **Assets**: "*the price that an asset would bring on the date of acquisition of the asset as the result of bona fide bargaining between a well-informed buyer and seller that are not otherwise in a position to generate business for each other*." [Emphasis added.]
- **Compensation**: "*the compensation that would be paid at the time the parties enter into the service arrangement as the result of bona fide bargaining between well-informed parties that are not otherwise in a position to generate business for each other*." [Emphasis added.]
- **Rental of Equipment or Office Space**: "*the price that rental property would bring at the time the parties enter into the rental arrangement as the result of bona fide bargaining between a well-informed lessor and lessee that are not otherwise in a position to generate business for each other*." [Emphasis added.]

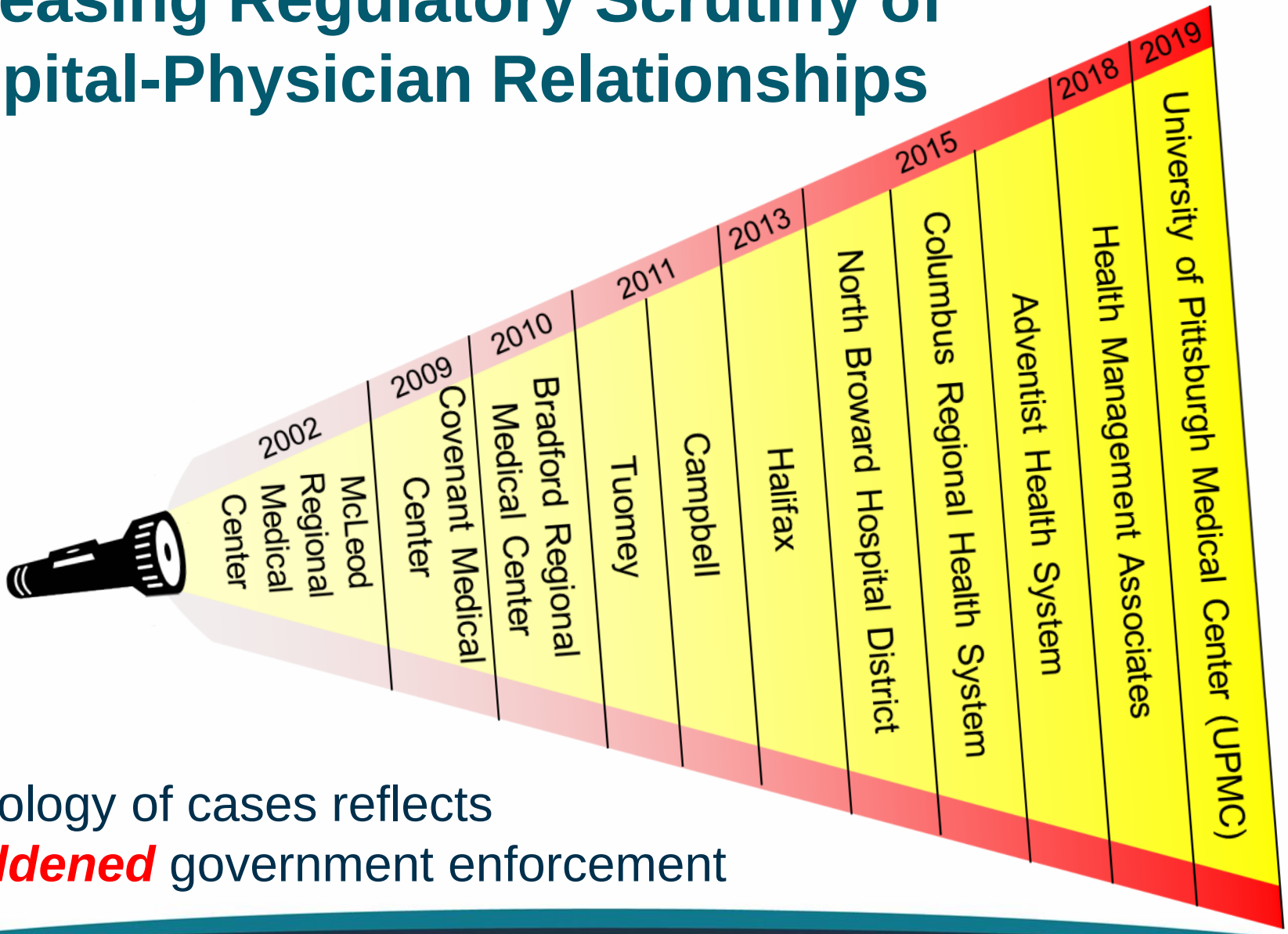
"Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" CMS-1720-F, Unpublished Version, https://public-inspection.federalregister.gov/2020-26140.pdf (Accessed 11/24/20), p. 539.

Fair Market Value (FMV)

- **U.S. ex rel. Obert-Hong v. Advocate Health Care** footnote - FMV may differ from traditional economic valuation formulae, which take into account referrals
  - Because AKS prohibits any inducement for referrals, they must be excluded from any calculation of fair value
- **American Lithotripsy Society v. Thompson** - Proving that an arrangement is FMV is imperative in complying with Stark's requirements
  - *"Payment exceeding fair market value is in effect deemed payment for referrals"*
- In court, FMV determination may be based on a *"battle of the experts"*

"U.S. ex rel. Obert-Hong v. Advocate Health Care" 211 F.Supp.2d 1045, 1049 (N.D. Ill. 2002). "Am. Lithotripsy Soc'y v. Thompson" 215 F.Supp.2d 23, 27 (D.D.C. 2002).

Increasing Regulatory Scrutiny of Hospital-Physician Relationships



Chronology of cases reflects ***emboldened*** government enforcement

Relevant Fraud & Abuse Case Law

U.S. ex rel. Richard Raugh v. McLeod Regional Medical Center

- *"[t]he claims for services referred, ordered or arranged by those physicians were alleged to be false in three respects:*
  - *First, Section 1877 of the Social Security Act, 42 USC 139nn (also known as Stark II), prohibited McLeod from billing Medicare for items or services referred or ordered by physicians with whom it had such financial relationships.*
  - *Second, McLeod forfeited its right to submit those claims to the federal health care programs by paying remuneration intended to induce those and other referrals in violation of the Anti-Kickback Statute, 42 USC 1320a-7(b).*
  - *And third, McLeod certified falsely on Medicare cost reports that the services identified or summarized were not provided or procured through payment directly or indirectly of a kickback or billed in violation of federal law."*

"McLeod Regional Medical Center to Pay U.S. Over $15 Million to Resolve False Claims Act Allegations" United States Department of Justice, Press Release, November 1, 2002, http://www.justice.gov/opa/pr/2002/November/02_civ_634.htm (Accessed 10/8/20).

Relevant Fraud & Abuse Case Law

U.S. v. Covenant Medical Center

- Five of Covenant's physicians were reportedly among the highest-paid physicians in the entire U.S., making as much as $2.1 million, despite Covenant's tax exempt status
  - Amounts significantly exceeded the 75th percentile for physician compensation in respective specialties
- Significant discrepancies between the compensation paid to the five Covenant physicians, as compared to compensation paid to physicians in the region and around the country

"Covenant Medical Center to Pay U.S. $4.5 Million to Resolve False Claims Act Allegations" Press Release, United States Department of Justice, August 25, 2009, http://www.usdoj.gov/opa/pr/2009/August/09-civ-849.html (Accessed 10/8/20); "Covenant to pay feds $4.5M to settle fraud allegations" Waterloo Cedar Falls Courier, August 25, 2009, http://www.wcfcourier.com/articles/2009/08/25/news/breaking_news/doc4a94156271f78380125347.txt (Accessed 10/8/20).

Relevant Fraud & Abuse Case Law

U.S. v. Bradford Regional Medical Center

- Two physicians and the Medical Center had a direct financial relationship through non-compete clause of a sublease agreement for a nuclear camera
- Court used a FMV analysis to determine legal impermissibility of the sublease arrangement, applying Stark's definition of FMV and *"value or volume"* standard
- Significant exchange was the non-compete payments that required physicians to not engage in nuclear camera business

"Executive Summary of Report of Charles T. Day, CPA" Case 1:04-cv-00186-MBC, September 10, 2008, p. 17.

Relevant Fraud & Abuse Case Law

U.S. v. Bradford Regional Medical Center

- Court remarked:
  - *"A 'fair market value' to the doctors to get out of the nuclear camera business was roughly the amount of money they would make by staying in the business and referring their patients to their own camera"*
  - *"to the hospital, 'fair market value'…was roughly the amount of money they would expect to gain from the doctors no longer referring their patients to their own camera"*
  - *"While the value agreed upon by parties who are in a position to refer business to each other and who take into account anticipated referrals will be a fair value* ***as between the parties****, such an arrangement is not 'fair market value' under the Stark Act"*

"Executive Summary of Report of Charles T. Day, CPA" Case 1:04-cv-00186-MBC, September 10, 2008, p. 48-50.

Relevant Fraud & Abuse Case Law

U.S. ex rel. Drakeford v. Tuomey

- Rural hospital paid 19 part-time physicians an amount beyond FMV by taking into account the *volume* or *value* of referrals
  - 10-year contract for part-time employment
  - Guaranteed base pay
  - Productivity bonuses (up to 80% of the physician's collections)
  - Incentive bonuses (7% of the earned productivity bonus)
  - Paid physicians malpractice and billing/collection costs

U.S. ex rel. Drakeford v. Tuomey, 792 F.3d 364, 387 (4th Cir. 2015)

Relevant Fraud & Abuse Case Law

U.S. ex rel. Drakeford v. Tuomey

- Physician productivity fell between the 50th and 75th percentile, but compensation was over the 90th percentile
- Provides insight into what constitutes reasonable wRVU compensation
  - Government expert – Compensation per wRVU should not exceed the 75th MGMA percentile without substantial justification
- July 2, 2015 – 4th Circuit affirmed $237 million verdict against Tuomey

"Michael K. Drakeford, M.D. v. Tuomey Healthcare System, Inc." Case No. 10-1819 (March 30, 2012); "What we have learned: From Halifax, Tuomey, North Broward, Adventist, and Columbus Regional and Current Legal Issues" By Robert A. Wade, Esq. Krieg Devault, November 30, 2016, https://www.hcca-info.org/Portals/0/PDFs/Resources/Conference_Handouts/Regional_Conference/2016/indianapolis/Wadeprint2.pdf (Accessed 10/8/20); "In long running Tuomey saga, the Fourth Circuit provides a roadmap for constitutional challenges to excessive FCA awards" By Scott D. Stein, Lexology, July 6, 2015, http://www.lexology.com/library/detail.aspx?g=0946e8fc-f90d-48ee-b557-06b3cc78ae92 (Accessed 10/8/20).

Relevant Fraud & Abuse Case Law

U.S. v. Campbell

- Recruitment initiative
  - Included *"enter[ing] into part-time employment contracts with local community cardiologists in private practices, who had patients they could refer to University Hospital for cardiac-related procedures."*
- The case establishes that providers may open themselves up to potential *Stark* liability *as individuals* by referring patients to healthcare entities with whom they have a financial relationship if fixed compensation amount can be seen as an *remuneration* for patient referrals in the absence of services performed by the physician as called for in the employment agreement

United States v. Campbell, No. CIV.A. 08-1951, 2011 WL 43013, at *1 (D.N.J. Jan. 4, 2011).

Relevant Fraud & Abuse Case Law

U.S. ex rel. Baklid-Kunz v. Halifax

- Kickbacks paid to providers through incentives & pooled compensation
  - Physicians compensated two to four times their respective annual base salary
  - Incentives equivalent to 15% of the hospital's oncology program's operating margin
- Neurosurgeons paid over $2 million annually (greater than 100% of the 90th percentile of neurosurgeon compensation) and annual bonuses over $1 million
- **March 10, 2014** - Halifax settled with U.S. government for $85 million

"United States Government Intervenes in Health Care Fraud Suit Against Halifax Hospital After Two Years of Investigating Fraud and Stark Allegations" Press Release, September 19, 2011 Wilbanks & Bridges, http://www.wilbanksgouinlock.com/pdf/Final%20Press%20Release%20MBW%209-19-11.pdf (Accessed 10/8/20).

Relevant Fraud & Abuse Case Law

U.S. ex rel. Reilly v. North Broward Hospital District

Relator's Third Amended Complaint

- Complaint alleges North Broward employed physicians at a loss, which losses were offset by inpatient and ancillary fees generated by referrals
- Complaint alleges North Broward compensated employed physicians:
  - *"(1) at levels which exceeded the fair market value of their personal services,*
  - *(2) at levels which were not commercially reasonable if the physicians were not in a position to generate referral business for Broward Health, and*
  - *(3) at levels which were determined and paid based in part on the volume and value of inpatient and outpatient referrals by such physicians to Broward Health hospitals and clinics*." [emphasis added]

"United States ex rel. Reilly v. North Broward Hospital District, et al." Case No. 10-60590-CV (S.D.Fla. September 11, 2012), Relator's Third Amended Complaint Under Federal False Claims Act, p. 8.

Relevant Fraud & Abuse Case Law

U.S. ex rel. Reilly v. North Broward Hospital District

- North Broward allegedly tracked the volume and value of referrals by employed physicians in "*Contributive Margin Reports*"
- The complaint alleges that these reports track "*the revenue from every admission, every ancillary, anything that's done to patients of employed physicians*."
- Complaint alleged that employing physicians at a loss "*is only sustainable by anticipating and allocating hospital referral profits to cover the massive direct losses from excessive physician compensation*"
- North Broward settled the case for $69.5 million in September 2015

"United States ex rel. Reilly v. North Broward Hospital District, et al.," Case No. 10-60590-CV (S.D.Fla., 2012), Relator's Third Amended Complaint Under Federal False Claims Act, p. 8, 29-31. "Florida Hospital District Agrees to Pay United States $69.5 Million to Settle False Claims Act Allegations" U.S. Department of Justice, September 15, 2015, https://www.justice.gov/usao-sdfl/pr/florida-hospital-district-agrees-pay-united-states-695-million-settle-false-claims-act#:~:text=North%20Broward%20Hospital%20District%2C%20a,Act%20by%20engaging%20in%20improper (Accessed 10/8/20).

Relevant Fraud & Abuse Case Law

U.S. ex rel. Barker v. Columbus Regional Health System

- Two lawsuits filed by the same relator; together, both lawsuits allege Columbus Regional allowed its physicians to **upcode** for evaluation and management (E&M) services, compensation *in excess of FMV*, and medical directorship arrangements that were not *commercially reasonable*
- Columbus Regional alleged to have given medical directorships to four oncologists in one physician practice, when only ten of the physicians in that practice saw patients
- Columbus Regional alleged to have paid one oncologist, Dr. Andrew Pippas, in excess of a 2:1 compensation to collections ratio
  - Base pay for Dr. Pippas determined by number of work RVUs performed

"United States ex rel. Barker v. Columbus Regional Healthcare System et al." Case No. 4-14-cv-304 (M.D.Ga. December 29, 2014), Relator's Complaint, p. 12, 14, 27. "United States ex rel. Barker v. Columbus Regional Healthcare System et al." Case No. 4-12-cv-108 (M.D. Ga., May 10, 2013), Relator's Amended Complaint, p. 11.

Relevant Fraud & Abuse Case Law

U.S. ex rel. Barker v. Columbus Regional Health System

- Complaint discusses reports provided by outside consultants regarding whether compensation paid to Dr. Pippas fit within FMV
  - Reports issued in 2008, 2009, and 2013
  - None of the reports analyze the commercially reasonableness of the compensation paid to Dr. Pippas, nor the commercial reasonableness of his medical directorship
- Parties settled the case in September 2015 for $25 million, with the possibility of further payments up to $10 million

"United States ex rel. Barker v. Columbus Regional Healthcare System et al." Case No. 4-14-cv-304 (M.D.Ga., 2014), Relator's Complaint, p. 15-17, 23-24. "Georgia Hospital System and Physician to Pay More than $25 Million to Settle Alleged False Claims Act and Stark Law Violations" U.S. Department of Justice, September 4, 2015, http://www.justice.gov/opa/pr/georgia-hospital-system-and-physician-pay-more-25-million-settle-alleged-false-claims-act-and (Accessed 10/8/20).

Relevant Fraud & Abuse Case Law

U.S. ex rel. Payne et al. v. Adventist Health System et al.

- Complaint alleges Adventist hospitals employed physicians at a loss, knowing that referrals from employed physicians would offset those losses
  - "*Compensating the doctors whose practices they have purchased at levels that not only exceed what (Adventist) can rationally pay while maintaining a physician practice that could be economically viable on its own merits, but that even more dramatically exceed what (Adventist's) employee physicians could reasonably expect to earn if those physicians had continued to own and operate the business themselves*." [Complaint, p. 56]
- Complaint alleges Adventist could bear the losses only because Adventist hospitals tracked physician referrals
- One relator is former risk manager of Park Ridge Health, an Adventist-affiliated hospital in Hendersonville, NC

"United States ex rel. Payne et al. v. Adventist Health System et al." Case No. 3:12cv856-W (W.D.N.C., 2013), Relator's Amended Complaint, p. 56-57.

Relevant Fraud & Abuse Case Law

U.S. ex rel. Payne et al. v. Adventist Health System et al.

Relator's Amended Complaint

- Park Ridge Agreement with Southeastern Sports Medicine (SESM)
  - Professional Services Agreement with Park Ridge, wherein SESM physicians would exclusively practice at Park Ridge locations in return for payment per RVU
  - Park Ridge lost $2.9 million in 2011 under agreement with SESM
  - Park Ridge gained $3.6 million from inpatient and ancillary referrals from SESM from January-September 2011
- Lawsuit settled in September 2015 for $115 million

"United States ex rel. Payne et al. v. Adventist Health System et al." Case No. 3:12cv856-W (W.D.N.C., 2013), Relator's Amended Complaint, p. 60, 68. "Adventist Health System Agrees to Pay $115 Million to Settle False Claims Act Allegations" U.S. Department of Justice, September 21, 2015, http://www.justice.gov/opa/pr/adventist-health-system-agrees-pay-115-million-settle-false-claims-act-allegations (Accessed 9/22/15).

Relevant Fraud & Abuse Case Law

U.S. ex rel. Bookwalter v. UPMC (2019)

- UPMC hospitals are accused of:
  - Pay exceeding collections – Hospitals credited with surgeons 100% of the wRVUs they generate, even if the hospital cannot collect on all of them
  - Pay exceeding 90th percentile of industry normative benchmarks
  - "Extreme Work Units" – Surgeons were regularly generating wRVUs 2-3 times the 90th percentile of industry normative benchmarks
  - Per-wRVU bonuses exceeded Medicare reimbursement rate
- Court utilizing similar reasoning as in *Tuomey* case
- Perpetuation of the Practice Loss Postulate
- Case is currently in the discovery phase

United States ex rel. Bookwalter v. UPMC, 946 F.3d 162, 177 (3d Cir. 2019)

FMV & Commercial Reasonableness

- An arrangement must simultaneously be at *Fair Market Value* and be *Commercially Reasonable* to be deemed legally permissible
  - **Fair Market Value** - Looks to the reasonableness of the range of dollars paid for a product or service
  - **Commercial Reasonableness** - Looks to the reasonableness of the business arrangement generally

Determining Commercial Reasonableness

- Some questions to consider:
  - Is it necessary to have a physician perform that service?
  - Is it necessary to have a physician of that specialty perform that service?
- Both the level of services and the consideration paid must be *Commercially Reasonable* for the arrangement to survive regulatory scrutiny

"Exempt Healthcare Organizations: Meeting Commercial Reasonableness Thresholds" By Robert James Cimasi and Michael Meissner, Consultants' Training Institute, December 12, 2012, p. 22.

Definitions of Commercial Reasonableness

Stark Final Rule (November 2020)

- *"Commercially reasonable means that the particular arrangement furthers a legitimate business purpose of the parties to the arrangement and is sensible, considering the characteristics of the parties, including their size, type, scope, and specialty. An arrangement may be commercially reasonable even if it does not result in profit for one or more of the parties."* [Emphasis added.]

"Definitions" 42 C.F.R. § 411.351; "Medicare Program; Modernizing and Clarifying the Physician Self-Referral Regulations" CMS-1720-F, Unpublished Version, https://public-inspection.federalregister.gov/2020-26140.pdf (Accessed 11/24/20), p. 128.

Definitions of Commercial Reasonableness

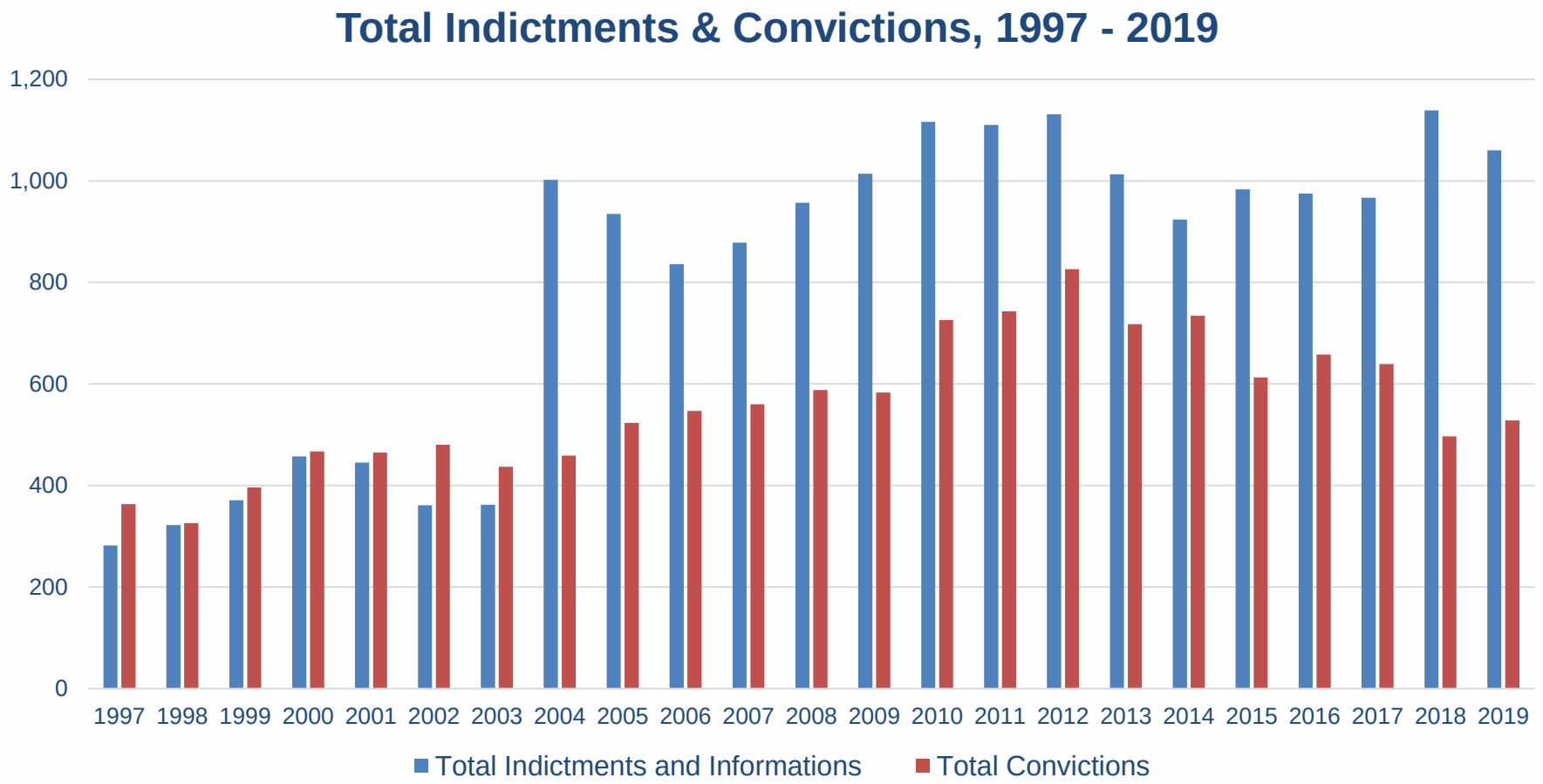
IRS

- Factors considered when determining the *commercial reasonableness* of a physician compensation arrangement:
  - Specialized training and experience of the physician
  - The nature of duties performed and the amount of responsibility
  - Time spent performing duties
  - Size of the organization
  - National and local economic conditions
  - Salary ranges for equivalent physicians in comparable organizations
  - History of pay for the employee
  - Availability of similar services in the geographic area

"Business Expenses," Department of the Treasury, Internal Revenue Service, Publication 525 (2014), p. 7.

Fraud & Abuse Enforcement

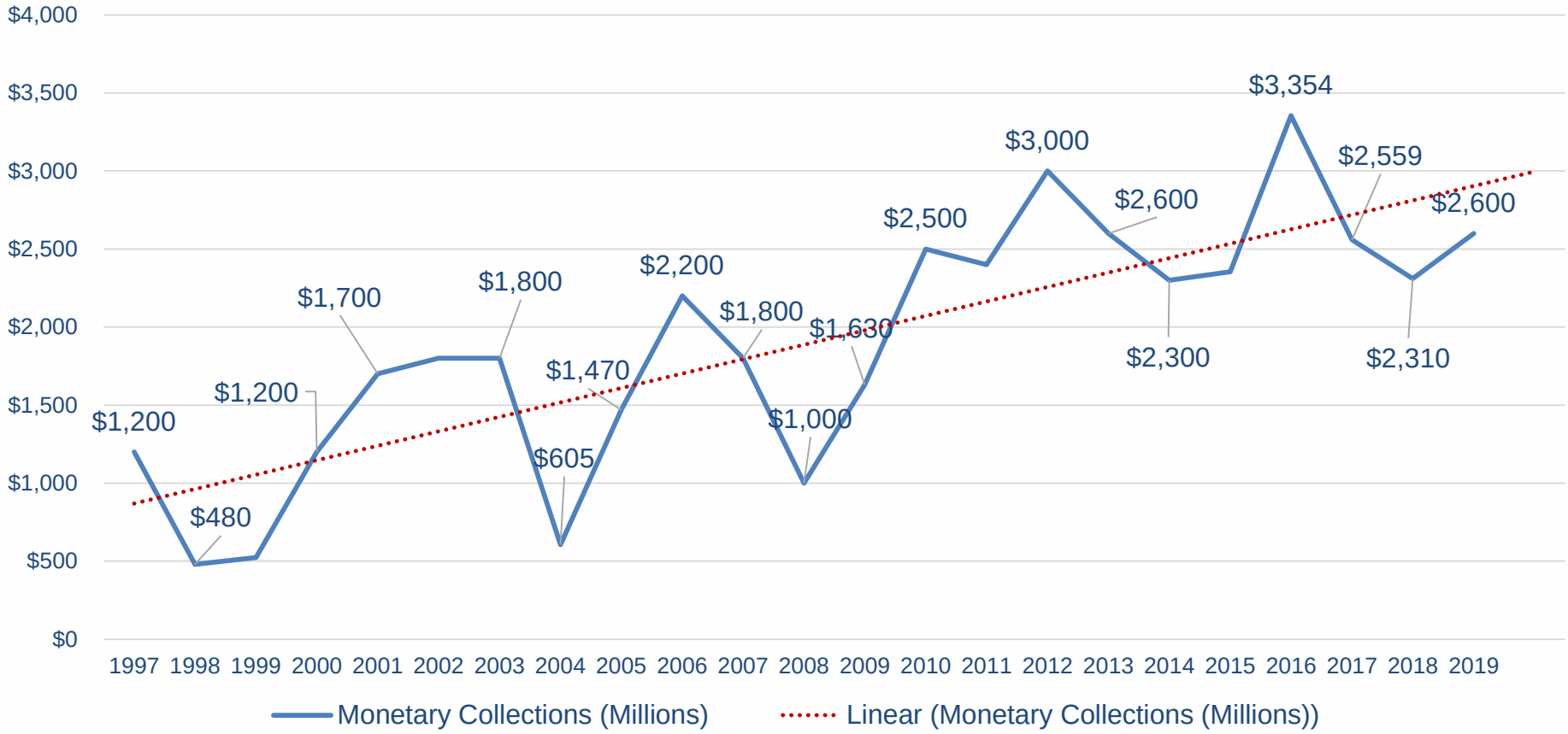
Fraud & Abuse Enforcement



Complied from the "Health Care Fraud Abuse Control Program—Annual Report" for FY 1997-2019, U.S. Department of Health and Human Services and U.S. Department of Justice.

Fraud & Abuse Enforcement

Fraud and Abuse Monetary Collections (Millions)



Complied from the "Health Care Fraud Abuse Control Program—Annual Report" for FY 1997-2019, U.S. Department of Health and Human Services and U.S. Department of Justice.

Fraud & Abuse Regulatory Agencies

- Office of Inspector General (OIG)
- Centers for Medicare and Medicaid Services (CMS)
- Internal Revenue Service (IRS)
- Department of Justice (DOJ), through the development of initiatives such as the Fraud Enforcement and Recovery Act (FERA) and the Healthcare Enforcement Action Team (HEAT)

Fraud Enforcement Recovery Act (FERA)

- Signed in May 2009
- No specific intent needed to defraud
- Government need only show a person acted *"knowingly"* by:
  - Having actual knowledge of the information
  - Acting in *deliberate ignorance* of the truth or falsity of the information
  - Acting in *reckless disregard* of the truth or falsity of the information

"Fraud Enforcement and Recovery Act, Sec. 4" Public Law 111-21, 123 Stat. 1617 (May 20, 2009), p. 1623-1624.

Health Care Fraud Prevention & Enforcement Action Team (HEAT)

- Mission
  - Gather resources across government to help prevent waste, fraud & abuse in Medicare & Medicaid
  - Reduce skyrocketing healthcare costs & improve quality of care
  - Highlight best practices by providers & public sector employees who are dedicated to ending waste, fraud & abuse in Medicare
  - Target doctors and physicians who prescribe opioids which lack a legitimate medical purpose
  - Build upon existing partnerships between DOJ & HHS to reduce fraud & recover taxpayer dollars
  - HEAT has recovered $20.5 billion since 2009

Health Care Fraud and Abuse Control Program: Annual Report for Fiscal Year 2018, U.S. Department of Justice, U.S. Department of Health & Human Services, May 2019, https://oig.hhs.gov/publications/docs/hcfac/FY2018-hcfac.pdf (Accessed 10/8/20), p. 1.

Medicare Fraud Strike Force

- A multi-agency team of investigators at all governmental levels
- Part of HEAT
- Established in March 2007
- 14 locations, concentrated in the eastern U.S.
- Designed to combat Medicare fraud through using Medicare data analysis techniques and focusing on community policing
- Recovered $3.82 billion since the beginning of the program

"Medicare Fraud Strike Force" Office of Inspector General, https://oig.hhs.gov/fraud/strike-force/ (Accessed 10/8/20).

Fraud & Abuse Reimbursement Monitoring Programs

Recovery Audit Contractors (RACs)

- Tasked with improving payment accuracy and increased program transparency by identifying improper Medicare payments to providers based on three categories of errors:
  - Payment for medically unnecessary services
  - Payment for incorrectly coded services
  - Payment for services not supported by sufficient documentation

"Implementation of Recovery Auditing at the Centers for Medicare and Medicaid Services: FY 2010 Report to Congress" Centers For Medicare and Medicaid Services, 2011, p. 2-4.

Fraud & Abuse Reimbursement Monitoring Programs

Zone Program Integrity Contractors (ZPIC)

- CMS contractors that utilize post-payment reviews as part of their mission to detect Medicare fraud
- ZPICs identify these potentially fraudulent providers by comparing "*billing patterns* [that] *are unusual or aberrant in relation to those of similar providers*" to determine whether these claims show potential evidence of fraud

"Medicare: Further Action Could Improve Improper Payment Prevention and Recoupment Efforts" By Kathleen M. King, To Subcommittee on Energy Policy, Health Care and Entitlements, Committee on Oversight and Government Reform, House of Representatives, Washington, D.C.: United States Government Accountability Office, May 20, 2014, p. 10-11.

Fraud & Abuse Reimbursement Monitoring Programs

Comprehensive Error Rate Testing (CERT) Program

- Created by CMS to determine improper *Medicare fee-for-service payments*
- CMS uses the CERT program's results to provide Congress with an estimate of the annual amount of improper Medicare payments made to providers during a given year

"Review of CERT Errors Overturned Through the Appeals Process for Fiscal Years 2009 and 2010" By Daniel R. Levinson, Office of the Inspector General, March 2012, A-01-11-00504, p. 1.

Fraud & Abuse Reimbursement Monitoring Programs

ACA Fraud Identification Programs

- Strengthening of prison sentences through Federal Sentencing Guidelines
- Promotion of Transparency through Physician Payments Sunshine Act
  - Transactions between companies and physicians must be publicly reported

"Patient Protection and Affordable Care Act, Sec. 10606" Public Law 111-148, 124 STAT. 119 (March 23, 2010), p. 689, 1006-1008; "Doctors Face New Scrutiny Over Gifts: New Health Law Calls for Increased Disclosures" By Peter Loftus, The Wall Street Journal, August 22, 2013, http://online.wsj.com/article/SB10001424127887323455104579014812178937016.html?dsk=y&cb=logged0.6060728852902819 (Accessed 10/8/20).

Privacy Laws

Health Insurance Portability & Accountability Act of 1996 (HIPAA)

- Possession of confidential healthcare information is regulated on a federal level
- Most widely used for safeguarding the privacy of *Protected Health Information* (PHI)
- HIPAA Privacy Rule – Provides standards for use and disclosure of individuals' PHI
  - Goal - To assure that individuals' health information is properly protected, while allowing the flow of health information needed to provide and promote high quality healthcare and to protect the public's health and well-being

"Summary of the HIPAA Privacy Rule" OCR Privacy Brief, U.S. Department of Health and Human Services, May 2003, https://www.hhs.gov/sites/default/files/privacysummary.pdf (Accessed 10/8/20), p. 1, 4, 9.

Health Insurance Portability & Accountability Act of 1996 (HIPAA)

HIPAA Privacy Rule

- "*Covered entity*" – Includes "*health plans, healthcare clearinghouses, and any health care provider who transmits health information in electronic form in connection with a transaction for which the Secretary of HHS has adopted* [HIPAA] *standards*."
- Transactions falling under the *Privacy Rule* include:
  - Claims for reimbursement
  - Benefit eligibility inquiries
  - Referral authorization requests
  - Other transactions for which HHS has established particular standards

"Summary of the HIPAA Privacy Rule" Department of Health and Human Services, May 2003, https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/summary/privacysummary.pdf (Accessed 10/8/20), p. 2.

Health Information Technology for Economic & Clinical Health (HITECH) Act

- Incorporated into the American Recovery and Reinvestment Act of 2009
- Intended to promote widespread adoption of health IT
- Allows patients to request an electronic copy of their medical records as well as an audit trail that shows all disclosures of their PHI
- Prohibits the sale of a patient's PHI without their authorization
- Requires individuals to be notified if there is an unauthorized disclosure or use of their PHI

"American Recovery and Reinvestment Act of 2009," Public Law No. 111-5, 123 STAT. 115 (Feb. 17, 2009); "What is the HITECH Act?" HIPAA Journal, https://www.hipaajournal.com/what-is-the-hitech-act/#:~:text=HITECH%20Act%20Summary,HIPAA%20Privacy%20and%20Security%20Rules. (Accessed 10/9/20).

Custodial Rights to Patient Charts

- Patient rights with respect to their medical records
  - Right to view and obtain much of their health information and to have corrections made
  - Right of access to inspect and obtain a copy of their PHI from the entity with access to such information
- Providers have right to the custody of patient medical charts and records and patient recall lists
  - Charts and records constitute an intangible asset of the physician practice that may be transferred and valued

"Personal Health Records and the HIPAA Privacy Rule" U.S. Department of Health and Human Services, https://www.hhs.gov/sites/default/files/ocr/privacy/hipaa/understanding/special/healthit/phrs.pdf (Accessed 10/8/20).

Other Healthcare Regulations

Antitrust Regulations

- **Sherman Act**: Prohibits any *"contract, combination. . .or conspiracy, in restraint of trade or commerce"*
- **Clayton Act**: Prohibits acquisitions which are likely to "*substantially lessen competition, or tend to create a monopoly*"
- **Federal Trade Commission (FTC) Act**: Prohibits "*unfair methods of competition in or affecting commerce*," and gives FTC authority to bring enforcement actions
- Goal of antitrust regulations – To ensure a competitive marketplace in which consumers will have a wide range of high quality, cost-effective healthcare choices

Emergency Medical Treatment & Active Labor Act (EMTALA)

- Enacted in 1986 by the *Consolidated Omnibus Budget Reconciliation Act of 1985*
- Requires participating hospitals to provide an "*appropriate medical screening examination*" to any patient who presents to the hospital's *emergency department* (ED)
  - "*Participating hospitals*" – Hospitals that participate in Medicare and have an ED
- Patients who suffer harm as a "*direct result*" of a hospital's EMTALA violation may bring a claim against the hospital (EMTALA provides for civil penalties against the hospital)
  - Patients lack a private right of action under EMTALA against the specific treating physician

"Medical Screening Requirement" 42 U.S.C. § 1395dd(a). "Definitions" 42 U.S.C. § 1395dd(e)(2). "Personal Harm" 42 U.S.C. § 1395dd(d)(2)(A). "Examination and Treatment for Emergency Medical Conditions and Women in Labor" 42 U.S.C. § 1395dd(d)(1)(A)-(B). "Specialty Hospitals: Focused Factories or Cream Skimmers?" By Kelly Devers, Linda R. Brewster, and Paul B. Ginsburg, Center for Studying Health System Change, Issue Brief No. 62 (April 2003), http://www.hschange.com/CONTENT/552/ (Accessed 10/8/20).

Food and Drug Administration (FDA)

- Regulates food, dietary supplements, pharmaceuticals, vaccines, blood products and other biologics, medical devices, electronic products, cosmetics, veterinary products, and tobacco products
- Both pharmaceuticals and medical devices are required to have approval from the FDA prior to commercialization of the pharmaceutical or medical device
  - The future economic benefit from the patent cannot be realized until after the approval is gained from the FDA

"What Does FDA Regulate" U.S. Food and Drug Administration, https://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm (Accessed 10/8/20).

Corporate Practice of Medicine Doctrine

- Created by the American Medical Association (AMA) to protect the public, as well as physicians
  - Bans unlicensed individuals and entities from engaging in the practice of medicine by restricting them from employing licensed physicians
- Regulated on a state level

"Corporate Medicine in 21st Century Health Care" By John W. Jones, Esq., Physician's News Digest, June 2007, https://physiciansnews.com/2007/06/13/corporate-medicine-in-21st-century-health-care/ (Accessed 10/8/20).

Employee Retirement Income Security Act (ERISA)

- Protects individuals who participate in health benefit plans through private sector employers by providing rights to information and a grievance process for receiving benefits
- Does not require an employer to offer health benefits, but regulates those employers who *do* offer benefits and stipulates generally that employers allocate their benefits fairly

"ERISA and Healthcare Plan Enforcement" FindLaw, 2010, http://employment.findlaw.com/employment/employment-employee-wages-benefits/employment-employee-wages-benefits-health-insurance-top/employment-employee-wages-benefits-erisa.html (Accessed 10/8/20).

Consolidated Omnibus Budget Reconciliation Act (COBRA)

- Passed in 1986 as an amendment to ERISA
- Requires employers who employ 20 or more workers to offer continued healthcare insurance for a period after a "*qualifying event*"
- Provides certain retirees and their dependents the right to purchase a continuation of group health plan coverage from their previous employer-based plan

The Patient Protection & Affordable Care Act (ACA)

ACA Individual Mandate

- The ACA required U.S. citizens and legal residents to carry health insurance
- Individuals who refuse to buy insurance faced a tax penalty
- On December 22, 2017, the tax penalty associated with the Individual Mandate provision was reduced to $0 as part of the *Tax Cuts and Jobs Act* (effective 2019)

"Individual Shared Responsibility Provision – Reporting and Calculating the Payment" Internal Revenue Service, November 21, 2017, https://www.irs.gov/affordable-care-act/individuals-and-families/aca-individual-shared-responsibility-provision-calculating-the-payment (Accessed 10/8/20); "Tax Cuts and Jobs Act" H.R, 1 (January 3, 2017), p. 39; "Actions Overview H.R. 1 – 115th Congress (2017-2018)" Congress.gov, https://www.congress.gov/bill/115th-congress/house-bill/1/actions (Accessed 10/8/20).

Constitutionality of ACA California v. Texas

- Lawsuit brought by Texas Attorney General (AG) & 20 other Republican AGs, as well as 2 individuals
- Oral arguments were held before the U.S. Supreme Court on November 10, 2020:
- The Court will decide (by June 2021):
  1. Do the plaintiffs have standing to challenge the ACA?
  2. Is the Individual Mandate of the ACA now unconstitutional because it has a penalty of $0 for not buying health insurance?
  3. If the Individual Mandate is unconstitutional, is it severable from the remainder of the ACA?

"California, et al. v. Texas, et al. and Texas, et al. v. California, et al." Oral Argument Transcript, November 10, 2020, available at: https://www.supremecourt.gov/oral_arguments/argument_transcripts/2020/19-840_i426.pdf (Accessed 11/23/20).

ACA Health Insurance Exchanges

- Established to create a more organized and competitive market for health insurance
  - Offer a choice of health plans
  - Establish common rules regarding the offering and pricing of insurance
  - Provide information to help consumers better understand the options available to them
- Serves individuals and smaller employers

"Explaining Health Care Reform: Questions About Health Insurance Exchanges" Kaiser Family Foundation, January 16, 2020, https://www.kff.org/health-reform/issue-brief/explaining-health-care-reform-questions-about-health/ (Accessed 8/28/13).

Pertinent ACA Provisions

Health Insurance Underwriting Rules	Mandates	Insurance Affordability	Insurance Marketplace
Prohibits pre-existing condition exclusion, and coverage denial	~~Individual Mandate~~	Premium tax credits	Qualified health plans (QHPs)
Guaranteed issue	Employer mandate	Cost-sharing reductions	Marketplaces
Community rated premiums			Essential Health Benefits

"Patient Protection and Affordable Care Act" Public Law 111-148, 124 STAT. 119, § 1201; 42 U.S.C. §§ 300gg-3, 300gg-4

ACA Impact on Medicare

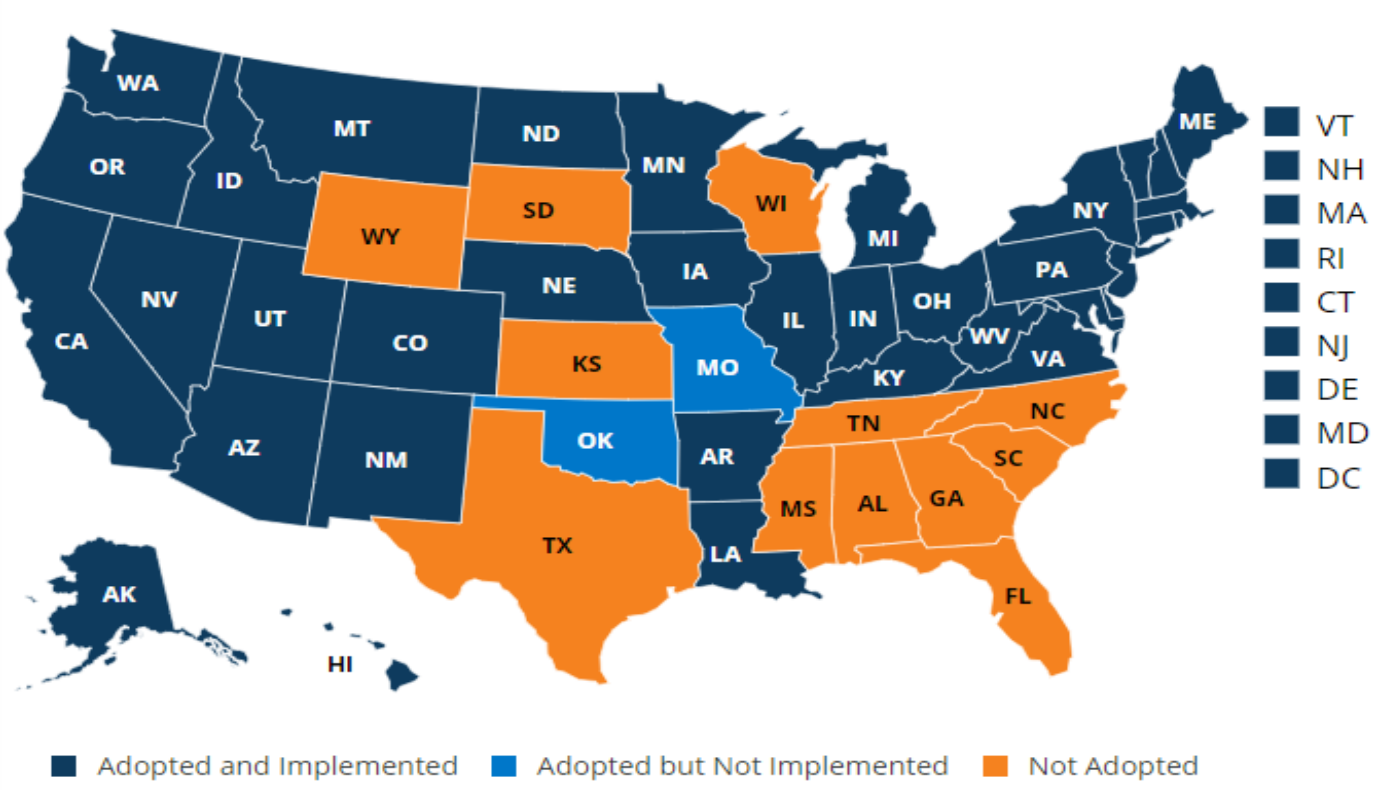
Medicare is required to:

- Reduce payments to many providers through the application of productivity adjustments to market basket updates
- Significantly enhance the provision of coordination of care and reform healthcare delivery systems
- Support quality, transparency, and fraud & abuse enforcement initiatives
- Add restrictions on revenue spending for Medicare Advantage plans
- Address impact of physician ownership of healthcare facilities
- Enact programs to incentivize hospitals to reduce unnecessary readmissions and hospital-acquired conditions
- Reduce the costs of prescription drugs for Medicare Part D beneficiaries in the coverage gap

"Patient Protection and Affordable Care Act" Public Law 111-148, 124 STAT. 119, §§ 2551, 3401, 3022, 3201, 5501 et seq., 6002, 6003, 6004 (March 23, 2010).

ACA Medicaid Expansion

As of October 2020:



"Status of State Medicaid Expansion Decisions: Interactive Map" Kaiser Family Foundation, October 1, 2020, https://www.kff.org/medicaid/issue-brief/status-of-state-medicaid-expansion-decisions-interactive-map/ (Accessed 10/8/20).

Accountable Care Organizations

- Holds groups of healthcare providers responsible for the quality and cost of healthcare delivery provided to the patient population
- Those that achieve spending and quality targets designated by payors receive a share of the savings
- 4 main types of accountable care organization (ACO) contracts based on payor program participation:
  - Medicare Shared Savings Program (MSSP)
  - Non-MSSP Medicare
  - Medicaid
  - Commercial

ACO Fraud & Abuse Waivers

- To encourage participation in CMS initiatives like the MSSP Pathways to Success, CMS makes available waivers of fraud and abuse laws (i.e., Stark Law, AKS, and Civil Monetary Penalties (CMP) Law)
- Help enable ACOs align clinical delivery performance with financial model to change the way care is delivered
- Allow for many creative and innovative arrangements that may otherwise be stifled because of fraud and abuse laws
  - Examples include joint ventures, leases and licenses, management services, donations of EHR, and more.
- One benefit for hospitals/health systems to sponsor their own ACO is easier access to waivers

Price Transparency

- CMS will require all hospitals, starting in 2021, to:
  - Post all "standard charges":
    - Gross Charges
    - Payor-specific Charges
    - Cash Price
    - For use by third-party collectors in machine-readable format
  - Post payor-negotiated charges
    - For up to 300 services
      - 70 pre-selected by CMS
      - Considered "*shoppable*"
      - Includes full amount of all services included in a visit

"Transparency in Coverage" Centers for Medicaid & Medicare Services, October 30, 2020, https://www.cms.gov/CCIIO/Resources/Regulations-and-Guidance/Downloads/CMS-Transparency-in-Coverage-9915F.pdf (Accessed 11/3/20).

Conclusion

- Complexities of tax-exempt organizations
- Increasing regulatory scrutiny of hospital-physician relationships
- Evolving regulatory environment of the healthcare industry on the federal, state, and local levels
- Impact of the ACA